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

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 21

[Docket No. FAA–2017–0863]

Airworthiness Criteria: Glider Design Criteria for Alexander Schleicher GmbH & Co. Models ASG 32 & ASG 32 Mi Gliders

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Airworthiness design criteria.

SUMMARY: These airworthiness design criteria for the Alexander Schleicher GmbH & Co. models ASG 32 & ASG 32 Mi gliders. The administrator finds the design criteria, which make up the certification basis for the ASG 32 & ASG 32 Mi gliders, acceptable.

DATES: These airworthiness design criteria are effective December 7, 2017.

FOR FURTHER INFORMATION CONTACT: Mr. Jim Rutherford, AIR–692, Federal Aviation Administration, Policy & Innovation Division, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, MO 64106, telephone (816) 329–4165, facsimile (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Background

On August 23, 2016, Alexander Schleicher GmbH & Co. submitted an application for type validation of the ASG 32 glider and ASG 32 Mi powered glider in accordance with the Technical Implementation Procedures for Airworthiness and Environmental Certification Between the FAA and the European Aviation Safety Agency (EASA), Revision 5, dated September 15, 2015. Both models will be documented on a single type certificate. The model ASG 32 is a two-seat, mid-wing, glider constructed from carbon-, glass-, and synthetic-fiber reinforced plastic and features a 65.6 foot (20 meter) wingspan with flaps, double-panel Schempp-Hirth airbrakes on the upper wing surface, winglets, water ballast tanks in the wing, and optional tanks in the fuselage. The glider also features a retractable landing gear with hydraulic disc brakes and a conventional T-type tailplane. The model ASG 32 Mi adds a retractable engine and fixed pitch propeller mounted in the center fuselage behind the cockpit which allows the glider to be self-launching. Both glider versions have a maximum weight of 1,874 pounds (850 kilograms). The EASA type certificated the ASG 32 and ASG 32 Mi gliders under Type Certificate Number (No.) EASA.A.599 on February 11, 2016. The associated EASA Type Certificate Data Sheet (TCDS) No. EASA.A.599 defined the certification basis Alexander Schleicher GmbH & Co. submitted to the FAA for review and acceptance.

The applicable requirements for glider certification in the United States can be found in FAA Advisory Circular (AC) 21.17–2A, ''Type Certification—Fixed-Wing Gliders (Sailplanes), Including Powered Gliders,'' dated February 10, 1993. AC 21.17–2A has been the basis for certification of gliders and powered gliders in the United States for many years. AC 21.17–2A states that applicants may utilize the Joint Aviation Requirements (JAR)–22, ''Sailplanes and Powered Sailplanes,'' or another accepted airworthiness criteria, or a combination of both, as the accepted means for showing compliance for glider type certification.

Type Certification Basis

The certification basis is based on EASA Certification Specification (CS)–22, ''Sailplanes and Powered Sailplanes'', amendment 2, dated March 05, 2009. In addition to CS–22 requirements, the applicant will comply with other requirements from the certification basis referenced in EASA TCDS No. EASA.A.599, including special conditions and equivalent safety findings.

Discussion of Comments

Notice of proposed airworthiness design criteria for the Alexander Schleicher GmbH & Co. models ASG 32 & ASG 32 Mi gliders was published in the **Federal Register** on September 6, 2017 (82 FR 42049). No comments were received; therefore, these airworthiness design criteria are adopted as proposed.

The Airworthiness Design Criteria

Applicable Airworthiness Criteria under § 21.17(b).

Based on the Special Class provisions of § 21.17(b), the following airworthiness requirements form the FAA Certification Basis for this design:

1. 14 CFR part 21, effective February 1, 1965, including amendments 21–1 through 21–98 as applicable.

2. EASA CS–22, amendment 2, dated March 05, 2009.

3. EASA Special Condition No. SC–A.22.1.01, ''Increase in maximum mass for sailplanes and powered sailplanes.''

4. EASA Equivalent Safety Finding to CS–22.335(f)—Alternate method to calculate the Design Maximum Speed (V_D) using the Organisation Scientifique et Technique Internationale du Vol á Voile (OSTIV), Airworthiness Standards for Sailplanes, dated July 1997.

5. EASA Equivalent Safety Finding to CS–22.585(a)—Alternate basis for lower towing loads and subsequent lower lauching hook attachment loads.

6. ''Standards for Structural Substantiation of Sailplane and Powered Sailplane Parts Consisting of Glass or Carbon Fiber Reinforced Plastics,'' Luftfahrt-Bundesamt (LBA) document no. I4–FVK/91, issued July 1991.

7. ''Guideline for the analysis of the electrical system for powered sailplanes,'' LBA document no. I334–MS 92, issued September 15, 1992.

8. Operations allowed: VFR-Day

9. EASA Type Certificate Data Sheet No. EASA.A.599, Issue 02, dated March 17, 2016.

10. Date of application for FAA Type Certificate: August 23, 2016.

Issued in Kansas City, Missouri on October 31, 2017.

Pat Mullen,

Manager, Small Airplane Standards Branch, Aircraft Certification Service.

[FR Doc. 2017–24102 Filed 11–6–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0816; Product Identifier 2017–NE–29–AD; Amendment 39–19093; AD 2017–22–13]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Rolls-Royce plc (RR) RB211–Trent 970–84 and RB211–Trent 972–84 turbofan engines. This AD requires an inspection of the drains mast. This AD was prompted by cracks found in the transition duct area of the drains mast. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective November 22, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 22, 2017.

We must receive comments on this AD by December 22, 2017.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

For service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE24 8BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936; email: *http://www.rolls-royce.com/contact/civil_team.jsp;* Internet: *https://customers.rolls-royce.com/public/rollsroycecare.* You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7125. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0816.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0816; 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 mandatory continuing airworthiness information (MCAI), regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Eugene Triozzi, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7148; fax: 781–238–7199; email: *Eugene.triozzi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not precede it by notice and opportunity for public comment. We invite 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–2017–0816; Product Identifier 2017–NE–29–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this AD. We will consider all comments received by the closing date and may amend this AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2017–0075R1, dated May 5, 2017 (referred to hereinafter as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> RB211 Trent 900 engines have been found in service with cracks in the transition duct area of the drains mast, which is part of the fire wall in Zone 1. Cracks were found on both pre-Mod 72–H499 drains masts, Part Number (P/N) FW29847, and post-Mod 72–H499 drains masts, P/N KH31996. This condition, if not detected and corrected, could, in combination with a fire in the surrounding area, lead to a breach of the fire wall, possibly resulting in an uncontrolled fire and consequent reduced control of the aeroplane. To address this potential unsafe condition, RR published Alert Non-Modification Service Bulletin (NMSB) RB.211–71–AJ576 to provide inspection instructions for engines with drains mast P/N KH31996 and post-Mod 80–H632 vent ejector installed, which have been determined as more susceptible to cracking.

You may obtain further information by examining the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0816.

Related Service Information Under 1 CFR Part 51

RR has issued Alert Non-Modification Service Bulletin No. RB.211–71–AJ576, Initial Issue, dated March 17, 2017. The Alert NMSB describes procedures for inspection, repair, and replacement of the drains mast. 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 and Requirements of This AD

This product has been approved by the aviation authority of the United Kingdom, and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This AD requires inspection and if necessary, replacement of the drains mast.

FAA's Determination of the Effective Date

No domestic operators use this product. Therefore, we find that notice and opportunity for prior public comment are unnecessary and that good cause exists for making this amendment effective in less than 30 days.

Costs of Compliance

We estimate that this AD affects no engines installed on airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	2 work-hours × $85 per hour = $170	$10,000	$10,170	$0

Authority for This Rulemaking

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

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

This 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 engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

We 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 this AD:

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

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

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

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

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):

2017–22–13 Rolls-Royce plc: Amendment 39–19093; Docket No. FAA–2017–0816; Product Identifier 2017–NE–29–AD.

(a) Effective Date

This AD is effective November 22, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce plc (RR) RB211–Trent 970–84 and RB211–Trent 972–84 turbofan engines with a drains mast, part number (P/N) KH31996, installed.

(d) Subject

Joint Aircraft System Component (JASC) 7170, Powerplant/Engine Drains.

(e) Reason

This AD was prompted by cracks found in the transition duct area of the drains mast. We are issuing this AD to prevent failure of the drains mast, engine fire, and damage to the airplane.

(f) Compliance

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

(g) Required Actions

Within 12 months time since new (TSN) or within 12 months after the effective date of this AD, whichever occurs later, visually inspect the external areas of the transition duct area of the drains mast for a crack, as depicted in Figure 1 of RR Alert Non-Modification Service Bulletin (NMSB) RB.211–71–AJ576, Initial Issue, dated March 17, 2017. If there is a crack:

(1) Before further flight, replace the drains mast with a part eligible for installation, or

(2) Before further flight, seal the crack using the Accomplishment Instructions, paragraph 3.B. of RR Alert NMSB RB.211–71–AJ576, Initial Issue, dated March 17, 2017, and within 100 flight cycles, remove and replace the drains mast with a part eligible for installation.

(h) Definition

(1) For the purposes of this AD, a part eligible for installation is a part not listed in this AD, or a part that has passed the inspection required by this AD.

(2) For the purposes of this AD, a flight cycle is a take-off and landing.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO 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. You may email your request to: *ANE-AD-AMOC@faa.gov.*

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

(j) Related Information

(1) For more information about this AD, contact Eugene Triozzi, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7148; fax: 781–238–7199; email: *eugene.triozzi@faa.gov.*

(2) Refer to MCAI EASA AD 2017–0075R1, dated May 5, 2017, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2017–0816.

(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 the AD specifies otherwise.

(i) Rolls-Royce plc (RR) Alert Non-Modification Service Bulletin RB.211–71–AJ576, Initial Issue, dated March 17, 2017.

(ii) Reserved.

(3) For RR service information identified in this AD, contact Rolls-Royce plc, Corporate Communications, P.O. Box 31, Derby, England, DE24 8BJ; phone: 011–44–1332–242424; fax: 011–44–1332–249936; email: *http://www.rolls-royce.com/contact/civil_team.jsp;* Internet: *https://customers.rolls-royce.com/public/rollsroycecare.*

(4) You may view this service information at FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7125.

(5) You may view this service information 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 Burlington, Massachusetts, on November 1, 2017.

Karen M. Grant,

Acting Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2017–24156 Filed 11–6–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0490; Product Identifier 2017–NE–13–AD; Amendment 39–19082; AD 2017–22–02]

RIN 2120–AA64

Airworthiness Directives; IPECO Pilot and Co-Pilot Seats

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Ipeco Holdings Ltd. (Ipeco) pilot and co-pilot seats. This AD requires modification and reidentification of the affected seats. This AD was prompted by reports of unexpected movement of pilot and co-pilot seats on takeoff and landing. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective December 12, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 12, 2017.

ADDRESSES: For service information identified in this final rule, contact Ipeco Holdings Ltd., Aviation Way, Southend on Sea, SS2 6UN, United Kingdom; phone: 44 1702 549371; fax: 44 1702 540782; email: *sales@Ipeco.com.* You may view this service information at the FAA, Engine and Propeller Standards Branch, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0490.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0490; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, 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: Neil Doh, Aerospace Engineer, Boston ACO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7757; fax: 781–238–7199; email: *neil.doh@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to the specified products. The NPRM was published in the **Federal Register** on June 16, 2017 (82 FR 27629). The NPRM proposed to correct an unsafe condition for the specified products. The MCAI states:

> Occurrences have been reported of pilot/co-pilot unexpected rearward movement during take-off and landing. Investigations determined that horizontal guide block wear, presence of burrs on horizontal centre track, and horizontal track lock system weakness (spring tension too low) were various causes which contributed to the seat not being correctly locked.
>
> This condition, if not corrected, could lead to further cases of unwanted flight crew seat movement, possibly resulting in reduced control of the aeroplane.

You may obtain further information by examining the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0490.

Comments

We 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.

Request To Shorten Compliance Time

The Air Line Pilots Association (ALPA) requested that the FAA work with EASA to reevaluate the compliance time for this AD. ALPA indicated that the requirements of this AD could be accomplished in a shorter timeframe that would enhance safety.

ALPA did not provide data or a detailed explanation with respect to its request for a shorter time frame. Consequently, upon further review of the risk analysis with EASA, we determined the proposed time frame for accomplishment of this AD is appropriate.

Miscellaneous Comments

We received miscellaneous comments not relevant to this AD. No further response is required.

Conclusion

We reviewed the available data, including the comments received, and determined that air safety and the public interest require adopting this AD as proposed.

Related Service Information Under 1 CFR Part 51

Ipeco has issued Service Bulletin (SB) Number 063–25–08, Revision 00; SB Number 063–25–09, Revision 00; and SB Number 063–25–10, Revision 00; all dated May 31, 2016. These SBs provide instructions, differentiated by the part numbers of the affected pilot and co-pilot seats, for the modification and reidentification of these seats. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

We estimate that this AD affects an unknown number of pilot and co-pilot seats installed on 55 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modify crew seats	2 work-hours × $85 per hour = $170	$125	$295	$16,225

Authority for This Rulemaking

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

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

This 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 engines, propellers, and associated appliances to the Manager, Engine and Propeller Standards Branch, Policy and Innovation Division.

Regulatory Findings

We 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 this AD:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

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):

2017–22–02 Ipeco Holdings Ltd.: Amendment 39–19082; Docket No. FAA–2017–0490; Product Identifier 2017–NE–13–AD.

(a) Effective Date

This AD becomes effective December 12, 2017.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to Ipeco Holdings Ltd. (Ipeco) pilot and co-pilot seats with a part number listed in the Planning Information section of Ipeco Service Bulletins (SBs) Number 063–25–08, Revision 00; Number 063–25–09, Revision 00; and Number 063–25–10, Revision 00; all dated May 31, 2016.

(2) These seats are installed on, but not limited to, ATR–GIE Avions de Transport Regional ATR 42 and ATR 72 airplanes.

(d) Subject

Joint Aircraft System Component (JASC) Code 2510, Flight Compartment Equipment.

(e) Reason

This AD was prompted by reports of unexpected movement of pilot and co-pilot seats on takeoff and landing. We are issuing this AD to prevent unexpected movement of pilot and co-pilot seats on takeoff and landing. The unsafe condition, if not corrected, could result in reduced control of the airplane.

(f) Compliance

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

(2) Within 2 years after the effective date of this AD, modify and re-identify affected each pilot and co-pilot seat. Use the Accomplishment Instructions of Ipeco SB Number 063–25–08, Revision 00; Ipeco SB 063–25–09, Revision 00; or Ipeco SB 063–25–10, Revision 00; all dated May 31, 2016; as appropriate, to do the modification and reidentification.

(g) Installation Prohibition

Do not install any pilot or co-pilot seat identified in paragraph (c) of this AD unless the seat is modified and reidentified as specified in paragraph (f)(2) of this AD.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Boston 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 Boston ACO Branch, send it to the attention of the person identified in paragraph (i) of this AD.

(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.

(i) Related Information

(1) For more information about this AD, contact Neil Doh, Aerospace Engineer, Boston ACO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7757; fax: 781–238–7199; email: *neil.doh@faa.gov.*

(2) Refer to MCAI European Aviation Safety Agency AD 2016–0256, dated December 16, 2016, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2017–0490.

(j) 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) Ipeco Service Bulletin (SB) Number 063–25–08, Revision 00; dated May 31, 2016.

(ii) Ipeco SB Number 063–25–09, Revision 00; dated May 31, 2016.

(iii) Ipeco SB Number 063–25–10, Revision 00; dated May 31, 2016.

(3) For Ipeco service information identified in this AD, contact Ipeco Holdings Ltd., Aviation Way, Southend on Sea, SS2 6UN, *United Kingdom;* phone: 44 1702 549371; fax: 44 1702 540782; email: *sales@Ipeco.com.*

(4) You may view this service information at FAA, Engine and Propeller Standards Branch, Policy and Innovation Division, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(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 Burlington, Massachusetts, on October 19, 2017.

Karen M. Grant,

Acting Manager, Engine and Propeller Standards Branch, Aircraft Certification Service.

[FR Doc. 2017–24127 Filed 11–6–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2016–C–2767]

Listing of Color Additives Exempt From Certification; Calcium Carbonate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of calcium carbonate to color hard and soft candy, mints, and chewing gum. We are taking this action in response to a color additive petition submitted by the Wm. Wrigley Jr. Company.

DATES: This rule is effective December 8, 2017. See section X for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by December 7, 2017. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of December 7, 2017.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before December 7, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of December 7, 2017. Objections 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 objections in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection 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 objection, that information will be posted on *https://www.regulations.gov.*

• If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection 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 objections submitted to the Dockets Management Staff, FDA will post your objection, 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–2016–C–2767 for ''Listing of Color Additives Exempt from Certification; Calcium Carbonate.'' Received objections, 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 with the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections 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.'' We will review this copy, including the claimed confidential information, in our 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: Judith Kidwell, Center for Food Safety and Applied Nutrition (CFSAN) (HFS–265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740–3835, 240–402–1071.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** on October 7, 2016 (81 FR 69740), we announced that we filed a color additive petition (CAP 6C0307) submitted by Wm. Wrigley Jr. Company (petitioner), c/o Exponent, 1150 Connecticut Ave. NW., Suite 1100, Washington, DC 20036. The petition proposed to amend the color additive

regulations in part 73 (21 CFR part 73) *Listing of Color Additives Exempt from Certification* to provide for the safe use of calcium carbonate to color hard and soft candy, mints, and chewing gum. The proposed use excludes chocolate or the chocolate portion of candy, as the current standards of identity for chocolate do not allow for the addition of color additives (see 21 CFR 163.123, 163.124, 163.130, 163.135, 163.140, 163.145, 163.153, 163.155). After the petition was filed, the petitioner clarified that calcium carbonate is intended for use only in ink applied to the surface of the chewing gum.

II. Background

Calcium carbonate is obtained from ground limestone or produced synthetically through a precipitation process using calcium oxide, water, and carbon dioxide. Calcium is abundant in the human body and is an integral component of bones, teeth, and other biological structures. Calcium constantly diffuses in and out of the bone and is resorbed by the kidney. Excess intake of calcium may result in hypercalcemia, hypercalciuria, gastrointestinal issues, kidney stones, interference with iron and zinc absorption, possible vascular and soft tissue calcification, and renal and cardiovascular damage. Carbonate is present in the human body as a critical component of the pH buffering system. The components of carbonate (carbon and oxygen) are ubiquitous in the human diet and body, and carbonate itself does not belong to a class of structures that is associated with any adverse effects or toxicity.

Calcium carbonate that is pharmaceutical grade is currently approved under § 73.1070 for use as a color additive in drugs in amounts consistent with good manufacturing practices (GMP). Additionally, food grade calcium carbonate and ground limestone (consisting of not less than 94 percent calcium carbonate) are affirmed as generally recognized as safe in § 184.1191 and § 184.1409 (21 CFR 184.1191 and 184.1409), respectively. These regulations do not include limitations for use in food other than current GMP. The petitioner proposed that to ensure that only food grade calcium carbonate is used to color hard and soft candy, mints, and chewing gum, the substance must meet the specifications of the Food Chemicals Codex, 10th edition (FCC 10). We have reviewed these specifications and agree that they should be incorporated into the regulation as set forth in this document. The petitioner proposed to use calcium carbonate to color soft and hard candy, mints, and chewing gum in amounts consistent with GMP. The maximum GMP use level for calcium carbonate in hard and soft candy, mints, and chewing gum will be determined by the desired coloring effect. We have determined that the amount of calcium carbonate used in these foods is self-limiting because the addition of the color additive above a certain level will not achieve the desired coloring effect and negatively interferes with organoleptic properties, such as taste and texture. Because the amount of the color additive used in these foods is self-limiting, we have determined that there is no need for a specific upper limit on the percent by weight of calcium carbonate in hard and soft candy, mints, and chewing gum (Ref. 1).

III. Safety Evaluation

Under section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(b)(4)), a color additive cannot be listed for a particular use unless the data and information available to FDA establish that the color additive is safe for that use. Furthermore, under section 721(b)(4) of the FD&C Act, a color additive is deemed to be suitable and safe for the purpose of listing for use generally in or on food, while there is in effect a published finding declaring such substance exempt from the term ''food additive'' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s) of the FD&C Act (21 U.S.C. 321(s)). FDA's color additive regulations in 21 CFR 70.3(i) define ''safe'' to mean that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.

To establish with reasonable certainty that a color additive intended for use in foods is not harmful under its intended conditions of use, we consider the projected human dietary exposure to the color additive, the additive's toxicological data, and other relevant information (such as published literature) available to us. We compare an individual's estimated exposure, or estimated daily intake (EDI), of the color additive from all food sources to an acceptable daily intake level established by toxicological data. The EDI is determined by projections based on the amount of the color additive proposed for use in particular foods or drugs and on data regarding the amount consumed from all sources of the color additive. We commonly use the EDI for the 90th percentile consumer of a color additive as a measure of high chronic exposure.

A. Estimated Dietary Exposure

The petitioner indicated that, given the types of candies to be colored and the variable conditions under which calcium carbonate would be used, the use of the assumption that all candies would contain calcium carbonate at the maximum GMP level would lead to an overestimate of exposure. However, because only hard and soft candy, mints, and chewing gum that are colored white would result in a potential exposure to calcium carbonate from the proposed use, the petitioner reviewed the 2009–2012 National Health and Examination Survey (NHANES) food codes and identified 51 food codes in which calcium carbonate could potentially be used as a color additive that represent the intended use in hard and soft candy, mints, and chewing gum. Although we identified additional food codes that could contain calcium carbonate, these codes were intentionally excluded by the petitioner because there were no associated eating occasions for these additional food codes over the survey years. We agree with the selected 51 food codes and the exclusion of the other food codes (Ref. 2). Furthermore, the petitioner used market data to refine their exposure estimate; however, these data were limited to those products that were introduced in the last 5 years and may not fully represent the market. Therefore, to be conservative, we estimated exposure to calcium carbonate using 2-day food consumption data from the 2009–2012 NHANES for the identified 51 food codes at the GMP use levels and made no adjustment for market data. Exposure to calcium carbonate and to calcium was estimated for the U.S. population 2 years of age and older and children 2 to 5 years of age (Ref. 2).

For the U.S. population 2 years of age and older, exposure estimates for calcium carbonate at the mean and 90th percentile from the proposed uses were 170 milligrams/person/day (mg/p/d) and 400 mg/p/d, respectively. For children 2 to 5 years of age, exposure estimates for calcium carbonate at the mean and 90th percentile were 125 mg/p/d and 270 mg/p/d, respectively.

Calcium carbonate is a source of calcium for the consumer once ingested and metabolized by the body. Therefore, as part of our evaluation, we also estimated exposure to calcium from the petitioned uses of calcium carbonate by assuming that the amount of calcium provided by calcium carbonate as a color additive is 40 percent of the total weight of calcium carbonate. For the U.S. population 2 years of age and older,

estimated exposure to calcium from the proposed uses of calcium carbonate at the mean and 90th percentile were 70 mg/p/d and 160 mg/p/d, respectively. For children 2 to 5 years of age, estimated exposure to calcium at the mean and 90th percentile were 50 mg/p/d and 110 mg/p/d, respectively.

Additionally, we estimated exposure to calcium from background dietary sources, drugs, and dietary supplements using 2-day food consumption data for all foods and nutrient data for calcium in those foods based on the U.S. Department of Agriculture's National Nutrient Database for Standard Reference. This estimate also included exposure to calcium from dietary supplements (including non-prescription antacids that contain calcium) based on NHANES 2-day survey data (Ref. 2).

For the U.S. population 2 years of age and older, exposure to calcium from background dietary sources, drugs, and dietary supplements at the mean and 90th percentile were estimated to be 1,125 mg/p/d and 1,900 mg/p/d, respectively. For children 2 to 5 years of age, exposure estimates at the mean and 90th percentile were 1,000 mg/p/d and 1,600 mg/p/d, respectively. Because our exposure estimates for dietary supplements include calcium from all sources, not just calcium carbonate, we believe that this exposure estimate is sufficiently conservative to include any exposure to calcium from the use of calcium carbonate to color drugs (Ref. 2).

We estimated exposure to calcium from background dietary sources, drugs, dietary supplements and the proposed uses of calcium carbonate at the mean and 90th percentile for the U.S. population 2 years of age and older and children 2 to 5 years of age. Based on these calculations, exposure estimates for calcium for the U.S. population 2 years of age and older at the mean and 90th percentile were 1,150 mg/p/d and 1,925 mg/p/d, respectively. For children 2 to 5 years of age, exposure estimates for calcium at the mean and 90th percentile were 1,025 mg/p/d and 1,625 mg/p/d, respectively (Ref. 2).

B. Safety of the Petitioned Uses of Calcium Carbonate

To support the safety of the petitioned use of calcium carbonate, the petitioner referenced safety information on calcium from the 2011 Institute of Medicine (IOM) Report on Dietary Reference Intakes for Calcium and Vitamin D (Ref. 3) and the European Food Safety Authority (EFSA) Panel on Dietetic Products, Nutrition and Allergies' reevaluation of the safety of calcium (Ref. 4). In 2011, the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes of the Food and Nutrition Board of the IOM conducted an extensive review of relevant published scientific literature on calcium to update current dietary reference intakes and Upper Tolerable Intake Levels (UL). In their 2011 assessment of calcium, the IOM established a UL of 1,000 mg/p/d for infants 0 to 6 months of age and 1,500 mg/p/d for infants 6 to 12 months of age. For children 1 to 8 years of age, IOM did not change the UL of 2,500 mg/p/d from the previous IOM report in 1997. For children 9 to 18 years of age, IOM increased the UL to 3,000 mg/p/d. For adults 19 to 50 years of age, the IOM established a UL of 2,500 mg/p/d; for adults 51 years and older, the IOM established a UL of 2,000 mg/p/d.

The IOM considers the UL as the highest average daily intake level of a nutrient that poses no risk of adverse effects when the nutrient is consumed over long periods of time. The UL is determined using a risk assessment model developed specifically for nutrients. The dose-response assessment, which concludes with an estimate of the UL, is built upon three toxicological concepts commonly used in assessing the risk of exposures to chemical substances: No-observed-adverse-effect level, lowest-observed-effect level, and application of an uncertainty factor. We considered the ULs established by the IOM relative to the exposure estimates for calcium as the primary basis for assessing the safety of the petitioned uses of calcium carbonate.

The estimated dietary exposure to calcium from the petitioned uses, dietary sources, and dietary supplements at the 90th percentile for the U.S. population 2 years of age and older is estimated to be 1,925 mg/p/d, which is below the IOM's UL of 2,000–3,000 mg/p/d. For children 2 to 5 years of age, the exposure estimate at the 90th percentile is 1,625 mg/p/d, which also is below the IOM's UL of 2,500 mg/p/d for this age group. Additionally, the body of literature on calcium carbonate and calcium does not present evidence of safety concerns at the expected dietary exposures discussed above. Thus, we conclude that the petitioned use of calcium carbonate as a color additive in soft and hard candy, mints, and chewing gum is safe (Ref. 5).

IV. Incorporation by Reference

FDA is incorporating by reference the Food Chemicals Codex, 10th ed. (2016), pp. 213–214 (calcium carbonate) and p. 754 (limestone, ground), which was approved by the Office of the Federal Register. You may purchase a copy of the material from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (*http://www.usp.org*). Copies also may be examined at FDA's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039.

The FCC is a compendium of internationally recognized standards for the purity and identity of food ingredients. To ensure that only food grade calcium carbonate and ground limestone (consisting of not less than 94 percent calcium carbonate) are used in hard and soft candy, mints, and chewing gum, the additive must meet the specifications and identity in the appropriate FCC monograph.

V. Conclusion

FDA reviewed the data and information in the petition and other available relevant material and determined the use of calcium carbonate to color hard and soft candy, mints, and chewing gum at GMP levels is safe. We further conclude that the additive will achieve its intended technical effect and is suitable for the petitioned uses. We note that these uses do not extend to chocolate or the chocolate portion of candy because the standards of identity for chocolate do not allow for the addition of color additives (see 21 CFR 163.123, 163.124, 163.130, 163.135, 163.140, 163.145, 163.153, 163.155). Based on the available information, we are amending the color additive regulations in part 73 as set forth in this document. In addition, based on the factors listed in 21 CFR 71.20(b), we conclude that certification of calcium carbonate to color hard and soft candy, mints, and chewing gum is not necessary for the protection of public health (Ref. 1).

VI. Public Disclosure

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, we will delete from the documents any materials that are not available for public disclosure.

VII. Analysis of Environmental Impact

We previously considered the environmental effects of this rule, as stated in the October 7, 2016, **Federal Register** notice of petition for CAP 6C0307 (81 FR 69740). We stated that we had determined, under 21 CFR

25.32(k), that this action ''is of a type that does not individually or cumulatively have a significant effect on the human environment'' such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect our previous determination.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Section 301(ll) of the Federal Food, Drug, and Cosmetic Act

Our review of this petition was limited to section 721 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)) prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1) to (ll)(4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this color additive. Accordingly, this final rule should not be construed to be a statement that a food containing this color additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all color additive final rules that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

X. Objections

This rule is effective as shown in the **DATES** section, except as to any provisions that may be stayed by the filing of proper objections. If you will be adversely affected by one or more provisions of this regulation, you may file with the Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

Any objections received in response to the regulation may be seen at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.* We will publish notice of the objections that we have received or lack thereof in the **Federal Register**.

XI. 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 also are available electronically at *https://www.regulations.gov.* References that are published articles and books are not on display.

1. Memorandum from N. Hepp, Color Technology Team, Office of Cosmetics and Colors (OCAC), CFSAN, FDA to C. Johnston, Division of Petition Review, Office of Food Additive Safety (OFAS), CFSAN, FDA, October 27, 2016.
2. Memorandum from D. Doell, Division of Petition Review, OFAS, CFSAN, FDA to J. Kidwell, Division of Petition Review, OFAS, CFSAN, FDA, February 16, 2017.
3. Committee to Review Dietary Reference Intakes for Vitamin D and Calcium, Food and Nutrition Board, Institute of Medicine, ''Dietary Reference Intakes for Calcium and Vitamin D,'' National Academies Press, Washington, DC, 2011.
4. European Food Safety Authority (EFSA). ''Scientific Opinion on the Tolerable Upper Intake Level of Calcium.'' *EFSA Journal,* vol. 10(7), p. 2814, 2012.
5. Memorandum from T. Thurmond, Division of Petition Review, OFAS, CFSAN, FDA to J. Kidwell, Division of Petition Review, OFAS, CFSAN, FDA, February 17, 2017.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Incorporation by reference, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

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

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Section 73.70 is added to subpart A to read as follows:

§ 73.70 Calcium carbonate.

(a) *Identity.* (1) The color additive calcium carbonate is a fine, white powder consisting essentially of calcium carbonate ($CaCO_3$) prepared either by grinding naturally occurring limestone or synthetically, by precipitation.

(2) Color additive mixtures for food use made with calcium carbonate may contain only those diluents that are suitable and that are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* The color additive meets the specifications of the Food Chemicals Codex, 10th ed. (2016), pp. 213–214 (calcium carbonate) and p. 754 (limestone, ground), which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (internet address *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or 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/code_of_federal_regulations/cfr/ibr_locations.html.*

(c) *Uses and restrictions.* Calcium carbonate may be safely used in amounts consistent with good manufacturing practice to color soft and hard candies and mints, and in inks used on the surface of chewing gum, except that it may not be used to color chocolate for which standards of identity have been promulgated under section 401 of the Federal Food, Drug,

and Cosmetic Act unless added color is authorized by such standards.

(d) *Labeling requirements.* The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes must conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and, therefore, batches thereof are exempt from the certification requirements of section 721(c) of the Federal Food, Drug, and Cosmetic Act.

Dated: November 1, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24194 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 862

[Docket No. FDA–2017–N–4394]

Medical Devices; Clinical Chemistry and Clinical Toxicology Devices; Classification of the Total 25-Hydroxyvitamin D Mass Spectrometry Test System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the total 25-hydroxyvitamin D mass spectrometry test system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the total 25-hydroxyvitamin D mass spectrometry test system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective November 7, 2017. The classification was applicable on May 18, 2017.

FOR FURTHER INFORMATION CONTACT: Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993–0002, 301–796–5866, *steven.tjoe@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the total 25-hydroxyvitamin D mass spectrometry test system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On March 20, 2017, AB Sciex LLC submitted a request for De Novo classification of the Vitamin D 200M Assay for the Topaz System. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the generals controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable

assurance of the safety and effectiveness of the device.

Therefore, on May 18, 2017, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 862.1840. We have named the generic type of device total 25-hydroxyvitamin D mass spectrometry test system, and it is identified as a device intended for use in clinical laboratories for the quantitative determination of total 25-hydroxyvitamin D (25–OH–D) in serum or plasma to be used in the assessment of vitamin D sufficiency.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—TOTAL 25-HYDROXYVITAMIN D MASS SPECTROMETRY TEST SYSTEM RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Clinical action based on falsely elevated inaccurate Vitamin D results may lead to unnecessary supplementation of Vitamin D.	General controls; Special control (1) (21 CFR 862.1840(b)(1)); and, Special control (2) (21 CFR 862.1840(b)(2)).
Clinical action based on falsely low inaccurate Vitamin D results may lead to a delay in supplementation of Vitamin D.	General controls; Special control (1) (21 CFR 862.1840(b)(1)); and, Special control (2) (21 CFR 862.1840(b)(2)).
Clinical action based on uninterpretable results due to lack of established device specific reference range values for the representative population.	General controls; and, Special control (3) (21 CFR 862.1840(b)(3)).
Clinical action based on the misinterpretation of Vitamin D2 or Vitamin D3 results as total Vitamin D results.	General controls; and, Special control (4) (21 CFR 862.1840(b)(4)).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k).

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine by order that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness of the device. We believe this may be such a device. The notice of intent to exempt the device from premarket notification requirements is published elsewhere in this issue of the **Federal Register**.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR parts 801 and 809, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 862

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 1. The authority citation for part 862 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 862.1840 to subpart B to read as follows:

§ 862.1840 Total 25-hydroxyvitamin D mass spectrometry test system.

(a) *Identification.* A total 25-hydroxyvitamin D mass spectrometry test system is a device intended for use in clinical laboratories for the quantitative determination of total 25-hydroxyvitamin D (25–OH–D) in serum or plasma to be used in the assessment of vitamin D sufficiency.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The device must have initial and annual standardization verification by a certifying vitamin D standardization organization deemed acceptable by FDA.

(2) The 21 CFR 809.10(b) compliant labeling must include detailed descriptions of performance testing conducted to evaluate precision, accuracy, linearity, interference, including the following:

(i) Performance testing of device precision must, at a minimum, use intended sample type with Vitamin D concentrations at medically relevant decision points. At least one sample in the precision studies must be an unmodified patient sample. This testing must evaluate repeatability and reproducibility using a protocol from an FDA-recognized standard.

(ii) Performance testing of device accuracy must include a minimum of 115 serum or plasma samples that span the measuring interval of the device and compare results of the new device to results of a reference method or a legally marketed standardized mass spectrometry based vitamin D assay. The results must be described in the 21 CFR 809.10(b)(12) compliant labeling of the device.

(iii) Interference from vitamin D analogs and metabolites including vitamin D2, vitamin D3, 1-hydroxyvitamin D2, 1-hydroxyvitamin D3, 3-Epi-25-Hydroxyvitamin D2, 3-Epi-25-Hydroxyvitamin D3, 1,25-Dihydroxyvitamin D2, 1,25-Dihydroxyvitamin D3, 3-Epi-1,25-Dihydroxyvitamin D2, and 3-Epi-1,25-Dihydroxyvitamin D3, 25, 26-Dihydroxyvitamin-D3, 24 (R), 25-dihydroxyvitamin-D3, 23 (R), 25-dihydroxyvitamin-D3 must be described in the 21 CFR 809.10(b)(7) compliant labeling of the device.

(3) The 21 CFR 809.10(b) compliant labeling must be supported by a reference range study representative of

the performance of the device. The study must be conducted using samples collected from apparently healthy male and female adults at least 21 years of age and older from at least 3 distinct climatic regions within the United States in different weather seasons. The ethnic, racial, and gender background of this study population must be representative of the U.S. population demographics.

(4) The results of the device as provided in the 21 CFR 809.10(b) compliant labeling and any test report generated must be reported as only total 25-hydroxyvitamin D.

Dated: October 31, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–24161 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2017–N–4341]

Medical Devices; Immunology and Microbiology Devices; Classification of the Genetic Health Risk Assessment System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is classifying the genetic health risk assessment system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the genetic health risk assessment system's classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective November 7, 2017. The classification was applicable on April 6, 2017.

FOR FURTHER INFORMATION CONTACT: Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993–0002, 301–796–5866, *steven.tjoe@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the genetic health risk assessment system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1))). We refer to these devices as ''postamendments devices'' because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the FD&C Act.

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or PMA in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On June 28, 2016, 23andMe, Inc. submitted a request for De Novo classification of the 23andMe Personal Genome Service (PGS) Test. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 6, 2017, FDA issued an order to the requester classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 866.5950. We have named the generic type of device genetic health risk assessment system, and it is identified as a qualitative in vitro molecular diagnostic system used for detecting variants in genomic deoxyribonucleic acid (DNA) isolated from human specimens that will provide information to users about their genetic risk of developing a disease to inform lifestyle choices and/or conversations with a health care professional. This assessment system is for over-the-counter use. This device does not determine the person's overall risk of developing a disease.

FDA has identified the following risks to health associated specifically with this type of device and the measures required to mitigate these risks in table 1.

TABLE 1—GENETIC HEALTH RISK ASSESSMENT SYSTEM RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Incorrect understanding of the device and test system	General controls, Special control (1) (21 CFR 866.5950(b)(1)), Special control (3) (21 CFR 866.5950(b)(3)), and Special control (4) (21 CFR 866.5950 (b)(4)).
Incorrect test results (false positives, false negatives)	General controls, Special control (2) (21 CFR 866.5950(b)(2)), and Special control (3) (21 CFR 866.5950(b)(3)).
Incorrect interpretation of test results	General controls, Special control (1) (21 CFR 866.5950(b)(1)), Special control (3) (21 CFR 866.5950(b)(3)), and Special control (4) (21 CFR 866.5950(b)(4)).

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k) of the FD&C Act.

Section 510(m)(2) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) if, after notice of our intent to exempt and consideration of comments, we determine by order that premarket notification is not necessary to provide reasonable assurance of safety and effectiveness of the device. We believe this may be such a device. The notice of intent to exempt the device from premarket notification requirements is published elsewhere in this issue of the **Federal Register**.

III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR parts 801 and 809, regarding labeling have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 2. Add § 866.5950 to subpart F to read as follows:

§ 866.5950 Genetic health risk assessment system.

(a) *Identification.* A genetic health risk assessment system is a qualitative in vitro molecular diagnostic system used for detecting variants in genomic deoxyribonucleic acid (DNA) isolated from human specimens that will provide information to users about their genetic risk of developing a disease to inform lifestyle choices and/or conversations with a health care professional. This assessment system is for over-the-counter use. This device does not determine the person's overall risk of developing a disease.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The 21 CFR 809.10 compliant labeling and any prepurchase page and test report generated, unless otherwise specified, must include:

(i) A section addressed to users with the following information:

(A) The limiting statement explaining that this test provides genetic risk information based on assessment of specific genetic variants but does not report on a user's entire genetic profile. This test [does not/may not, as appropriate] detect all genetic variants related to a given disease, and the absence of a variant tested does not rule out the presence of other genetic variants that may be related to the disease.

(B) The limiting statement explaining that other companies offering a genetic risk test may be detecting different genetic variants for the same disease, so the user may get different results using a test from a different company.

(C) The limiting statement explaining that other factors such as environmental and lifestyle risk factors may affect the risk of developing a given disease.

(D) The limiting statement explaining that some people may feel anxious about getting genetic test health results. This is normal. If the potential user feels very anxious, such user should speak to his or her doctor or other health care professional prior to collection of a sample for testing. This test is not a substitute for visits to a doctor or other health care professional. Users should consult with their doctor or other health

care professional if they have any questions or concerns about the results of their test or their current state of health.

(E) Information about how to obtain access to a genetic counselor, board-certified clinical molecular geneticist, or equivalent health care professional about the results of a user's test.

(F) The limiting statement explaining that this test is not intended to diagnose a disease, tell you anything about your current state of health, or be used to make medical decisions, including whether or not you should take a medication or how much of a medication you should take.

(G) A limiting statement explaining that the laboratory may not be able to process a sample, and a description of the next steps to be taken by the manufacturer and/or the customer, as applicable.

(ii) A section in your 21 CFR 809.10 labeling and any test report generated that is for health care professionals who may receive the test results from their patients with the following information:

(A) The limiting statement explaining that this test is not intended to diagnose a disease, determine medical treatment, or tell the user anything about their current state of health.

(B) The limiting statement explaining that this test is intended to provide users with their genetic information to inform lifestyle decisions and conversations with their doctor or other health care professional.

(C) The limiting statement explaining that any diagnostic or treatment decisions should be based on testing and/or other information that you determine to be appropriate for your patient.

(2) The genetic test must use a sample collection device that is FDA-cleared, -approved, or -classified as 510(k) exempt, with an indication for in vitro diagnostic use in over-the-counter DNA testing.

(3) The device's labeling must include a hyperlink to the manufacturer's public Web site where the manufacturer shall make the information identified in paragraph (b)(3) of this section publicly available. The manufacturer's home page, as well as the primary part of the manufacturer's Web site that discusses the device, must provide a hyperlink to the Web page containing this information and must allow unrestricted viewing access. If the device can be purchased from the Web site or testing using the device can be ordered from the Web site, the same information must be found on the Web page for ordering the device or provided in a publicly accessible hyperlink on the Web page for ordering the device. Any changes to the device that could significantly affect safety or effectiveness would require new data or information in support of such changes, which would also have to be posted on the manufacturer's Web site. The information must include:

(i) An index of the material being provided to meet the requirements in paragraph (b)(3) of this section and its location.

(ii) A section that highlights summary information that allows the user to understand how the test works and how to interpret the results of the test. This section must, at a minimum, be written in plain language understandable to a lay user and include:

(A) Consistent explanations of the risk of disease associated with all variants included in the test. If there are different categories of risk, the manufacturer must provide literature references that support the different risk categories. If there will be multiple test reports and multiple variants, the risk categories must be defined similarly among them. For example, ''increased risk'' must be defined similarly between different test reports and different variant combinations.

(B) Clear context for the user to understand the context in which the cited clinical performance data support the risk reported. This includes, but is not limited to, any risks that are influenced by ethnicity, age, gender, environment, and lifestyle choices.

(C) Materials that explain the main concepts and terminology used in the test that include:

(*1*) *Definitions:* Scientific terms that are used in the test reports.

(*2*) *Prepurchase page:* This page must contain information that informs the user about what information the test will provide. This includes, but is not limited to, variant information, the condition or disease associated with the variant(s), professional guideline recommendations for general genetic risk testing, the limitations associated with the test (*e.g.,* test does not detect all variants related to the disease) and any precautionary information about the test the user should be aware of before purchase. When the test reports the risk of a life-threatening or irreversibly debilitating disease or condition for which there are few or no options to prevent, treat, or cure the disease, a user opt-in section must be provided. This opt-in page must be provided for each disease that falls into this category and must provide specific information relevant to each test result. The opt-in page must include:

(*i*) An option to accept or decline to receive this specific test result;

(*ii*) Specification of the risk involved if the user is found to have the specific genetic test result;

(*iii*) Professional guidelines that recommend when genetic testing for the associated target condition is or is not recommended; and

(*iv*) A recommendation to speak with a health care professional, genetic counselor, or equivalent professional before getting the results of the test.

(*3*) *Frequently asked questions (FAQ) page:* This page must provide information that is specific for each variant/disease pair that is reported. Information provided in this section must be scientifically valid and supported by corresponding publications. The FAQ page must explain the health condition/disease being tested, the purpose of the test, the information the test will and will not provide, the relevance of race and ethnicity to the test results, information about the population to which the variants in the test is most applicable, the meaning of the result(s), other risk factors that contribute to disease, appropriate followup procedures, how the results of the test may affect the user's family, including children, and links to resources that provide additional information.

(iii) A technical information section containing the following information:

(A) Gene(s) and variant(s) the test detects using standardized nomenclature, Human Genome Organization nomenclature and coordinates as well as Single Nucleotide Polymorphism Database (dbSNP) reference SNP numbers (rs#).

(B) Scientifically established disease-risk association of each variant detected and reported by the test. This risk association information must include:

(*1*) Genotype-phenotype information for the reported variants.

(*2*) Table of expected frequency and risks of developing the disease in relevant ethnic populations and the general population.

(*3*) A statement about the current professional guidelines for testing these specific gene(s) and variant(s).

(*i*) If professional guidelines are available, provide the recommendations in the professional guideline for the gene, variant, and disease, for when genetic testing should or should not be performed, and cautionary information that should be communicated when a particular gene and variant is detected.

(*ii*) If professional guidelines are not available, provide a statement that the professional guidelines are not available for these specific gene(s) and variant(s).

(C) The specimen type (*e.g.,* saliva, capillary whole blood).

(D) Assay steps and technology used.

(E) Specification of required ancillary reagents, instrumentation, and equipment.

(F) Specification of the specimen collection, processing, storage, and preparation methods.

(G) Specification of risk mitigation elements and description of all additional procedures, methods, and practices incorporated into the directions for use that mitigate risks associated with testing.

(H) Information pertaining to the probability of test failure (*i.e.,* percentage of tests that failed quality control) based on data from clinical samples, a description of scenarios in which a test can fail (*i.e.,* low sample volume, low DNA concentration, etc.), how users will be notified of a test failure, and the nature of followup actions on a failed test to be taken by the user and the manufacturer.

(I) Specification of the criteria for test result interpretation and reporting.

(J) Information that demonstrates the performance characteristics of the test, including:

(*1*) Accuracy of study results for each claimed specimen type.

(*i*) Accuracy of the test shall be evaluated with fresh clinical specimens collected and processed in a manner consistent with the test's instructions for use. If this is impractical, fresh clinical samples may be substituted or supplemented with archived clinical samples. Archived samples shall have been collected previously in accordance with the instructions for use, stored appropriately, and randomly selected. In some limited circumstances, use of contrived samples or human cell line samples may also be appropriate and used as an acceptable alternative. The contrived or human cell line samples shall mimic clinical specimens as much as is feasible and provide an unbiased evaluation of the device accuracy.

(*ii*) Accuracy must be evaluated by comparison to bidirectional Sanger sequencing or other methods identified as appropriate by FDA. Performance criteria for both the comparator method and the device must be predefined and appropriate to the device's intended use. Detailed study protocols must be provided.

(*iii*) Test specimens must include all genotypes that will be included in the tests and reports. The number of samples tested in the accuracy study for each variant reported must be based on the variant frequency using either the minimum numbers of samples identified in this paragraph or, when determined appropriate and identified by FDA, a minimum number of samples determined using an alternative method. When appropriate, the same samples may be used in testing to demonstrate the accuracy of testing for multiple genotypes by generating sequence information at multiple relevant genetic locations. At least 20 unique samples representing the wild-type genotype must be tested. To test samples that are heterozygous for the reported variant(s), common variants (>0.1 percent variant frequency in the relevant population) must be tested with at least 20 unique samples. Rare variants (≤0.1 percent variant frequency in the relevant population) must be tested with at least three unique samples. To test samples that are homozygous for the reported variant(s), variants with ≥2 percent variant frequency in a relevant population must be tested with at least 20 unique samples. Variants with a frequency in the relevant population <2 percent and ≥0.5 percent must be tested with at least 10 unique samples. Variants with a frequency in the relevant population <0.5 percent must be tested with at least three unique samples. If variants with a frequency of <0.5 percent are not found within the relevant population and homozygous samples are not tested, then the test results for this homozygous rare variant must not be reported to the user.

(*iv*) Information about the accuracy study shall include the number and type of samples that were compared to bidirectional Sanger sequencing or other methods identified as appropriate by FDA. This information must either be reported in tabular format and arranged by clinically relevant variants or reported using another method identified as appropriate by FDA. As an example, for samples with different genotypes DD, Dd, and dd, the following table represents data from the accuracy study presented in tabular format:

		Comparator		
		DD	Dd	dd
Device	DD	A_1	B_1	C_1
	Dd	A_2	B_2	C_2
	Dd	A_3	B_3	C_3
	no calls or *invalid*	A_4	B_4	C_4
Total		N_{DD}	N_{Dd}	N_{dd}

where:

D and d = Variants; d = Risk variant;

A_1, A_2, A_3, A_4 are numbers of samples with DD result by the comparator and DD, Dd, dd, or 'no calls' or 'invalid' results by the device correspondingly and N_{DD} is the total number of samples with DD result by the comparator ($N_{DD}=A_1+A_2+A_3+A_4$);

B_1, B_2, B_3, B_4 are numbers of samples with Dd result by the comparator and DD, Dd, dd, or 'no calls' or 'invalid' results by the device correspondingly and N_{Dd} is the total number of samples with Dd result by the comparator ($N_{Dd}=B_1+B_2+B_3+B_4$);

C_1, C_2, C_3, C_4 are numbers of samples with dd result by the comparator and DD, Dd, dd, or 'no calls' or 'invalid' results by the device correspondingly and N_{dd} is the total number of samples with dd result by the comparator ($N_{dd}=C_1+C_2+C_3+C_4$);

(*v*) The accuracy represents the degrees of agreement between the device results and the comparator results. The accuracy must be evaluated by measuring different percent agreements (PA) of device results with the comparator results and percent of 'no calls' or 'invalid calls.' Calculate the rate of 'no calls' and 'invalid calls' for each comparator output as %Inv(DD) = A_4/N_{DD}, %Inv(Dd) = B_4/N_{Dd}, %Inv(dd) = C_4/N_{dd}. If 'no calls' or 'invalid calls' are required to be retested according to the device instructions for use, the percent of final 'no calls' or 'invalid calls' must be provided. In the table presenting the results of the accuracy study, use only the final results (*i.e.,* after retesting the initial 'no calls' or 'invalid calls', if required according to the instructions for use). Samples that resulted in a 'no call' or 'invalid call' after retesting must not be included in the final calculations of agreement. If the percentages of 'no calls' or 'invalid calls' for each comparator output are similar, combine these estimates as $(A_4 + B_4 + C_4)/(N_{DD} + N_{Dd} + N_{dd})$ and provide a 95 percent two-sided confidence interval. The percent of final 'no calls' or 'invalid calls' must be clinically acceptable.

(*vi*) Point estimates of percent agreement for each genotype must be calculated as the number of correct calls for that genotype divided by the number of samples known to contain that genotype excluding 'no calls' or 'invalid calls'. The calculations must be performed as follows:

$$PA(DD|DD)=A_1/(A_1+A_2+A_3);$$

$$PA(Dd|DD)=A_2/(A_1+A_2+A_3); \text{ and } PA(dd|DD)=1- PA(DD|DD)- PA(Dd|DD).$$

$$PA(Dd|Dd)=B_2/(B_1+B_2+B_3);$$

$$PA(DD|Dd)=B_1/(B_1+B_2+B_3); \text{ and } PA(dd|Dd)=1-PA(DD|Dd)-PA(Dd|Dd).$$

$$PA(dd|dd)=C_3/(C_1+C_2+C_3);$$

$$PA(Dd|dd)=C_2/(C_1+C_2+C_3) \text{ and } PA(DD|dd)=1-P(Dd|dd)-PA(dd|dd).$$

(*vii*) For percent agreements for DD, Dd and dd (PA(DD|DD), PA(Dd|Dd) and PA(dd|dd)) as described in paragraph (b)(3)(iii)(J)(*1*)(*vi*) of this section, the 95 percent two-sided confidence intervals must be provided. The accuracy point estimates for percent agreements for DD, Dd and dd must be ≥99 percent per reported variant and overall. Any variants that have a point estimate for either PA(DD|DD), PA(Dd|Dd), or PA(dd|dd) of <99 percent compared to bidirectional sequencing or other methods identified as appropriate by FDA must not be incorporated into test claims and reports. Accuracy results generated from clinical specimens versus contrived samples or cell lines must be presented separately. Results must be summarized and presented in tabular format by sample type and by genotype or must be reported using another method identified as appropriate by FDA (see paragraph (b)(3)(iii)(J)(*1*)(*iv*) of this section).

(*viii*) Information must be reported on the Technical Positive Predictive Value (TPPV) related to the analytical (technical) performance of the device for genotypes in each relevant subpopulation (*e.g.,* ethnicity, gender, age, geographical location, etc.). TPPV is the percentage of individuals with the genotype truly present among individuals whose test reports indicate that this genotype is present. The TPPV depends on the accuracy measures of percent agreements and on the frequency of the genotypes in the subpopulation being studied. The f(DD) is the frequency of DD and f(Dd) is the frequency of Dd in the subpopulation being studied; TPPV must be calculated as described in paragraphs (b)(3)(iii)(J)(*1*)(*ix*) through (*xi*) of this section.

(*ix*) For variants where the point estimates of PA(DD|DD), PA(Dd|Dd) and PA(dd|dd) are less than 100 percent, use these point estimates in TPPV calculations.

(*x*) Point estimates of 100 percent in the accuracy study may have high uncertainty about performance of the test in the population. If these variants are measured using highly multiplexed technology, calculate the random error rate for the overall device. The accuracy study described in paragraph (b)(3)(iii)(J) of this section in those cases is more to determine that there is no systematic error in such devices. In those cases, incorporate that rate in the estimation of the percent agreements as calculated in paragraph (b)(3)(iii)(J)(*1*)(*vi*) of this section and include it in TPPV calculations.

(*xi*) The TPPV for subpopulations with genotype frequencies of f(dd), f(Dd) and f(DD) = 1 − f(dd) − f(Dd) in the subpopulation is calculated as:

The TPPV for subpopulations with genotype frequencies of f(dd), f(Dd) and f(DD)=1-f(dd)-f(Dd) in the subpopulation is calculated as:

TPPV for a device result of dd = [PA(dd|dd)•f(dd)]/[PA(dd|dd)•f(dd)+PA(dd|Dd)•f(Dd)+PA(dd|DD)•f(DD)]

TPPV for a device result of Dd =[PA(Dd|Dd)•f(Dd)]/[PA(Dd|DD)•f(DD)+PA(Dd|Dd)•f(Dd)+PA(Dd|dd)•f(dd)]

(*2*) Precision and reproducibility data must be provided using multiple instruments and multiple operators, on multiple non-consecutive days, and using multiple reagent lots. The sample panel must either include specimens from the claimed sample type (*e.g.,* saliva) representing all genotypes for each variant (*e.g.,* wild type, heterozygous, and homozygous) or, if an alternative panel composition of specimens is identified by FDA as appropriate, a panel composed of those specimens FDA identified as appropriate. A detailed study protocol must be created in advance of the study and must include predetermined acceptance criteria for performance results. The percentage of samples that failed quality control must be indicated (*i.e.,* the total number of sample replicates for which a sequence variant cannot be called (no calls) or that fail sequencing quality control criteria divided by the total number of replicates tested). It must be clearly documented whether results were generated from clinical specimens, contrived samples, or cell lines. The study results shall report the variants tested in the study and the number of replicates for each variant, and what conditions were tested (*i.e.,* number of runs, days, instruments, reagent lots, operators, specimens/type, etc.). Results must be evaluated and presented in tabular format and stratified by study parameter (*e.g.,* by site, instrument(s), reagent lot, operator, and sample variant). The study must include all extraction steps from the claimed specimen type or matrix, unless a separate extraction reproducibility study for the claimed sample type is performed. If the device is to be used at more than one laboratory, different laboratories must be included in the reproducibility study and reproducibility across sites must be evaluated. Any no calls or invalid calls in the study must be listed as a part of the precision and reproducibility study results.

(*3*) *Analytical specificity data:* Data must be provided that evaluates the effect of potential endogenous and exogenous interferents on test performance, including specimen extraction and variant detection. Interferents tested must include those reasonably likely to be potentially relevant to the sample type used for the device.

(*4*) *Interfering variant data:* Nucleotide mutations that can interfere with the technology must be cited and evaluated. Data must be provided to demonstrate the effect of the interfering variant(s) on the performance of the correct calls. Alternatively, for each suspected interfering mutation for which data is not provided demonstrating the effect of the interfering variant, the manufacturer must identify the suspected interfering

variants in the labeling and indicate that the impact that the interfering variants may have on the assay's performance has not been studied by providing a statement that reads ''It is possible that the presence of [insert clearly identifying information for the suspected interfering variant] in a sample may interfere with the performance of this test. However, its effect on the performance of this test has not been studied.''

(*5*) *Analytical sensitivity data:* Data must be provided demonstrating the minimum amount of DNA that will enable the test to perform correctly in 95 percent of runs.

(*6*) *Reagent stability:* The manufacturer must evaluate reagent stability using wild-type, heterozygous, and homozygous samples. Reagent stability data must demonstrate that the reagents maintain the claimed accuracy and reproducibility. Data supporting such claims must be provided.

(*7*) *Specimen type and matrix comparison data:* Specimen type and matrix comparison data must be generated if more than one specimen type can be tested with this device, including failure rates for the different specimens.

(K) Clinical performance summary.

(*1*) Information to support the clinical performance of each variant reported by the test must be provided.

(*2*) Manufacturers must organize information by the specific variant combination as appropriate (*e.g.,* wild type, heterozygous, homozygous, compound heterozygous, hemizygous genotypes). For each variant combination, information must be provided in the clinical performance section to support clinical performance for the risk category (*e.g.,* not at risk, increased risk). For each variant combination, a summary of key results must be provided in tabular format or using another method identified as appropriate by FDA to include the appropriate information regarding variant type, data source, definition of the target condition (*e.g.,* disease), clinical criteria for determining whether the target disease is present or absent, description of subjects with the target disease present and target disease absent (exclusion or inclusion criteria), and technical method for genotyping. When available, information on the effect of the variant on risk must be provided as the risk of a disease (lifetime risk or lifetime incidences) for an individual compared with the general population risk.

(*i*) If odds ratios are available, using information about the genotype distribution either among individuals with the target disease absent, or in the general population, or information about the risk variant frequency and odds ratios, the likelihood ratios for the corresponding device results along with 95 percent confidence intervals must be calculated. Using information about pretest risk (π), an estimate of likelihood ratio (LR), and a relationship between post-test risk R as $R/(1-R) = LR \cdot \pi/(1-\pi)$, the post-test risk R must be calculated.

(*ii*) When available, likelihood ratios (LR) for different test results must be presented in a tabular format along with references to the source data or using another method identified as appropriate by FDA as stated in paragraph (b)(3)(iii)(K)(2) of this section. When these values are not directly available in published literature, likelihood ratios can be separately calculated along with the 95 percent confidence interval with references to the source data. Note that a minimum requirement for the presence of the variant's effect on the risk is that a corresponding LR is statistically higher than 1 (a lower bound of 95 percent two-sided confidence interval is larger than 1). It means that the post-test risk is statistically higher than the pretest risk (an observed value of the difference between the post-test and pretest risks).

(L) Materials that explain the main concepts and terminology used in the test that includes, but is not limited to:

(*1*) *Definitions:* Scientific terms that are used in the test reports.

(*2*) *Prepurchase page:* This page must contain information that informs the user about what the test will provide. This includes, but is not limited to, variant information, the condition or disease associated with the variant(s), professional guideline recommendations for general genetic risk testing, the limitations associated with the test (*e.g.,* test does not detect all variants related to the disease) and any precautionary information about the test the user should be aware of before purchase. When the test reports the risk of a life-threatening or irreversibly debilitating disease or condition for which there are few or no options to prevent, treat, or cure the disease, a user opt-in section must be provided. This opt-in page must be provided for each disease that falls into this category and must provide specific information relevant to each test result. The opt-in page must include:

(*i*) An option to accept or decline to receive this specific test result;

(*ii*) Specification of the risk involved if the user is found to have the specific genetic test result;

(*iii*) Professional guidelines that recommend when genetic testing for the associated target condition is or is not recommended; and

(*iv*) A recommendation to speak with a health care professional, genetic counselor, or equivalent professional before getting the results of the test.

(*3*) Frequently asked questions (FAQ) page: This page must provide information that is specific for each variant/disease pair that is reported. Information provided in this section must be scientifically valid and supported by corresponding publications. The FAQ page must explain the health condition/disease being tested, the purpose of the test, the information the test will and will not provide, the relevance of race and ethnicity on the test results, information about the population to which the variants in the test is most applicable, the meaning of the result(s), other risks factors that contribute to disease, appropriate followup procedures, how the results of the test may affect the user's family, including children, and links to resources that provide additional information.

(M) User comprehension study: Information on a study that assesses comprehension of the test process and results by potential users of the test must be provided.

(*1*) The test manufacturer must provide a genetic risk education module to naïve user comprehension study participants prior to their participation in the user comprehension study. The module must define terms that are used in the test reports and explain the significance of genetic risk reports.

(*2*) The test manufacturer must perform pre- and post-test user comprehension studies. The comprehension test questions must include directly evaluating a representative sample of the material being presented to the user as described in paragraph (b)(3)(ii) of this section.

(*3*) The manufacturer must provide a justification from a physician and/or genetic counselor that identifies the appropriate general and variant-specific concepts contained within the material being tested in the user comprehension study to ensure that all relevant concepts are incorporated in the study.

(*4*) The user study must meet the following criteria:

(*i*) The study participants must comprise a statistically sufficient sample size and demographically diverse population (determined using methods such as quota-based sampling) that is representative of the intended user population. Furthermore, the study participants must comprise a diverse

range of age and educational levels and have no prior experience with the test or its manufacturer. These factors shall be well defined in the inclusion and exclusion criteria.

(*ii*) All sources of bias must be predefined and accounted for in the study results with regard to both responders and non-responders.

(*iii*) The testing must follow a format where users have limited time to complete the studies (such as an onsite survey format and a one-time visit with a cap on the maximum amount of time that a participant has to complete the tests).

(*iv*) Users must be randomly assigned to study arms. Test reports in the user comprehension study given to users must define the target condition being tested and related symptoms, explain the intended use and limitations of the test, explain the relevant ethnicities in regard to the variant tested, explain genetic health risks and relevance to the user's ethnicity, and assess participants' ability to understand the following comprehension concepts: The test's limitations, purpose, appropriate action, test results, and other factors that may have an impact on the test results.

(*v*) Study participants must be untrained, be naïve to the test subject of the study, and be provided the labeling prior to the start of the user comprehension study.

(*vi*) The user comprehension study must meet the predefined primary endpoint criteria, including a minimum of a 90 percent or greater overall comprehension rate (*i.e.,* selection of the correct answer) for each comprehension concept. Other acceptance criteria may be acceptable depending on the concept being tested. Meeting or exceeding this overall comprehension rate demonstrates that the materials presented to the user are adequate for over-the-counter use.

(*vii*) The analysis of the user comprehension results must include results regarding reports that are provided for each gene/variant/ethnicity tested, statistical methods used to analyze all data sets, and completion rate, non-responder rate, and reasons for nonresponse/data exclusion. A summary table of comprehension rates regarding comprehension concepts (*e.g.,* purpose of test, test results, test limitations, ethnicity relevance for the test results, etc.) for each study report must be included.

(4) The intended use of the device must not include the following indications for use:

(i) Prenatal testing;

(ii) Determining predisposition for cancer where the result of the test may lead to prophylactic screening, confirmatory procedures, or treatments that may incur morbidity or mortality to the patient;

(iii) Assessing the presence of genetic variants that impact the metabolism, exposure, response, risk of adverse events, dosing, or mechanisms of prescription or over-the-counter medications; or

(iv) Assessing the presence of deterministic autosomal dominant variants.

Dated: November 1, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–24159 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2015–N–3455]

Medical Devices; Exemption From Premarket Notification; Class II Devices; Autosomal Recessive Carrier Screening Gene Mutation Detection System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or Agency) is publishing an order to exempt autosomal recessive carrier screening gene mutation detection systems from the premarket notification requirements, subject to certain limitations. This exemption from 510(k), subject to certain limitations, is immediately in effect for autosomal recessive carrier screening gene mutation detection systems. This exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations. FDA is also amending the codified language for the autosomal recessive carrier screening gene mutation detection system devices classification regulation to reflect this final determination.

DATES: This order is effective November 7, 2017.

FOR FURTHER INFORMATION CONTACT: Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993–0002, 301–796–5866.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(k)) and the implementing regulations, 21 CFR part 807 subpart E, require persons who intend to market a device to submit and obtain FDA clearance of a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a legally marketed device that does not require premarket approval.

On December 13, 2016, the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) was signed into law. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended, section 510(m)(2) provides that, 1 calendar day after the date of publication of the final list under paragraph (1)(B), FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act, upon its own initiative or a petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 60-calendar-day comment period. Within 120 days of publication of such notice, FDA must publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.

II. Criteria for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (referred to herein as the Class II 510(k) Exemption Guidance) (Ref. 1).

III. Device Description

On February 19, 2015, FDA completed its review of a De Novo request for classification of the 23andMe

Personal Genome Service (PGS) Carrier Screening Test for Bloom syndrome. FDA classified the 23andMe PGS Carrier Screening Test for Bloom syndrome, and substantially equivalent devices of this generic type, into class II (special controls) under the generic name ''Autosomal recessive carrier screening gene mutation detection system.'' This type of device is a qualitative in vitro molecular diagnostic system used for genotyping of clinically relevant variants in genomic DNA isolated from human specimens intended for prescription use or over-the-counter (OTC) use. The device is intended for autosomal recessive disease carrier screening in adults of reproductive age. The device is not intended for copy number variation, cytogenetic, or biochemical testing.

FDA believes that De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for determining substantial equivalence for future devices within that type (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or a premarket approval application in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining ''substantial equivalence''). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

In the **Federal Register** of October 27, 2015 (80 FR 65774), FDA published a notice (''October 2015 notice'') announcing its intent to exempt autosomal recessive carrier screening gene mutation detection system devices from premarket notification requirements, subject to certain limitations, and provided opportunity for interested persons to submit comments by November 27, 2015. After reviewing comments received (summarized in section IV), FDA is now providing its final determination for autosomal recessive carrier screening gene mutation detection system devices by exempting this type of device from premarket notification requirements, subject to certain limitations as identified in this notice. FDA is also amending the codified language for the autosomal recessive carrier screening gene mutation detection system devices classification regulation to reflect this final determination. Persons with pending 510(k) submissions for devices that are now exempt from premarket notification, subject to the limitations, should withdraw their submissions.

IV. Comments on the Proposed Exemption and FDA Response

In response to the October 2015 notice announcing FDA's intent to exempt autosomal recessive carrier screening gene mutation detection system devices from premarket notification requirements, FDA received submissions from three commenters—a device industry manufacturer, a professional organization, and a health care organization—supporting an exemption from premarket notification for this type of device.

To make it easier to identify comments and our responses, the word ''Comment'' and a comment number appear in parentheses before each comment's description, and the word ''Response'' in parentheses precedes each response. Similar comments are grouped together under the same number. Specific issues raised by the comments and the Agency's responses follow.

(Comment 1) Two commenters requested that FDA clarify that the list of autosomal recessive carrier diseases included in the October 2015 notice is not exhaustive or expand the list of diseases and conditions covered by the exemption to include all diseases and conditions described in the scientific literature as inherited in an autosomal recessive manner. One commenter further requested that FDA clarify that the determination of the applicability of § 866.5940 (21 CFR 866.5940) should be based upon scientific and clinical literature as to the autosomal recessive nature of the disease or condition.

(Response) The diseases and conditions listed in table 1 of the October 2015 notice were based upon a limited review of the scientific and clinical literature at that time. After consideration of the public comments, FDA agrees that the autosomal recessive diseases and conditions listed in that table should be treated as illustrative, and not an exhaustive list. Based on FDA's review of current scientific and clinical literature, FDA would not consider screening for autosomal recessive carrier status by detection of clinically relevant gene mutations associated with a large variety of diseases and conditions, in addition to those listed in table 1 of the October 2015 notice, to constitute a different intended use from that of a legally marketed device in the generic type under § 866.5940 for purposes of § 866.9 (21 CFR 866.9). Because FDA agrees that the list of diseases and conditions provided in the October 2015 notice is not comprehensive, and that applicability of § 866.5940 should be based upon scientific and clinical literature as to the autosomal recessive nature of a particular disease or condition, we are not providing a revised list in this final order.

(Comment 2) One commenter requested clarification that § 866.5940 applies to OTC carrier detection devices for the determination of carrier status by detection of clinically relevant gene mutations associated with cystic fibrosis.

(Response) In the October 2015 notice, FDA stated ''[a] gene mutation detection system indicated for the determination of carrier status by detection of clinically relevant gene mutations associated with Cystic Fibrosis is not 510(k)-exempt since it is a class II device subject to premarket notification and special controls under 21 CFR 866.5900—*Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system.*'' Similarly, in the final order announcing the classification of an autosomal recessive carrier screening gene mutation detection system into class II (80 FR 65626, October 27, 2015), FDA stated ''A gene mutation detection system indicated for the determination of carrier status by detection of clinically relevant gene mutations associated with cystic fibrosis is separately classified under 21 CFR 866.5900—*Cystic fibrosis transmembrane conductance regulator (CFTR) gene mutation detection system (class II, special controls),* and is thus not included in the de novo classification.''

However, after considering the comments regarding this exemption action, and after reviewing the devices that are classified as CTFR gene mutation detection systems under § 866.5900 (21 CFR 866.5900), FDA is now clarifying that an OTC gene mutation detection system indicated for the determination of autosomal recessive carrier status by detection of clinically relevant gene mutations associated with cystic fibrosis (''OTC Cystic Fibrosis carrier screening test'') is included within the scope of the classification regulation for an autosomal recessive carrier screening gene mutation detection system (§ 866.5940) and this exemption action.

At the time FDA classified a CFTR gene mutation detection system under § 866.5900, we were not aware of any OTC Cystic Fibrosis carrier screening tests, and it was not our intent at the time to classify this test for OTC use. We also note that, to date, the only Cystic Fibrosis carrier screening tests that have been cleared by FDA under § 866.5900 are for prescription use only. Finally,

FDA does not believe that the special controls under § 866.5900(b) would reasonably assure the safety and effectiveness of OTC Cystic Fibrosis carrier screening tests, as such special controls were developed to be applicable to prescription use only tests. For example, when classifying a CFTR gene mutation detection system into class II, FDA determined that the special controls under § 866.5900(b), in conjunction with general controls, provided a reasonable assurance of the safety and effectiveness of the device. One risk to health that FDA identified was that ''errors in interpretation of results may lead to improper clinical recommendations and medical patient management.'' The special controls concerning generation of test results, interpretation of test results, and precautions for interpretation of the test results were developed only for prescription use only tests with health care providers in mind (*see* Section 6—Device Description; Test Results/Reporting, Section 10—Labeling; Interpretation of Results, and Section 10—Labeling; Precautions for interpretations of the ''Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems'' (October 26, 2005) (Ref. 2).

Therefore, FDA is clarifying that with regard to gene mutation detection systems indicated for the determination of carrier status by detection of clinically relevant gene mutations associated with cystic fibrosis, the classification regulation § 866.5900 is only applicable to prescription use only tests. FDA is further clarifying that we would not consider a gene mutation detection system indicated for use as an OTC device for the determination of carrier status by detection of clinically relevant gene mutations associated with cystic fibrosis to constitute a different intended use from that of a legally marketed device in the generic type § 866.5940 for purposes of § 866.9(a). As such, OTC Cystic Fibrosis carrier screening tests are within the scope of the classification regulation for an autosomal recessive carrier screening gene mutation detection system (§ 866.5940) and are included within the scope of this action.

(Comment 3) One commenter requested that the exemption be expanded to include carrier screening for X-linked conditions. The commenter further requested that the exemption be expanded to allow for the reporting of diagnostic results.

(Response) The October 2015 notice and this final order concern the exemption from premarket notification of autosomal recessive carrier screening gene mutation detection systems in the generic type § 866.5940. Devices within the scope of the § 866.5940 regulation for autosomal recessive carrier screening gene mutation detection systems are intended for autosomal recessive carrier screening in adults of reproductive age. The requested indications for carrier screening for X-linked conditions and for reporting of diagnostic results are outside the scope of the § 866.5940 regulation. As this final order concerns only exemption of devices within the § 866.5940 regulation, the request to expand the exemption to include carrier screening for X-linked conditions or for the reporting of diagnostic results is outside the scope of this action.

(Comment 4) The three commenters were generally supportive of the regulation and special controls established for the device type, including for the special controls that relate to genetic counseling (*e.g.,* § 866.5940(b)(1) and (b)(4)(iii)(A)). Two commenters requested FDA provide additional recommendations that relate to the special control requirements related to genetic counseling.

(Response) FDA appreciates the comments supporting the regulation and special controls established for the device type. FDA believes that the class II special controls established for the device type, along with the applicable general controls, provides reasonable assurance of the safety and effectiveness of the device type. FDA notes that while the comments received did not propose specific amendments to the special control requirements, such discussion is outside the scope of the October 2015 notice and this final order, which concerns the exemption from premarket notification of autosomal recessive carrier screening gene mutation detection systems in the generic type § 866.5940.

V. Exemption for Autosomal Recessive Carrier Screening Gene Mutation Detection System Devices

FDA has assessed the need for 510(k) clearance for this type of device by considering the factors discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the Class II 510(k) Exemption Guidance, as previously discussed in the October 2015 notice, and has determined they weigh in favor of 510(k) exemption, subject to certain limitations discussed later in this order. Therefore, for the reasons set forth in the **Federal Register** of October 27, 2015, and as informed by the comments received and FDA's understanding and experience with autosomal recessive carrier screening gene detection systems, FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of autosomal recessive carrier screening gene detection systems, so long as the limitations on exemption described later in this document are not met.

VI. Limitations on Exemption

This exemption from 510(k) for an autosomal recessive carrier screening gene mutation detection system applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. Therefore, a manufacturer of an autosomal recessive carrier screening gene mutation detection system would still be required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into commercial distribution when the device meets any of the conditions described in § 866.9, except § 866.9(c)(2) to the extent it may include an autosomal recessive carrier screening gene mutation detection system, for the reasons explained in the October 2015 notice.

Specifically, an autosomal recessive carrier screening gene mutation detection system is not exempt from the premarket notification requirement if such device: (1) Has an intended use that is different from the intended use of a legally marketed device in that generic type; *e.g.,* the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or (2) operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type; *e.g.,* a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a DNA probe or nucleic acid hybridization or amplification technology rather than culture or immunoassay technology; or (3) is an in vitro device that is intended: for use in the diagnosis, monitoring or screening of neoplastic diseases with the exception of immunohistochemical devices; for measuring an analyte which serves as a surrogate marker for screening, diagnosis, or monitoring of life threatening diseases, such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction, or to monitor therapy; for assessing the

risk of cardiovascular diseases; for use in diabetes management; for identifying or inferring the identity of a microorganism directly from clinical material; for detection of antibodies to microorganisms other than immunoglobulin G (IgG) and IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma; for noninvasive testing; or for near-patient testing (point of care).

Exemption from the requirement of premarket notification does not exempt a device from other applicable regulatory controls under the FD&C Act, including the applicable general and special controls. Indeed, FDA's decision to grant 510(k) exemption for these devices is based, in part, on the special controls, in combination with general controls, providing sufficiently rigorous mitigations for the risks identified for this generic type.

This exemption from 510(k), subject to the limitations described above, is immediately in effect for autosomal recessive carrier screening gene mutation detection systems. This exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with Federal regulation. Specifically, regulated industry will no longer have to invest time and resources in premarket notifications, including preparation of documents and data for submission to FDA, payment of user fees associated with 510(k) submissions, and responding to questions and requests for additional information from FDA during 510(k) review for devices in this exempted type.

VII. Analysis of Environmental Impact

We have determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart, E have been approved under OMB control number 0910–0120 and the collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

IX. References

The following references are on display in 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 also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA Guidance, ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf.*
2. FDA Guidance for Industry and FDA Staff ''Class II Special Controls Guidance Document: CFTR Gene Mutation Detection Systems,'' October 26, 2005, available at: *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071104.pdf.*

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l*, 371.

■ 2. In § 866.5940, revise paragraph (b) introductory text to read as follows:

§ 866.5940 Autosomal recessive carrier screening gene mutation detection system.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9, except § 866.9(c)(2). Autosomal recessive carrier screening gene mutation detection system must comply with the following special controls:

* * * * *

Dated: November 1, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–24162 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

37 CFR Part 42

[Docket No. PTO–P–2016–0029]

RIN 0651–AD10

Rule on Attorney-Client Privilege for Trials Before the Patent Trial and Appeal Board

AGENCY: Patent Trial and Appeal Board, United States Patent and Trademark Office, U.S. Department of Commerce.

ACTION: Final rule.

SUMMARY: This final rule on attorney-client privilege amends the existing rules relating to the United States Patent and Trademark Office (Office or USPTO) trial practice for *inter partes* review, post-grant review, the transitional program for covered business method patents, and derivation proceedings that implemented provisions of the Leahy-Smith America Invents Act (''AIA'') providing for trials before the Office.

DATES: This rule is effective on December 7, 2017.

FOR FURTHER INFORMATION CONTACT: Edward Elliott, Attorney Advisor, by telephone at (571) 272–7024 or by email at *edward.elliott@uspto.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary: Purpose: This final rule clarifies situations where privilege is recognized for communications between clients and their domestic or foreign patent attorneys and patent agents.

Background

In February 2015, the USPTO held a roundtable and solicited comments on attorney-client privilege issues. *See* Notice of Roundtable and Request for Comments on Domestic and International Issues Related to Privileged Communications Between Patent Practitioners and Their Clients, 80 FR 3953 (Jan. 26, 2015). As part of that process, the USPTO requested comments on whether communications between patent applicants or owners with their U.S. patent agents or foreign patent practitioners should be recognized as privileged to the same

extent as communications with U.S. patent attorneys. Respondents unanimously supported a rule recognizing such privilege in courts. *See* USPTO, Summary of Roundtable and Written Comments, available at *http://www.uspto.gov/sites/default/files/documents/Summary%20of%20Privileged%20Communication%20Roundtable.pdf* (''Privilege Report'').

Some roundtable participants noted that rules regarding privilege for U.S. patent agents and foreign practitioners in PTAB discovery proceedings were difficult to discern, as there has been no explicit rule on privilege. When the issue arises before PTAB, Administrative Law Judges make legal determinations as to which communications may be protected from disclosure on a case-by-case basis, based on the Federal Rules of Evidence and common law. *See* 37 CFR 42.62(a); *see also GEA Process Engineering, Inc.* v. *Steuben Foods, Inc.,* IPR2014–00041, Paper 117 (PTAB 2014). U.S. courts have devised several different approaches to determine under what circumstances communications with these practitioners are privileged. As the Privilege Report notes, the common law on privilege for domestic and foreign patent practitioners varies across jurisdictions. Different approaches are taken, and results sometimes conflict. This may lead to administrative inefficiencies and inconsistencies in outcomes, as PTAB must select which set of common law rules to follow.

Administrative Law Judges in other agencies have treated certain confidential communications with a patent agent as privileged. *See, e.g.,* USITC Inv. No. 337–TA–339, slip op. at 2, 1992 WL 811804 (ITC 1992) (finding that confidential communications between a U.S. patent agent and his client in connection with a patent prosecution are privileged). In 2016, the Federal Circuit recognized that attorney-client privilege applies to U.S. patent agents acting within the scope of their authorized practice. *See In re Queen's University at Kingston,* 820 F.3d 1287 (Fed. Cir. 2016).

To address the aforementioned issues with privilege rules, the USPTO put forth a proposed PTAB rule for public comment in October 2016. *See* Rule Recognizing Privileged Communications Between Clients and Patent Practitioners at the Patent Trial and Appeal Board, 81 FR 71653 (Oct. 18, 2016). The Office received eighteen comments from bar associations, trade groups, law firms, and individuals. The Office expresses its gratitude for the thoughtful and comprehensive comments provided by the public, which are available online at *https://www.regulations.gov/docket?D=PTO-P-2016-0029.*

The vast majority of commenters expressed support for this rule, echoing the need for clarity and certainty in this area. The policy arguments they raised in favor are already covered extensively in the Privilege Report. Several commenters raised additional issues about specific language in the proposed rule, which are addressed herein. A few commenters opposed the rule based on misunderstandings of the scope and purpose of the rule, which are clarified herein as well. Based on the feedback, the Office presents the following final rule on recognizing privilege for patent attorneys and agents.

Responses to Comments

Nature of Privilege

Comments: Some comments expressed concern over the scope and interpretation of the proposed rule. One commenter objected to expanding those eligible to practice before PTAB to include agents. Others characterized the rule as primarily to protect communications between clients and counsel involved in PTAB proceedings.

Response: Attorney-client privilege exists to protect clients. It allows them to have full and frank discussions with attorneys when seeking legal advice, without fear that those discussions will be used against them in legal proceedings. The privilege vests with the client, not the attorney, and does not confer authorization to practice law, but rather flows from those already having such authorization. Because of this, recognizing privilege for patent agents does not determine what types of work they are authorized to perform. The authorized functions of patents agents, including representing clients before PTAB, are established in 37 CFR 11.5(b). Likewise, privilege does not confer additional power to patent agents because it vests in the client, not the agent or attorney. Applying the privilege to agents simply recognizes that they perform legal services and that clients deserve the same protections regardless of which type of authorized legal provider they choose. Further, some foreign jurisdictions rely entirely or almost entirely on non-attorney patent agents. In such jurisdictions, hiring an attorney to handle patent matters can be difficult or impossible. *See* the Privilege Report for further discussion of the policy considerations supporting privilege for patent agents.

More fundamentally, this rule is not intended primarily to protect communications between clients and their counsel for purposes of PTAB proceedings. Rather, it is primarily intended to protect communications made when seeking patents at the USPTO or foreign IP offices, such as when prosecuting applications or contemplating whether to file. The counsel on those communications may not be involved in any PTAB proceedings. Communications about prosecution are much more commonly implicated in PTAB discovery proceedings than communications about the PTAB proceeding itself. Perhaps this reflects the inherent asymmetry of privilege protections: Both parties are affected if their communications seeking legal advice about the PTAB proceeding are discoverable, whereas only the patent holder is affected by discovery of communications from prosecution. Regardless, the purpose of the rule is to protect any communications with authorized counsel from discovery in PTAB, not just communications about the instant proceeding.

Similarly, this privilege rule does not affect an attorney, agent, or applicant's duty to disclose material information to the USPTO at any time, as the duty of disclosure under 37 CFR 1.56 continues to be controlling. This duty is not at odds with privilege protections; the duty of disclosure governs all information known by a party and establishes whether information must be provided to the USPTO, while privilege governs material available to third party adversaries in adjudicated proceedings under part 42. For instance, the privilege rule does not apply in the filing and prosecution of a patent application. Further, the privilege only protects information exchanged for purposes of obtaining legal opinions or services, not underlying facts or business documents. The precise metes and bounds of what types of communications are protected by privilege are determined according to Federal law. Finally, this rule does not nullify privilege for others who are not covered by the rule, such as attorneys not admitted to practice before the USPTO or a foreign patent office. Other sources of privilege under Federal law remain unaffected.

Scope of Activities

Comments: Some commenters requested clarity on the scope of covered activities. One commenter asked the USPTO to clarify whether a communication with a registered patent agent about claim interpretation of an issued patent would qualify as privileged. Others asked for general clarification of what activities by patent agents would be covered, with one

requesting examples of activities that would qualify for the privilege. One commenter noted that 37 CFR 11.5(b)(1) may not provide an exhaustive list of authorized activities.

Response: We understand the commenters' desire for clarity on these issues. The USPTO has described the functions agents are authorized to perform before the Office in 37 CFR 11.5(b)(1). Whether a particular scenario falls within the bounds of an agent's authorization is subject to determination by an appropriate authority.

More precisely defining what types of work patent agents are and are not authorized to perform is a much larger issue that goes far beyond privilege considerations. This rulemaking is not the proper forum to address that issue. If the public feels that the general definition of authorized functions put forth by the USPTO in § 11.5(b)(1) should be updated, they should contact the USPTO to express interest in a more comprehensive process to consider that issue, which accounts for the numerous equities involved. We also note that regardless of any clarifications made to the scope of authorized duties for U.S. patent agents, the USPTO cannot alter or clarify the authorized functions of foreign patent agents in their home jurisdiction, which are established by foreign laws and regulations.

Federal Privilege

Comments: One comment suggested clarifying that the ''same protections of privilege'' refers to Federal privilege, since state courts have their own separate sources of privilege.

Response: We concur and have adjusted the rule to specify ''privilege under Federal law'' in paragraph (a).

Direct Communications

Comments: One comment suggested that the rule as written may only cover communications directly between a client and a foreign practitioner, and not communications made by the client's U.S. attorney with the foreign practitioner. According to the comment, communications made between a client's representatives in the absence of the client could be inadvertently excluded by the current phrasing of the rule.

Response: Under U.S. Federal law, attorney-client privilege generally encompasses communications with an attorney made by the client's representatives as well as the client. Similarly, privilege generally encompasses communications made with an attorney's employee or assistant, as well as communications between multiple attorneys working for a client. That is not to say such communications are necessarily privileged; they must still meet the other requirements for privilege, such as appropriate subject matter. However, these parties are generally regarded as parties that fall within the scope of privilege, rather than as third parties who break privilege.

Under the new rule, communications with such parties should similarly be entitled to privilege under the same circumstances as when the practitioner is an attorney. However, we recognize that there is potential for a narrower reading of the proposed rule that does not cover communications with such parties and therefore affords lesser protection to non-attorney practitioners. We have added paragraph (c) to the rule to clarify that the scope of coverage will be the same for practitioners as for attorneys under these types of scenarios and any other situations. For instance, privilege will extend to communications with the aforementioned parties under appropriate circumstances, not just to communications directly between the practitioner and the client.

Limitations and Exceptions

Comments: One comment suggested explicitly defining which ''limitations and exceptions'' should apply to the privilege.

Response: Exceptions to attorney-client privilege such as crime/fraud are based on longstanding common law, which continues to evolve. Our purpose here is not to redefine those exceptions. This may lead to growing discrepancies as the common law changes, which could lead to disparate treatment of privilege for patent attorneys and agents compared with other attorneys. Rather, this rule codifies who is eligible for the privilege, while leaving questions about exceptions and limitations for general jurisprudence to address in a broader manner.

Practitioners With Limited Recognition

Comments: A couple of commenters noted that the rule does not extend to all categories of practitioners, namely, those granted limited recognition under 37 CFR 11.9.

Response: The rule has been amended to cover USPTO practitioners meeting the registration requirements of 37 CFR 11.7. This includes practitioners under both §§ 11.6 and 11.9(b), who have demonstrated the requisite legal, scientific, and technical qualifications and moral character. Foreign practitioners practicing at the USPTO under § 11.9(c) can qualify for privilege under paragraph (b) of the new rule through their admittance to practice in a foreign jurisdiction. Students in the USPTO law school clinic program practicing under § 11.16 can qualify for privilege under paragraph (c) of the new rule since they work under the supervision of a registered practitioner. At this time, we are not convinced an extension to other categories of practitioners is necessary or appropriate. It is not clear that recognizing privilege for these individuals furthers any of the policy reasons for applying privilege to patent agents, or that these individuals play a significant role in providing legal services for applicants.

Relation to In re Queen's

Comments: A few commenters noted the parallels between this rule and the Federal Circuit's decision in *In re Queen's University,* wondering if a USPTO rule is still necessary and whether there would be any distinction between our rule and the Federal Circuit's. One commenter mentioned a supposed difference in coverage for third-party patent validity opinions by agents.

Response: The USPTO supports the Federal Circuit's finding of privilege for patent agents as a matter of public policy. The Privilege Report catalogs the many reasons that privilege for patent agents is warranted. A USPTO rule on privilege is still needed, for at least several reasons. The *Queen's* decision was a 2–1 panel result, which may be revisited in future cases either en banc at the Federal Circuit or at the Supreme Court. There are clarity benefits to having a rule explicitly codified rather than only in common law.

Also, the Federal Circuit decision only addresses domestic patent agents, not foreign attorneys and agents. Without comparable protections in U.S. tribunals for foreign practitioners, privileged communications with U.S. patent attorneys may effectively lose that protection through parallel communications with foreign practitioners prosecuting corresponding foreign applications, which often raise very similar legal issues. Having a U.S. attorney supervise communications with foreign practitioners is not only an undesirable policy, but may not be enough to preserve privilege in all circumstances. Because the U.S. attorney is generally not authorized to practice law in foreign jurisdictions, the foreign attorney might not be considered as working ''under the supervision'' of the U.S. attorney in all instances. Further, some jurisdictions use non-attorney patent agents exclusively or predominantly, so it may not be possible for applicants to rely on

privilege afforded by U.S. courts to foreign attorneys. The new privilege rule protects eligible communications with qualified foreign attorneys and agents from discovery at PTAB, preventing such back door exposure. The rule does not have extraterritorial effects; how communications with U.S. and foreign practitioners are treated by foreign courts is entirely up to the foreign jurisdiction.

Another reason for the USPTO's rule is administrative economy and judicial efficiency, as explained by commenter John Cross of the University of Louisville. The typical approach to privilege for foreign practitioners examines whether the foreign jurisdiction affords something like privilege for attorneys and agents. However, this inquiry can be intensive, difficult, and lead to inconsistent results, because many jurisdictions do not need a comparable protection when their constrained discovery system prevents communications with patent practitioners from even being discoverable. Similarly, U.S. courts that use a ''touch base'' standard often make complex inquiries into a foreign communication's nexus with the United States, which can lead to uncertain and inconsistent results. The USPTO rule simplifies such inquiries by instead considering whether the foreign practitioner was authorized to practice within their home jurisdiction by satisfying their jurisdiction's professional requirements, and whether the communications fall within their authorized scope of practice in that jurisdiction. These criteria are simpler to adjudicate and lead to more predictable and consistent results, helping applicants understand where privilege applies long before they appear at a tribunal.

Also, the USPTO rule applies regardless of the source of privilege for agents. Whether there is a separate agent-client privilege or agents are afforded attorney-client privilege on the basis of practicing patent law does not matter for purposes of this rule. The rule simply recognizes that privilege issues will be treated the same for agents as for attorneys within their scope of authorized practice.

Practice of Law

Comments: Two commenters suggested that the rule would promote the ''unauthorized practice of law'' by U.S. patent agents. It was suggested that participation by patent agents in PTAB proceedings would constitute unauthorized practice, and that agents participating in PTAB proceedings held concurrently with patent litigation on the same patents would constitute unauthorized litigation practice by those agents. One of these commenters also said that state bar rules may conflict with this PTAB rule.

Response: As previously mentioned, the rule does not grant additional powers to patent agents. Privilege is a protection that vests with the client, not the practitioner. Agents are already authorized to practice before PTAB in any USPTO proceedings. Practice before PTAB cannot be unauthorized practice of law because U.S. patent agents are authorized to do so.

The second objection suggests that practicing before PTAB is tantamount to practicing before Federal courts when there is concurrent litigation on the same patents. Because they are separate venues with separate practices and practitioners, this argument is not persuasive. Agents are authorized to advise and represent clients in PTAB proceedings because the issues are restricted to patent law matters they are authorized to perform. Federal courts have different jurisdiction than PTAB and consider a range of non-patent issues. The fact that certain patent issues, such as validity, may arise before both tribunals does not equate practice before both venues. Just because a practitioner is authorized to address the issue in one forum does not mean they are authorized to address it in other forums. This is true regardless of whether the practitioner is an agent or an attorney and whether the two forums are, for instance, PTAB and a Federal court, or a Federal court and a foreign court.

Finally, state bar rules generally are not germane to USPTO rules. The USPTO may properly regulate the conduct of practitioners before the Office, including PTAB proceedings, as authorized by Congress. Similarly, states can properly regulate the practice of law within their borders, subject to federalism principles and rules established by the Supreme Court. The USPTO and states have separate jurisdiction. States may of course consider the policy issues the USPTO has documented when deciding privilege matters within their own courts for domestic and foreign patent agents and attorneys.

Changes From the Proposed Rule

In response to comments received from the public, the USPTO makes the following changes from the proposed rule. The terms for types of practitioners (domestic and foreign) were adjusted slightly for uniformity with other rules. The application of Federal law was clarified. The USPTO registration requirement now points to 37 CFR 11.7 for more precision. Paragraph (c) was added to clarify that non-attorney practitioners are afforded privilege in all the same situations as attorneys, not just for direct communications between practitioner and client.

Rulemaking Considerations

A. Administrative Procedure Act (APA): This final rule revises the rules relating to Office trial practice for *inter partes* review, post-grant review, the transitional program for covered business method patents, and derivation proceedings. The changes being adopted in this notice do not change the substantive criteria of patentability. These changes involve rules of agency practice. *See, e.g.,* 35 U.S.C. 316(a)(5), as amended. These rules are procedural and/or interpretive rules. *See Bachow Commc'ns Inc.* v. *F.C.C.,* 237 F.3d 683, 690 (D.C. Cir. 2001) (Rules governing an application process are procedural under the Administrative Procedure Act.); *Inova Alexandria Hosp.* v. *Shalala,* 244 F.3d 342, 350 (4th Cir. 2001) (Rules for handling appeals were procedural where they did not change the substantive requirements for reviewing claims.); *Nat'l Org. of Veterans' Advocates* v. *Sec'y of Veterans Affairs,* 260 F.3d 1365, 1375 (Fed. Cir. 2001) (Rule that clarifies interpretation of a statute is interpretive.); *JEM Broad. Co.* v. *F.C.C.,* 22 F.3d 320, 328 (D.C. Cir. 1994) (Rules are not legislative because they do not ''foreclose effective opportunity to make one's case on the merits.'').

Accordingly, prior notice and opportunity for public comment are not required pursuant to 5 U.S.C. 553(b) or (c) (or any other law). *See Cooper Techs. Co.* v. *Dudas,* 536 F.3d 1330, 1336–37 (Fed. Cir. 2008) (stating that 5 U.S.C. 553, and thus 35 U.S.C. 2(b)(2)(B), do not require notice and comment rulemaking for ''interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice'' (quoting 5 U.S.C. 553(b)(A))). However, the Office chose to seek public comment before implementing the rule to benefit from the public's input.

B. Regulatory Flexibility Act: As prior notice and an opportunity for public comment are not required pursuant to 5 U.S.C. 553 or any other law, neither a regulatory flexibility analysis nor a certification under the Regulatory Flexibility Act (5 U.S.C. 601–612) is required. *See* 5 U.S.C. 603. Nonetheless, for the reasons set forth herein, the Senior Counsel for Regulatory and Legislative Affairs in the Office of General Law of the USPTO has certified

to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 605(b). This rule revises the rules of practice before PTAB to explicitly recognize that communications between non-attorney or foreign patent practitioners and their clients that pertain to authorized practice before the USPTO or foreign patent offices are privileged, and to define those persons who may avail themselves of this privilege. These changes are expected to create no additional burden to those practicing before the Board as this rule merely clarifies rights and protections for the practitioner and client and does not impose a change in practice or requirements. In fact, this rule may produce a small benefit from a reduction in uncertainty and mitigation of discovery costs. For the above reasons, the changes in this rule will not have a significant economic impact on a substantial number of small entities.

C. Executive Order 12866 (Regulatory Planning and Review): This rulemaking has been determined to be not significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The Office has complied with Executive Order 13563. Specifically, the Office has, to the extent feasible and applicable: (1) Made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) involved the public in an open exchange of information and perspectives among experts in relevant disciplines, affected stakeholders in the private sector, and the public as a whole, and provided on-line access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes.

E. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs): This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

F. Executive Order 13132 (Federalism): This rulemaking does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

G. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

H. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

I. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

J. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

K. Executive Order 12630 (Taking of Private Property): This rulemaking will not affect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

L. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the United States Patent and Trademark Office will submit a report containing the rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the Government Accountability Office. The changes in this final rule are not expected to result in an annual effect on the economy of 100 million dollars or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this final rule is not a ''major rule'' as defined in 5 U.S.C. 804(2).

M. Unfunded Mandates Reform Act of 1995: The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of 100 million dollars (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of 100 million dollars (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

N. National Environmental Policy Act: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 *et seq.*

O. National Technology Transfer and Advancement Act: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions which involve the use of technical standards.

P. Paperwork Reduction Act: The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549) requires that the Office consider the impact of paperwork and other information collection burdens imposed on the public. This final rule involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3549). This rulemaking does not add any additional information requirements or fees for parties before the Board. Therefore, the Office is not resubmitting information collection packages to OMB for its review and approval because the revisions in this rulemaking do not materially change the information collections approved under OMB control number 0651–0069.

Notwithstanding any other provision of 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 Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

List of Subjects in 37 CFR Part 42

Administrative practice and procedure, Inventions and patents.

For the reasons set forth in the preamble, 37 CFR part 42 is amended as follows.

PART 42—TRIAL PRACTICE BEFORE THE PATENT TRIAL AND APPEAL BOARD

■ 1. The authority citation for 37 CFR part 42 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2), 6, 21, 23, 41, 135, 311, 312, 316, 321–326; Public Law 112–29, 125 Stat. 284; and Pub. L. 112–274, 126 Stat. 2456.

■ 2. Add § 42.57 to read as follows:

§ 42.57 Privilege for patent practitioners.

(a) *Privileged communications.* A communication between a client and a USPTO patent practitioner or a foreign jurisdiction patent practitioner that is reasonably necessary and incident to the scope of the practitioner's authority shall receive the same protections of privilege under Federal law as if that communication were between a client and an attorney authorized to practice in the United States, including all limitations and exceptions.

(b) *Definitions.* The term ''USPTO patent practitioner'' means a person who has fulfilled the requirements to practice patent matters before the United States Patent and Trademark Office under § 11.7 of this chapter. ''Foreign jurisdiction patent practitioner'' means a person who is authorized to provide legal advice on patent matters in a foreign jurisdiction, provided that the jurisdiction establishes professional qualifications and the practitioner satisfies them. For foreign jurisdiction practitioners, this rule applies regardless of whether that jurisdiction provides privilege or an equivalent under its laws.

(c) *Scope of coverage.* USPTO patent practitioners and foreign jurisdiction patent practitioners shall receive the same treatment as attorneys on all issues affecting privilege or waiver, such as communications with employees or assistants of the practitioner and communications between multiple practitioners.

Joseph Matal,

Associate Solicitor, performing the functions and duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2017–24190 Filed 11–6–17; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2017–0280; FRL–9969–89–Region 5]

Air Plan Approval; Wisconsin; 2017 Revisions to NR 400 and 406

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve a revision to the Wisconsin State Implementation Plan (SIP) submitted by the Wisconsin Department of Natural Resources (WDNR) to EPA on May 16, 2017. The revision replaces the definition of ''emergency electric generator'' with a broader definition of ''restricted internal combustion engine''. In addition, the revision makes amendments to procedures for revoking construction permits as well as language changes and other administrative updates. Lastly, WDNR is removing from the SIP two Wisconsin Administrative Code provisions that affect eligibility of coverage under general and construction permits.

DATES: This direct final rule will be effective January 8, 2018, unless EPA receives adverse comments by December 7, 2017. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2017–0280 at *http://www.regulations.gov* or via email to *damico.genevieve@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, *etc.*) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the official comment (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Radhica Kanniganti, Environmental Engineer, Air Permits Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–8097, *kanniganti.radhica@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This supplementary information section is arranged as follows:

I. Review of State Submittals
II. What action is EPA taking?
III. Incorporation by Reference
IV. Statutory and Executive Order Reviews

I. Review of State Submittals

This final rulemaking addresses the May 16, 2017, WDNR submittal for SIP revision, revising the rules in the Wisconsin SIP to align them with Federal requirements. WDNR's submittal includes changes to the term ''electric generator'', replacing it with ''restricted internal combustion engine'' as well as other minor language and administrative changes. Specifically, NR 400.02(136m) replaces the existing definition of emergency ''electric generator'' with a broader definition of ''restricted internal combustion engine'' and NR 406.04(1)(w) amends the exemption language for ''emergency electric generators'', replacing it with exemption for ''restricted use reciprocating internal combustion engines''. NR 406.08(1) and NR 406.10 involve minor changes to language, and NR 406.11(1) amends procedures for revoking construction permits. These changes serve the purpose of aligning the state and Federal regulations and are consistent with the Federal program. WDNR is also requesting the removal of two provisions from the SIP. NR 406.16(2)(d) and NR 406.17(3)(e) affect the eligibility of coverage under general and registration construction permits based on whether the project constituted a Type 2 action under the previous ch. NR 150. However, the current ch. NR 150 was amended and no longer defines or sets requirements for Type 2 actions. Removing these provisions from Wisconsin's SIP ensures consistency with Wisconsin Environmental Protection Act (WEPA)

laws and does not affect consistency with the CAA. It is also consistent with Section 110(l) of the CAA. Sources covered under registration and general permits are still subject to all emission caps and applicable requirements set out in those permits.

II. What action is EPA taking?

EPA is approving revisions to Wisconsin's rules NR 400 and NR 406. EPA finds WDNR's submittal to be consistent with the CAA and applicable Federal requirements. WDNR's May 16, 2017, submittal requests that EPA approve the following rules into Wisconsin's SIP: (1) NR 400.02(136m), NR 406.04(1)(w), NR 406.08(1), NR 406.10 and NR 406.11(1). The submittal also requests removal of NR 406.16(2)(d) and NR 406.17(3)(e) from the SIP.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective January 8, 2018 without further notice unless we receive relevant adverse written comments by December 7, 2017. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. If we do not receive any comments, this action will be effective January 8, 2018.

III. Incorporation by Reference

In this rule, 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 the Wisconsin Regulations described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov,* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866.
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the 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 CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 8, 2018. 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. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of this **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: October 6, 2017.

Robert A. Kaplan,

Acting Regional Administrator, Region 5.

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.*

■ 2. Section 52.2570 is amended by revising paragraph (c)(113)(i)(D) and by adding paragraph (c)(137) to read as follows:

§ 52.2570 Identification of plan.

* * * * *

(c) * * *

(113) * * *

(i) * * *

(D) NR 400.02(73m) and (131m), 406.02(1) and (2), 406.04(2m), NR 406.11(1)(g)(1), 406.11(3), 406.16, 406.17, 406.18, 407.02(3m), 407.105, 407.107, 407.14 Note, 407.14(4)(c), 407.15(8)(a) and 410.03(1)(a)(6) and (7) as created and published in the (Wisconsin) Register, August 2005, No. 596, effective September 1, 2005. Sections NR 406.16(2)(d) and NR 406.17(3)(e) were repealed in 2015 and are removed without replacement; see paragraph (c)(137) of this section.

* * * * *

(137) On May 16, 2017, the Wisconsin Department of Natural Resources submitted a request to revise Wisconsin's air permitting rules NR 400.02(136m), NR 406.04(1)(w), NR 406.08(1), NR 406.10 and NR 406.11(1). These revisions replace the existing definition of ''emergency electric generator'' with a broader definition of ''restricted internal combustion engine'', amend procedures for revoking construction permits and include minor language changes and other administrative updates to ensure consistency with State and Federal regulations. Wisconsin has also requested to remove from the SIP NR 406.16(2)(d) and NR 406.17(3)(e), provisions affecting eligibility of coverage under general and registration construction permits, previously approved in paragraph (c)(113) of this section. This action ensures consistency with Wisconsin Environmental Protection Act (WEPA) laws.

(i) Incorporation by reference.

(A) Wisconsin Administrative Code, NR 400.02(136m) as published in the Wisconsin Administrative Register November 2015 No. 719A1, effective December 1, 2015.

(B) Wisconsin Administrative Code, NR 406.04(1)(w), NR 406.08(1), NR 406.10 and NR 406.11(1) as published in the Wisconsin Administrative Register November 2015 No. 719A1, effective December 1, 2015.

(ii) [Reserved]

[FR Doc. 2017–23048 Filed 11–6–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 140722613–4908–02]

RIN 0648–XF765

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region; Commercial Closure for Spanish Mackerel

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure (AM) for commercial Spanish mackerel in the northern zone of the Atlantic exclusive economic zone (EEZ) through this temporary rule. NMFS has determined that the revised commercial quota for Spanish mackerel in the northern zone of the Atlantic EEZ will be reached by November 7, 2017. Therefore, NMFS closes the northern zone of the Atlantic EEZ to commercial harvest of Spanish mackerel on November 7, 2017. This closure is necessary to protect the Spanish mackerel resource in the Atlantic.

DATES: The closure is effective at 12:01 a.m., local time, November 7, 2017, until 12:01 a.m., local time, March 1, 2018.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, or email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish includes king mackerel, Spanish mackerel, and cobia, and is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and Atlantic Region (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils and is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. All weights described for Spanish mackerel in the Atlantic EEZ apply as either round or gutted weight.

On November 20, 2014, NMFS published a final rule in the **Federal Register** to implement Framework Amendment 1 to the FMP (79 FR 69058). That final rule implemented a commercial annual catch limit (equal to the commercial quota) of 3.33 million lb (1.51 million kg) for the Atlantic migratory group of Spanish mackerel (Atlantic Spanish mackerel). Atlantic Spanish mackerel are divided into northern and southern zones for management purposes. The northern zone commercial quota for Atlantic Spanish mackerel is 662,670 lb (300,582 kg) for the current fishing year, March 1, 2017, through February 28, 2018 (50 CFR 622.384(c)(2)(i)).

Regulations at 50 CFR 622.384(c)(2)(iii) allow for quota transfers between the northern and southern zones with the approval from the Regional Administrator (RA) of the NMFS Southeast Region. North Carolina or Florida, in consultation with the other states in the respective zones, may request approval from the RA to transfer part or all of a respective zone's annual commercial quota to the other zone. For the purposes of quota closures as described in 50 CFR 622.8, the receiving zone's quota will be the original quota plus any transferred amount, for that fishing year only. Landings associated with any transferred quota will be included in the total landings for the Atlantic migratory group, which will be evaluated relative to the total ACL.

In a letter dated October 30, 2017, the State of Florida requested the transfer of 100,000 lb (45,359 kg) of Atlantic Spanish mackerel commercial quota from the southern zone to the northern zone to allow the commercial quota for both zones to be fully harvested. NMFS approved the transfer of commercial quota, and therefore, the revised northern zone commercial quota for Spanish mackerel is 762,670 lb (345,941 kg) and the revised southern zone commercial quota is 2,567,330 lb (1,164,521 kg) in the current fishing year, March 1, 2017, through February 28, 2018.

The northern zone for Atlantic Spanish mackerel extends in Federal waters off New York, New Jersey, Delaware, Maryland, Virginia, and North Carolina. The northern boundary of the northern zone extends from an intersection point off New York,

Connecticut, and Rhode Island at 41°18′16.249″ N. lat., 71°54′28.477″ W. long. and proceeds southeast to 37°22′32.75″ N. lat. and the intersection point with the outward boundary of the EEZ. The southern boundary of the northern zone extends from the North Carolina and South Carolina state border, along a line extending in a direction of 135°34′55″ from true north beginning at 33°51′07.9″ N. lat., 78°32′32.6″ W. long. to the intersection point with the outward boundary of the EEZ.

Regulations at 50 CFR 622.388(d)(1)(i) require NMFS to close the commercial sector for Atlantic Spanish mackerel in the northern zone when the commercial quota is reached, or is projected to be reached, by filing a notification to that effect with the Office of the Federal Register. NMFS has determined the revised commercial quota of 762,670 lb (345,941 kg) for Atlantic Spanish mackerel in the northern zone will be reached by November 7, 2017. Accordingly, the commercial sector for Atlantic Spanish mackerel in the northern zone is closed effective at 12:01 a.m., local time, November 7, 2017, through February 28, 2018, the end of the current fishing year.

During the commercial closure, a person on board a vessel that has been issued a valid Federal permit to harvest Atlantic Spanish mackerel may continue to retain this species in the northern zone under the recreational bag and possession limits specified in 50 CFR 622.382(a)(1)(iii) and (a)(2), as long as the recreational sector for Atlantic Spanish mackerel is open (50 CFR 622.384(e)(1)).

Also during the closure, Atlantic Spanish mackerel from the closed zone, including those harvested under the bag and possession limits, may not be purchased or sold. This prohibition does not apply to Atlantic Spanish mackerel from the closed zone that were harvested, landed ashore, and sold prior to the closure and were held in cold storage by a dealer or processor (50 CFR 622.384(e)(2)).

Classification

The RA for the NMFS Southeast Region has determined this temporary rule is necessary for the conservation and management of Atlantic Spanish mackerel and is consistent with the Magnuson-Stevens Act and other applicable laws.

This action is taken under 50 CFR 622.8, 622.384(e), and 622.388(d)(1)(i) and is exempt from review under Executive Order 12866.

These measures are exempt from the procedures of the Regulatory Flexibility Act, because the temporary rule is issued without opportunity for prior notice and opportunity for comment.

This action responds to the best scientific information available. The Assistant Administrator for NOAA Fisheries (AA) finds good cause to waive the requirements 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 procedures are unnecessary and contrary to the public interest. Such procedures are unnecessary because the rule implementing the commercial quota and the associated AM has already been subject to notice and public comment, and all that remains is to notify the public of the closure. Additionally, allowing prior notice and opportunity for public comment is contrary to the public interest because of the need to immediately implement this action to protect the Atlantic Spanish mackerel stock, because the capacity of the fishing fleet allows for rapid harvest of the commercial quota. Prior notice and opportunity for public comment would require time and could potentially result in a harvest well in excess of the established commercial quota.

For the aforementioned reasons, the AA also finds good cause to waive the 30-day delay in effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: November 2, 2017.

Emily H. Menashes,

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

[FR Doc. 2017–24220 Filed 11–2–17; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 170717675–7999–02]

RIN 0648–XF571

Fisheries of the Northeastern United States; Golden Tilefish Fishery; 2018 and Projected 2019–2020 Specifications

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

ACTION: Final rule.

SUMMARY: NMFS issues final specifications for the 2018 commercial golden tilefish fishery and projected specifications for 2019 and 2020. This action establishes allowable harvest levels and other management measures to prevent overfishing while allowing optimum yield, consistent with the Magnuson-Stevens Fishery Conservation and Management Act and the Tilefish Fishery Management Plan. It is also intended to inform the public of these specifications for the 2018 fishing year and projected specifications for 2019–2020.

DATES: Effective November 2, 2017 through October 31, 2018.

ADDRESSES: Copies of these specifications, including the Environmental Assessment, Regulatory Flexibility Act Analyses, and other supporting documents for the action, are available upon request from Dr. Christopher M. Moore, Executive Director, Mid-Atlantic Fishery Management Council, Suite 201, 800 N. State Street, Dover, DE 19901. The specifications document is also accessible via the Internet at: *http://www.greateratlantic.fisheries.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Cynthia Hanson, Fishery Management Specialist, (978) 281–9180.

SUPPLEMENTARY INFORMATION:

Background

The golden tilefish fishery is managed by the Mid-Atlantic Fishery Management Council under the Tilefish Fishery Management Plan (FMP), which outlines the Council's process for establishing annual specifications. Regulations implementing the Tilefish FMP appear at 50 CFR part 648, subparts A and N, which require the Council to recommend acceptable biological catch (ABC), annual catch limit (ACL), annual catch target (ACT), total allowable landings (TAL), and other management measures, for up to three years at a time. On September 7, 2017, NMFS proposed 2018–2020 specifications for the golden tilefish fishery (82 FR 42266) based on Council recommendations, and accepted public comment through September 22, 2017. Additional background information regarding the development of these specifications was provided in the proposed rule and is not repeated here.

Final Specifications

This action implements the approved ABCs, catch limits, and quota limits for the commercial golden tilefish fishery for the 2018 fishing year (Table 1), and projects specifications for fishing years 2019 and 2020 (Table 2), as outlined in the proposed rule. By providing projected quotas for 2019 and 2020, NMFS hopes to assist fishery

participants in planning ahead. The Council will review these specifications annually, and NMFS will provide notice prior to each fishing year to announce any necessary changes for 2019 and 2020. These specifications are approximately 14 percent lower than the 2017 ABC and overall commercial quota to ensure overfishing does not occur. For more information on the Council's recommendations and decisionmaking process, please see the proposed rule (82 FR 42266).

As explained in the proposed rule, the Mid-Atlantic Council developed these specifications in parallel with Framework Adjustment 2 to the Tilefish FMP. Framework 2 would revise how assumed discards are deducted in the specifications setting process, and the Council developed these specifications based on that new method. However, implementation of Framework 2 was delayed, and a proposed rule to implement Framework 2 is pending. Because the revision to the specification process has not been finalized, this action implements the 2018 golden tilefish specifications based on current regulations. For clarity, we also provide details of how the 2018 specifications would be changed under the process proposed by Framework 2 (Table 1). If Framework 2 is implemented as proposed, the 2018 specifications would be adjusted accordingly during the fishing year. This would result in a slight decrease in the incidental TAL and a slight increase to the IFQ TAL and by extension to individual IFQ allocations. The proposed 2019 and 2020 specifications in Table 2 anticipate the implementation of Framework 2.

TABLE 1—2018 GOLDEN TILEFISH SPECIFICATIONS AS IMPLEMENTED BY THIS ACTION, AND POTENTIAL REVISIONS UNDER TILEFISH FRAMEWORK ADJUSTMENT 2

	As implemented		Under framework 2	
	million lb	mt	million lb	mt
Overfishing Limit	2.332	1,058	2.332	1,058
ABC	1.636	742	1.636	742
ACL	1.636	742	1.636	742
IFQ ACT	NA	NA	1.554	705
Incidental ACT	NA	NA	0.082	37
TAL	1.627	738	NA	NA
IFQ TAL	1.546	701	1.554	705
Incidental TAL	0.081	37	0.072	33

TABLE 2—PROPOSED 2019 AND 2020 GOLDEN TILEFISH SPECIFICATIONS

	2019		2020	
	million lb	mt	million lb	mt
Overfishing Limit	2.421	1,098	2.291	1,039
ABC	1.636	742	1.636	742
ACL	1.636	742	1.636	742
IFQ ACT	1.554	705	1.554	705
Incidental ACT	0.082	37	0.082	37
IFQ TAL	1.554	705	1.554	705
Incidental TAL	0.072	33	0.072	33

As in previous years, no golden tilefish quota has been allocated for research set-aside. All other management measures in the golden tilefish fishery will remain unchanged for the 2018–2020 fishing years. The incidental trip limit will stay 500 lb (226.8 kg) (live weight), and the recreational catch limit will remain eight fish per-angler, per-trip. Annual IFQ allocations will be issued to individual quota shareholders in mid-October, before the November 1 start of the fishing year.

Comments and Responses

The public comment period for the proposed rule ended on September 22, 2017. Five comments were received from the public on this rule.

Comment 1: Three commenters wrote in support of this action and the reduction in quotas. They mentioned the importance of preemptive measures to preserve fish populations and ecosystems from overfishing while maintaining sustainable fishing practices.

Response 1: NMFS agrees. It is important to use the best available science to maintain healthy fish stocks and sustainable fishing practices. The Council's risk policy was applied to the most recent assessment outputs in the development of these specifications consistent with National Standard 2 and the Magnuson-Stevens Act. This resulted in a recommended reduction in quota even though golden tilefish are not currently overfished or experiencing overfishing.

Comment 2: One commenter questioned the necessity of quota reductions when overfishing is not occurring, and requested more information about Tilefish Framework Adjustment 2.

Response 2: As explained in the proposed rule and the response to Comment 1, catch limits and quotas are being reduced a result of the application of the Council's risk policy to the best available science to prevent overfishing from occurring in the golden tilefish fishery. The commenter is correct, the golden tilefish stock is not considered overfished or subject to overfishing; but this action is working to maintain that status into the future. Framework Adjustment 2 is currently in development through a separate rulemaking process, and does have more background information on the topics in question. The proposed rule is expected to publish in October; however, in the interim, more information can be found on the Council Web site at *http://www.mafmc.org/tilefish/*.

Comment 3: The commenter recommended a more drastic cut in quotas and claimed widespread corruption and collusion between NMFS and the commercial fishing industry for unregulated profit.

Response 3: The commenter presented no rationale or evidence supporting the claims. The most recent assessment determined that the golden tilefish stock is neither overfished, nor subject to overfishing. The Council's recommended quotas were set below the overfishing limit from the stock assessment in order to account for any scientific uncertainty. NMFS used the best scientific information available and is approving specifications for the golden tilefish fishery that are consistent with the FMP, all applicable legal requirements, and the recommendations of the Council.

Changes From the Proposed Rule

As explained above, the proposed rule anticipated the implementation of Framework 2 before these specifications were finalized. Because that has not happened, the specifications must be implemented under current regulations, but will be adjusted when Framework 2 is finalized near the end of December 2017.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this final rule is consistent with the Tilefish FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

This final rule is exempt from review under Executive Order 12866 because this action contains no implementing regulations.

This final rule does not duplicate, conflict, or overlap with any existing Federal rules.

This action does not contain a collection of information requirement for purposes of the Paperwork Reduction Act.

The Assistant Administrator for Fisheries, NOAA, finds good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effectiveness period for this rule, to ensure that the final specifications are in place as close to the start of the 2018 golden tilefish fishing year as possible, which began on November 1, 2017. A delay in effectiveness past the start of the 2018 fishing year would be contrary to the public interest, as it could create confusion, added burden, and potential economic harm to the commercial golden tilefish industry. If new specifications are not effective on that date, the regulations at § 648.292(a) state the current harvest quotas would automatically continue into the new fishing year. Therefore, NMFS would be required to issue initial IFQ permits using the 2017 quota amount, and then reissue those permits using the lower 2018 quota implemented by this rule after the start of the fishing year. Representatives of the commercial golden tilefish industry have been active participants in the Council's development of these specifications, and are anticipating the 2018 quota amount implemented by this action. Issuing two sets of IFQ allocations based on different quota amounts in a short period of time would cause unnecessary confusion and paperwork for the commercial golden tilefish industry. If IFQ shareholders fished or leased their initial allocation in the interim, they could be responsible for a quota overage once the new 2018 quotas became effective. Under the regulations, such an overage would need to be paid back in the following fishing year, which would decrease fishing opportunities in 2019.

Because the Council did not submit these specifications recommendations and the accompanying environmental assessment until early July, NMFS was unable to prepare this action early enough to allow for both an appropriate public comment period and full delay in effectiveness period. As noted above, the commercial tilefish industry has been a participant in the Council's process of developing these specifications and is anticipating these measures. Therefore, there is good cause to implement these quota specifications on November 2, 2017.

Final Regulatory Flexibility Analysis

The final regulatory flexibility analysis (FRFA) included in this final rule was prepared pursuant to 5 U.S.C. 604(a), and incorporates the initial regulatory flexibility analysis (IRFA) and a summary of analyses completed to support the action. A public copy of the environmental assessment/IRFA is available from the Council (see **ADDRESSES**). The preamble to the proposed rule included a detailed summary of the analyses contained in the IRFA, and that discussion is not repeated here.

A Summary of the Significant Issues Raised by the Public in Response to the IRFA, a Summary of the Agency's Assessment of Such Issues, and a Statement of Any Changes Made in the Final Rule as a Result of Such Comments

The comments NMFS received did not raise specific issues regarding the economic analyses summarized in the IRFA. Refer to the ''Comments and Responses'' section of this preamble for more detail. No changes to the proposed rule were required to be made as a result of public comment.

Description and Estimate of Number of Small Entities To Which the Rule Would Apply

This final rule affects small entities engaged in commercial fishing operations with Federal golden tilefish permits. For the purposes of the regulatory flexibility analysis (RFA) analysis, the ownership entities (or firms), not the individual vessels, are considered to be the regulated entities. Because of this, some vessels with golden tilefish permits may be considered to be part of the same firm because they may have the same owners. In terms of RFA, a business primarily engaged in commercial fishing is classified as a small business if it has combined annual receipts not in excess of $11 million, for all its affiliated operations worldwide. The current ownership data set used for this analysis is based on calendar year 2016 (the most recent complete year available) and contains average gross sales associated with those permits for calendar years 2014 through 2016. According to the commercial ownership database, 148 affiliate firms landed golden tilefish during the 2014–2016 period, with 145 of those business affiliates categorized as small, and 3 as large businesses.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements

No additional reporting, recordkeeping, or other compliance requirements are included in this final rule.

Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes

Specification of commercial quota is constrained by the conservation objectives set forth in the FMP and implemented at 50 CFR part 648 under the authority of the Magnuson-Stevens Act. The 2018–2020 catch limits and quotas contained in this final rule are 14 percent lower than those currently in place for 2017. However, this is the result of the Council's risk policy, which requires a formulaic buffer between the OFL and ABC that, in turn, lowers the TAL and quotas. Therefore, these lower catch levels in 2018 and projected for 2019 and 2020 are consistent with the best available

scientific information, the Council's tolerance for overfishing risk, and are intended to prevent overfishing from occurring.

As described in the proposed rule for this action, two other alternatives to the approved these specifications were considered. The status quo specifications (Alternative 2) were not consistent with the Council's risk policy. Alternative 3 would have had a comparable quota decrease over the three years with the approved specifications (Alternative 1), but fluctuating quotas and catch limits year to year. This was not selected because it did not support the annual consistency of quota/landings that the tilefish industry considers important to maintaining price and supply stability in this fishery.

All affected IFQ shareholders will receive decreases in their tilefish 2018 IFQ allocations in comparison to their respective tilefish 2017 IFQ allocations. However, the magnitude of the decrease varies depending on the shareholder's relative percentage of the total IFQ quota. Shareholders may also seek leases to offset individual quota decreases. NMFS does not anticipate this decrease will create a significant impact on the entities affected by this action.

Small Entity Compliance Guide

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as ''small entity compliance guides.'' The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a letter to permit holders that also serves as small entity compliance guide was prepared and will be sent to all holders of Federal permits issued for the golden tilefish fishery. In addition, copies of this final rule and guide (*i.e.,* permit holder letter) are available from NMFS (see **ADDRESSES**) and at the following Web site: *www.greateratlantic.fisheries.noaa.gov.*

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

Dated: November 1, 2017.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2017–24135 Filed 11–2–17; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 82, No. 214
Tuesday, November 7, 2017

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 340

[Docket No. APHIS–2015–0057]

RIN 0579–AE15

Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; withdrawal.

SUMMARY: We are withdrawing a proposed rule that would have revised our regulations regarding the importation, interstate movement, and environmental release of certain genetically engineered organisms. We are taking this action after considering the comments we received following the publication of the proposed rule.

DATES: We are withdrawing the proposed rule published January 19, 2017 (82 FR 7008) as of November 7, 2017.

FOR FURTHER INFORMATION CONTACT: Mr. Sidney Abel, Assistant Deputy Administrator, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737–1238; (301) 851–3896.

SUPPLEMENTARY INFORMATION: On January 19, 2017, we published in the **Federal Register** (82 FR 7008–7039, Docket No. APHIS–2015–0057) a proposal [1] to amend the regulations in 7 CFR part 340 regarding the importation, interstate movement, and environmental release of certain genetically engineered (GE) organisms.

We solicited comments concerning our proposal for 120 days ending May 19, 2017. We extended the deadline for comments until June 19, 2017, in a document published in the **Federal Register** on February 10, 2017 (Docket No. APHIS–2015–0057, 82 FR 10312–10313). We received 203 comments by that date. They were from GE developers, growers of GE crops, GE industry and agricultural trade associations, universities and academic researchers, organic producers and trade associations, consumer safety and environmental advocacy groups, a Federal agency, and private citizens.

Many commenters objected to the scope of the proposed rule. Some thought that our criteria for designating GE organisms as regulated organisms were too expansive, potentially resulting in our regulating a wider range of GE organisms than necessary and thereby increasing, rather than reducing, the regulatory burden for the biotechnology industry. Other commenters, however, thought that certain exemptions and exclusions contained in the proposed rule would effectively narrow the scope of our regulatory authority over GE organisms and increase the risk of the unintended presence of GE crops in organic and other non-GE crops.

The January 2017 proposed rule represented a major change from our existing ''regulate first/analyze later'' approach to one that entailed assessing new GE organisms to determine if they posed plant pest or noxious weed risks and then regulating only organisms that did present risks. Some commenters expressed concern that the proposed risk assessment process could prove lengthy, cumbersome, and confusing, thereby hindering innovation and preventing GE products from getting to market in a timely manner. Though we did provide exclusions that would have allowed GE organisms with certain plant/trait combinations to bypass the risk assessment process, these commenters viewed the exclusions as too narrow. Other commenters, however, took the opposite view. These commenters objected to our proposed exemption from the risk assessment process of products having plant/trait combinations corresponding to specific organisms that had been granted nonregulated status based on previous risk assessments. A number of these commenters also thought the proposed process as a whole would be insufficiently rigorous, with some objecting specifically to our proposal to no longer require the submission of field test data as part of the assessment process.

Another issue that drew many comments was our proposal to incorporate our noxious weed authority into the biotechnology regulations in part 340. Noting that noxious weeds are also regulated under the Plant Protection and Quarantine regulations in 7 CFR part 360, commenters expressed concern that this proposal could result in the creation of two parallel but inconsistent regulatory systems and thus more regulatory uncertainty.

Finally, many commenters expressed opposition to genetic engineering in general, as well as concerns about a wide range of issues, many of which were outside the scope of the proposed rule. For example, commenters stated that the Animal and Plant Health Inspection Service (APHIS) should consider non-safety-based risks, such as economic and social impacts, including impacts on the marketability of non-GE products. Other commenters requested that APHIS regulations include provisions related to the labeling of GE products and raised concerns regarding health effects of GE products and increased pesticide use.

Based on the scope of comments received on the January 2017 proposed rule, we have decided to withdraw the rule and to begin a fresh stakeholder engagement aimed at exploring alternative policy approaches. Because of rules limiting *ex parte* communications with respect to active rulemakings, publication of the 2017 proposed rule has constrained our ability to talk about alternatives with stakeholders. Withdrawing the proposed rule will lift this constraint and provide for a more open and robust policy dialogue.

Therefore, we are withdrawing the January 19, 2017, proposed rule referenced above. As we explore a full range of policy alternatives, we will consider the comments we received on the proposed rule, as well as new scientific knowledge, and continue to seek the active and open input of stakeholders.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

[1] To view the proposed rule, supporting documents, and the comments we received, go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0057*.

Done in Washington, DC, this 1st day of November 2017.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–24202 Filed 11–6–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–1059; Product Identifier 2017–CE–035–AD]

RIN 2120–AA64

Airworthiness Directives; Piper Aircraft, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Piper Aircraft, Inc. Models PA–28–140, PA–28–150, PA–28–160, PA–28–180, PA–28–235, PA–32–260, and PA–32–300 airplanes. This proposed AD was prompted by reports of corrosion found in an area of the main wing spar not easily accessible for inspection. This proposed AD would require installing an inspection access panel in the lower wing skin near the left and the right main wing spars if not already there, inspecting the left and the right main wing spars for corrosion, and taking all necessary corrective actions. We are proposing this AD to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by December 22, 2017.

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 Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida 32960; telephone: (772) 567–4361; Internet: *www.piper.com*. You may review this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1059 or in person at the Docket Management Facility 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 the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Dan McCully, Aerospace Engineer, FAA, Atlanta ACO Branch, 1701 Columbia Avenue, College Park, Georgia 30337; telephone: (404) 474–5548; fax: (404) 474–5606; email: *william.mccully@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2017–1059; Product Identifier 2017–CE–035–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

We received two reports of significant corrosion found on the main wing spars on certain Piper Aircraft, Inc. Models PA–28–140, PA–28–150, PA–28–160, PA–28–180, PA–28–235, PA–32–260, and PA–32–300 airplanes. The corrosion was found during maintenance in an area that is not easily accessible for inspection. This condition, if not detected and corrected, could cause the main wing spar to fail. This failure could result in loss of control.

Related Service Information Under 1 CFR Part 51

We reviewed Piper Aircraft, Inc. Service Bulletin No. 1304, dated August 23, 2017. The service bulletin describes procedures for installing an inspection access panel in the lower wing skin near the left and the right main wing spars, if not already there, inspect for corrosion, and, if corrosion is found, taking all necessary corrective actions. 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

We are proposing this AD because we 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 accomplishing the actions specified in the service information described previously.

Costs of Compliance

We estimate that this proposed AD affects 11,476 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Main wing spar inspection	2 work-hours × $85 per hour = $170 to inspect both wings.	Not Applicable	$170	$1,950,920

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Install inspection access panel in the lower wing skin near the left and the right main wing spars.	6 work-hours × $85 per hour = $510 to install the inspection access panel on both wings.	$175 for the kit that contains provisions for installing inspections access panels on both wings.	$685

The scope of damage found in the required inspection could vary significantly from airplane to airplane. We have no way of determining how much damage may be found on each airplane or the cost to repair damaged parts on each airplane or the number of airplanes that may require repair.

Authority for This Rulemaking

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

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

This 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 small airplanes and domestic business jet transport airplanes to the Director of the Policy and Innovation Division.

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Piper Aircraft, Inc.: Docket No. FAA–2017–1059; Product Identifier 2017–CE–035–AD.

(a) Comments Due Date

We must receive comments by December 22, 2017.

(b) Affected ADs

None.

(c) Applicability

This AD applies to the following Piper Aircraft, Inc. model airplanes that are certificated in any category:

TABLE 1 TO PARAGRAPH (c) OF THIS AD—AFFECTED MODELS AND SERIAL NUMBERS

Model	Serial Nos.
PA–28–140	28–20001 through 28–26946, and 28–7125001 through 28–7725290.
PA–28–150 and PA–28–160	28–1 through 28–4377, and 28–1760A.
PA–28–180	28–671 through 28–5859, 28–7105001 through 28–7205318, and 28–7305001 through 28–7505261.
PA–28–235	28–10001 through 28–11378, 28–7110001 through 28–7710089, and 28E–11.
PA–32–260	32–04, 32–1 through 32–1297, and 32–7100001 through 32–7800008.
PA–32–300	32–15, 32–21, 32–40000 through 32–40974, and 32–7140001 through 32–7840222.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 5711, Wing Spar.

(e) Unsafe Condition

This AD was prompted by reports of corrosion found in an area of the main wing spar not easily accessible for inspection. We are issuing this AD to detect and correct corrosion in the wing root area of the left and the right main wing spars. The unsafe condition, if not detected and corrected, could cause the main wing spar to fail, which could result in loss of control.

(f) Compliance

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

(g) Determine if Inspection Access Panels Are Already Present

Within the next 100 hours time-in-service (TIS) after the effective date of this AD or within the next 12 months after the effective date of this AD, whichever occurs first, inspect the lower wing skin near the main wing spar on both wings for the presence of an inspection access panel using Part I of the Instructions section of Piper Aircraft, Inc.

(Piper) Service Bulletin (SB) No. 1304, dated August 23, 2017.

(h) Install Inspection Access Panels

If it is determined that no inspection access panels are present during the inspection required in paragraph (g) of this AD, within the next 100 hours TIS after the effective date of this AD or within the next 12 months after the effective date of this AD, whichever occurs first install inspection access panels on the lower skin of the left wing and the right wing using Piper SB No. 1304, dated August 23, 2017.

(i) Inspect for Corrosion

Within the next 100 hours TIS after the effective date of this AD or within the next 12 months after the effective date of this AD, whichever occurs first, inspect the left and the right main wing spar for any evidence of corrosion using Part I of the Instructions section of Piper SB No. 1304, dated August 23, 2017.

(j) Corrective Actions

Before further flight after the inspection required in paragraph (i) of this AD, if evidence of corrosion is found, take all necessary corrective actions to remove the corrosion using Part I of the Instructions section of Piper SB No. 1304, dated August 23, 2017, and/or make all necessary repairs using Part II of the Instructions section of Piper SB No. 1304, dated August 23, 2017.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta 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)(1) of this AD.

(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) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (g) through (j) 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. 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

(1) For more information about this AD, contact Dan McCully, Aerospace Engineer, FAA, Atlanta ACO Branch, 1701 Columbia Avenue, College Park, Georgia 30337; telephone: (404) 474–5548; fax: (404) 474–5606; email: *william.mccully@faa.gov*.

(2) For service information identified in this AD, contact Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida 32960; telephone: (772) 567–4361; Internet: *www.piper.com*. You may review this referenced service information at the FAA, Policy and Innovation Division, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on October 30, 2017.

Melvin J. Johnson,

Acting Deputy Director, Policy & Innovation Division, Aircraft Certification Service.

[FR Doc. 2017–24083 Filed 11–6–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2017–N–6216]

General Hospital and Personal Use Devices; Reclassification of Sharps Needle Destruction Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing this proposed order to reclassify the needle destruction device, renaming the device to ''sharps needle destruction device,'' a postamendments class III device (regulated under product code MTV), into class II (special controls), subject to premarket notification. FDA is also identifying the proposed special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is proposing this reclassification on its own initiative based on new information. If finalized, this order will reclassify these types of devices from class III to class II and reduce regulatory burdens on industry as these types of devices will no longer be required to submit a premarket approval application (PMA) but can instead submit a less burdensome premarket notification (510(k)) before marketing their device.

DATES: Submit either electronic or written comments on the proposed order by January 8, 2018. Please see section XI of this document for the proposed effective date when the new requirements apply and for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 8, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 8, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2017–N–6216 for ''General Hospital and Personal Use Devices; Reclassification

of Sharps Needle Destruction Device.'' 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:

Christopher K. Dugard, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2561, Silver Spring, MD 20993, 240–402–6031, *christopher.dugard@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA acting by order can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard,* 366 F.2d 177, 181 (7th Cir. 1966); *Ethicon, Inc.* v. *FDA,* 762 F. Supp. 382, 388–391 (D.D.C. 1991)) or in light of changes in ''medical science'' (*Upjohn* v. *Finch,* 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the ''new information'' to support reclassification under 513(f)(3) must be ''valid scientific evidence'', as defined in section 513(a)(3) of the FD&C Act and 21 CFR 860.7(c)(2). (See, *e.g., General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA,* 766 F.2d 592 (D.C. Cir.1985), cert. denied, 474 U.S. 1062 (1986)).

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the ''valid scientific evidence'' upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending PMA (see section 520(c) of the FD&C Act (21 U.S.C. 360j(c)). Section 520(h)(4) of the FD&C Act provides that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This includes information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device, but does not include descriptions of methods of manufacture or product composition and other trade secrets.

Section 510(m) of the FD&C Act provides that a class II device may be exempted from the 510(k) premarket notification requirements, if the Agency determines that premarket notification is not necessary to reasonably assure the safety and effectiveness of the device.

II. Regulatory History of the Devices

On February 3, 1994, FDA issued a Memorandum to manufacturers and initial distributors of sharps containers and destroyers used by health care manufacturers to clarify the regulatory status of sharps destroyer devices (Ref. 1).

On March 6, 1997, FDA approved its first needle destruction device through its PMA process under section 515 of the FD&C Act (21 U.S.C. 360e). In the June 11, 1997, **Federal Register** notice (62 FR 31831), FDA announced a PMA approval order for Millenium Medical Supply's Incorporated Needle-Ease™ 2501[1] device and the availability of the Summary of Safety and Effectiveness Data for the Device (SSED) (Ref. 2). As of the date of issuance of this proposed order, FDA has approved 18 original PMAs for this device type.[2]

[1] FDA approved a modified needle destruction device on February 11, 1998. The device, as modified, is marketed under the trade name Needle-Ease®3500.

[2] See PMA database for original PMAs regulated under the product code MTV: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm.*

On March 2, 2001, FDA finalized guidance entitled, ''Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices,'' describing the Agency's recommendations for information to include in PMA applications for sharps needle destruction devices intended for use in health care settings (Ref. 3).

III. Device Description

A sharps needle destruction device is a postamendments device classified into class III under section 513(f)(1) of the FD&C Act. A sharps needle destruction device is a prescription device intended for home use or in professional health care facilities to destroy sharps or needles used for medical purposes by incineration or mechanical means. Sharps needle destruction devices are typically electrical devices that can destruct sharps and/or needles in a variety of methods (grinding, incinerating, etc.) that can be either portable or stationary. Some of these devices may also employ software to provide the user with greater control. Please note these devices were originally identified as needle destruction devices (product code MTV) in FDA SSEDs and product code database; however, FDA believes the identification of sharps needle destruction device more accurately describes this device type as it can be used to destroy devices other than needles (*e.g.,* sharps).

IV. Proposed Reclassification

As part of the Center for Devices and Radiological Health's 2014–2015 strategic priority ''Strike the Right Balance Between Premarket and Postmarket Data Collection,'' a retrospective review of class III devices subject to PMA was completed to determine whether or not, based on our current understanding of the technology, reclassification may be appropriate. On August 8, 2016, FDA published a document in the **Federal Register** entitled ''Retrospective Review of Premarket Approval Application Devices; Striking the Balance Between Premarket and Postmarket Data Collection'' in which FDA announced plans to reclassify sharps needle destruction devices identified with the MTV product code from class III to class II (81 FR 52445). FDA has found that sufficient information exists to establish special controls that, together with general controls, can provide a reasonable assurance of safety and effectiveness for sharps needle destruction devices.

In accordance with section 513(f)(3) of the FD&C Act and 21 CFR part 860, subpart C, FDA is proposing to reclassify this postamendments class III device into class II. FDA believes that there is sufficient information available to FDA through FDA's accumulated experience with these devices from review submissions, peer-reviewed literature, and knowledge of similar devices to establish special controls that effectively mitigate the risks to health identified in section V. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA is proposing to create a separate classification regulation for sharps needle destruction devices that will be reclassified from class III to II. Under this proposed order, if finalized, the sharps needle destruction devices will be identified as a prescription device. As such, the prescription device must satisfy prescription labeling requirements (see § 801.109 (21 CFR 801.109), *Prescription devices*). Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) and § 801.5 (21 CFR 801.5), as long as the conditions of § 801.109 are met. In this proposed order, if finalized, the Agency has identified the special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls, will provide a reasonable assurance of the safety and effectiveness for sharps needle destruction devices.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary for sharps needle destruction devices to provide reasonable assurance of the safety and effectiveness. Therefore, the Agency does not intend to exempt these proposed class II devices from 510(k) requirements. Persons who intend to market this type of device must submit to FDA a 510(k) and receive clearance prior to marketing the device.

V. Risks to Health

After considering the information available to FDA through review submissions, peer-reviewed literature, and knowledge of similar devices, FDA determined the probable risks to health associated with the use of sharps needle destruction devices are as follows:

- *Patient/user exposure to environmental contaminants.* Destroying a used sharp or needle may generate hazardous emissions from the device that may result in infection or respiratory problems for the patient and/or user. Contamination of the patient environment can occur through emission of toxic fumes or infectious aerosol when the device destroys a sharp by incineration or mechanical means, and may result from device malfunction (mechanical and/or software). The device may also become contaminated through regular usage and may cause cross-contamination.
- *Patient/user burns as a result of excessive heat discharge or spark formation.* Excessive heat or sparks may be generated and discharged from the device during destruction of sharps that may burn the user.
- *Electromagnetic interference.* While in operation, the device may interfere with other electrically powered devices, causing them to malfunction.
- *Electrical shock.* While in operation, the device may discharge electricity that could shock the user.
- *Sharps injury.* Incompletely destroyed sharps, physical device instability, device malfunctions, or use error may pose a risk for a sharps injury to the user.

VI. Summary of Reasons for Reclassification

FDA believes that the sharps needle destruction devices intended for home use or in professional health care facilities to reduce the incidence of needlesticks by destroying sharps and/or needles in a variety of methods (grinding, incinerating, etc.) should be reclassified from class III to class II in light of new information about the effectiveness of these devices. There is sufficient information to establish special controls for sharps needle destruction devices, in addition to general controls, which can provide reasonable assurance of safety and effectiveness of the device, as general controls themselves are insufficient to provide reasonable assurance of its safety and effectiveness. FDA believes that the risks to health associated with sharps needle destruction devices intended for home use or in professional health care facilities to reduce the incidence of needlesticks can be mitigated with special controls and that these mitigations will provide a reasonable assurance of its safety and effectiveness.

Based on a reconsideration of the available information and data, FDA believes that there is valid scientific evidence of effectiveness for sharps

needle destruction devices to reduce the incidence of needlesticks.

VII. Summary of Data Upon Which the Reclassification Is Based

FDA believes that the identified special controls, in addition to general controls, are necessary to provide reasonable assurance of safety and effectiveness of these devices. Taking into account the probable health benefits of the use of the device and the nature and known incidence of the risks of the device, FDA, on its own initiative, is proposing to reclassify this postamendments class III device into class II. FDA has considered and analyzed the following information: An inclusive search of the Agency's Manufacturer and User Facility Device Experience (MAUDE) database, which shows no adverse events for sharps needle destruction devices; data contained in PMAs approved 6 or more years before the date of this proposal (reviewed under section 520(h)(4) of the FD&C Act, also known as the 6-year rule); a review of sharps containers regulated under 21 CFR 880.5570, which have similar intended uses, but different technology, and are currently regulated as class II devices; and one relevant article found from a literature search that discussed the benefits and the probable risks of these devices (Ref. 4).

VIII. Proposed Special Controls

FDA believes that the following special controls, together with general controls, are sufficient to mitigate the risks to health described in section V and provide a reasonable assurance of safety and effectiveness for sharps needle destruction devices.

- Performance testing will demonstrate:
  - ○ The device's ability to contain or ventilate aerosols or fumes from device operation that may result in environmental contamination and cross-contamination. Performance testing will demonstrate that harmful fumes, such as ozone, are not emitted by the device during destruction of sharps needles.
  - ○ Excessive heat or sparks are not generated during device operation that may injure users or patients through characterization of the heat dissipation profile from the heat source to the enclosure surface, and the point of contact between the held syringe and the user. Performance testing will ensure the heat generated through normal operation of the device will not harm users or patients or affect circuit performance and useful life of the device.
  - ○ Complete destruction of sharps intended to be destructed to mitigate user injuries from incomplete sharps destruction by conducting performance testing such as simulated use demonstrating complete destruction of the sharps and/or needles intended to be destroyed.
  - ○ Mitigation of injuries from device instability through characterization of the vibrations and movement generated by the device to ensure device stability in the use environment.
- Validation of cleaning and disinfection instructions to demonstrate that the device can be safely and effectively reprocessed after use to minimize the risk of patient/user cross-contamination.
- Performance testing ensures electromagnetic compatibility with other devices under conditions which are consistent with the intended environment of device use.
- Electrical safety testing ensures the risk of shock to the patient/user is minimized.
- Software hazard analysis, as well as software verification and validation, ensures that software performs as intended and potential software malfunctions do not impact the performance of the device.
- Labeling to ensure proper use of the device, including warnings of the generation of excessive heat, potential for needle stick injuries, instructions for reprocessing, and instructions for installation (*e.g.,* on a stable surface, adequate ventilation).

Table 1 shows how FDA believes these special controls will mitigate each risk to health described in section V.

TABLE 1—RISKS TO HEALTH AND MITIGATION MEASURES FOR SHARPS NEEDLE DESTRUCTION DEVICES

Identified risk to health	Mitigation measures
Patient/user exposure to environmental contaminants.	Performance testing. Reprocessing validation. Software verification, validation, and hazard analysis. Labeling.
Patient/user burns	Performance testing. Labeling.
Electrical shock	Electrical Safety Testing. Labeling.
Electromagnetic interference.	Electromagnetic Compatibility (EMC) Testing. Labeling.
Sharps injury	Performance testing. Software verification, validation, and hazard analysis. Labeling.

In addition, FDA is proposing to limit these devices to prescription use under § 801.109. Prescription devices are exempt from the requirement for adequate directions for use for the layperson under section 502(f)(1) of the FD&C Act and § 801.5, as long as the conditions of § 801.109 are met (referring to 21 U.S.C. 352(f)(1)). Under 21 CFR 807.81, the device would continue to be subject to 510(k) notification requirements. FDA does not believe that clinical data is necessary to mitigate the identified risks to health for sharps needle destruction devices. FDA may request clinical data to evaluate substantial equivalence when a manufacturer includes new indications for use, such as indications for disease prevention or organism destruction.

This reclassification order and the identified special controls, if finalized, would provide sufficient detail regarding FDA's requirements to reasonably assure safety and effectiveness of sharps needle destruction devices. FDA intends to withdraw the final guidance entitled, ''Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA'' issued in 2001 upon finalization of this proposed reclassification order (Ref. 3).

IX. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed order contains no new collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520) is not required. This proposed order refers to previously approved collections of information

found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120 and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

XI. Proposed Effective Date

FDA proposes that any final order based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

XII. References

The following references are on display in 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 also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA memorandum ''To Manufacturers and Initial Distributors of Sharps Containers and Destroyers Used by Health Care Professionals,'' February 3, 1994, available at: *https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm070679.pdf.*

2. FDA ''Premarket Approval of Millenium Medical Supply Incorporated Needle-Ease™ 2501–ACTION,'' March 6, 1997, available at: *https://www.accessdata.fda.gov/cdrh_docs/pdf/p960044.pdf.*

3. ''Premarket Approval Applications (PMA) for Sharps Needle Destruction Devices; Final Guidance for Industry and FDA,'' March 2, 2001, available at: *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073601.pdf.*

4. Tamplin S.A., D. Davidson, B. Powis, and Z. O'Leary, ''Issues and Options for the Safe Destruction and Disposal of Used Injection Materials,'' *Waste Management,* vol. 25, pp. 655–665, 2005.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.,* as amended) and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 880 be amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 880.6210 to subpart G to read as follows:

§ 880.6210 Sharps needle destruction device.

(a) *Identification.* A sharps needle destruction device is a prescription device that is intended to destroy needles or sharps used for medical purposes by incineration or mechanical means.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Performance testing must demonstrate the following during operation of the device:

(i) The device safely contains or ventilates aerosols or fumes from device operation.

(ii) Excessive heat or sparks are not generated that may injure users or patients.

(iii) Simulated use testing must demonstrate sharps and/or needles are completely destroyed using a range of types and sizes of sharps sufficient to represent actual use.

(iv) Simulated use testing must demonstrate that the device is physically stable on the surface for which it is intended to be mounted to ensure the risk of harm to the patient/user as a result of the device falling is minimized.

(2) Validation of cleaning and disinfection instructions must demonstrate that the device can be safely and effectively reprocessed after use per the recommended cleaning and disinfection protocol in the instructions for use.

(3) Analysis and/or testing must validate electromagnetic compatibility (EMC) and electrical safety, including the safety of any battery used in the device, under conditions which are consistent with the intended environment of device use.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Labeling must include:

(i) A clear description of the device and its technological features;

(ii) How the device is to be used, including validated cleaning and disinfection instructions;

(iii) Relevant precautions and warnings based on performance and in-use testing to ensure proper use of the device; and

(iv) Instructions to install device in adequately ventilated area and stable area.

Dated: November 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24191 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 381

[Docket No. 16–CRB–0002–PBR (2018–2022)]

Determination of Rates and Terms for Public Broadcasting (PB III)

AGENCY: Copyright Royalty Board (CRB), Library of Congress.

ACTION: Proposed rule.

SUMMARY: The Copyright Royalty Judges solicit comments on proposed rates and terms for use of certain works in connection with noncommercial broadcasting for the period commencing January 1, 2018, and ending on December 31, 2022.

DATES: Comments and objections, if any, are due on or before November 27, 2017.

ADDRESSES: You may submit comments and objections, identified by docket number 16–CRB–0002–PBR (2018–2022), by any of the following methods:

CRB's electronic filing application: Submit comments online in eCRB at *https://app.crb.gov/.*

U.S. mail: Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Overnight service (only USPS Express Mail is acceptable): Copyright Royalty Board, P.O. Box 70977, Washington, DC 20024–0977; or

Commercial courier: Address package to: Copyright Royalty Board, Library of Congress, James Madison Memorial Building, LM–403, 101 Independence Avenue SE., Washington, DC 20559–6000. Deliver to: Congressional Courier Acceptance Site, 2nd Street NE. and D Street NE., Washington, DC; or

Hand delivery: Library of Congress, James Madison Memorial Building, LM–401, 101 Independence Avenue SE., Washington, DC 20559–6000.

Instructions: Unless submitting online, commenters must submit an original, five paper copies, and an electronic version on a CD. All submissions must include the CRB's name and docket number. All submissions will be posted without change to eCRB on *https://www.crb.gov* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to eCRB, the Copyright Royalty Board's electronic filing and case management system, at *https://app.crb.gov/* and search for docket number 16–CRB–0002–PBR (2018–2022). For documents not yet uploaded to eCRB (because it is a new system), go to the agency Web site at *https://www.crb.gov/* or contact the CRB Program Specialist.

FOR FURTHER INFORMATION CONTACT: Anita Blaine, CRB Program Specialist, by telephone at (202) 707–7658 or email at *crb@loc.gov.*

SUPPLEMENTARY INFORMATION:

Background

Section 118 of the Copyright Act, title 17 of the United States Code, establishes a statutory license for the use of certain copyrighted works in connection with noncommercial television and radio broadcasting. Chapter 8 of the Copyright Act requires the Copyright Royalty Judges (''Judges'') to conduct proceedings every five years to determine the rates and terms for the section 118 license. 17 U.S.C. 801(b)(1), 804(b)(6). In accordance with section 804(b)(6), the Judges commenced the proceeding to set rates and terms for the period 2018–2022 on January 5, 2016. 77 FR 71104.

In the **Federal Register** notice, the Judges requested interested parties to submit petitions to participate. 81 FR 256 (January 5, 2016). Petitions to Participate (''PTP''s) were received from: The American Society of Authors, Composers and Publishers (''ASCAP''); SESAC, Inc.; Broadcast Music, Inc. (''BMI''); Educational Media Foundation (''EMF''); National Public Radio (''NPR'') and the Public Broadcasting Service (''PBS''), jointly; National Religious Broadcasters Noncommercial Music License Committee (''NRBNMLC''); the Church Music Publishers' Association (''CMPA''); [1] the National Music Publishers' Association (''NMPA''), The Harry Fox Agency (''HFA''), National Association of College and University Business Officers (''NACUBO''), and David Powell.[2]

The Judges set the timetable for the three-month negotiation period, *see* 17 U.S.C. 803(b)(3), and directed the participants to submit written direct statements no later than November 7, 2016. Notice of Participants, Commencement of Voluntary Negotiation Period, and Case Scheduling Order (Mar. 25, 2016). The Judges amended the case schedule twice to accommodate ongoing negotiations. *See* Order for Further Proceedings and Modified Case Schedule (Aug. 12, 2016). In July and September 2016, several participants filed notices of settlement and proposed rates and terms for adoption. No participant filed a written direct statement. *See* Order Requiring Submission of Proposed Regulations by National Public Radio and Public Broadcasting System at 1 (Oct. 19, 2017).

There are two ways copyright owners and public broadcasting entities [3] may negotiate rates and terms under the section 118 statutory license. First, copyright owners may negotiate rates and terms with specific public broadcasting entities for the use of all of the copyright owners' works covered by the license. Section 118(b)(2) provides that such license agreements ''shall be given effect in lieu of any determination by the * * * Copyright Royalty Judges,'' provided that copies of the agreement are submitted to the Judges ''within 30 days of execution.'' 17 U.S.C. 118(b)(2). The Judges received one agreement in this category for which no further action is required.[4]

Second, copyright owners and public broadcasting entities may negotiate rates and terms for categories of copyrighted works and uses that would be binding on all owners and entities using the same license and submit them to the Judges for approval. Section 801(b)(7)(A) provides that the Copyright Royalty Judges shall provide to those that would be bound by the terms, rates, or other determination set by any agreement in a proceeding to determine royalty rates an opportunity to comment on the agreement and shall provide to participants in the proceeding under section 803(b)(2) that would be bound by the terms, rates, or other determination set by the agreement an opportunity to comment on the agreement and object to its adoption as a basis for statutory terms and rates; and that the Copyright Royalty Judges may decline to adopt the agreement as a basis for statutory terms and rates for participants that are not parties to the agreement, if any participant described in clause (i) objects to the agreement and the Copyright Royalty Judges conclude, based on the record before them if one exists, that the agreement does not provide a reasonable basis for setting statutory terms and rates.

17 U.S.C. 801(b)(7)(A).

On or about September 1, 2017, the Judges received a joint submission from ASCAP, BMI, HFA, NACUBO, NMPA, NRBNMLC, and SESAC containing proposed regulations that integrated the several separately filed proposals within this category. On October 25, 2017, the Judges received two more proposals within this category, one from NPR and PBS and a joint proposal from HFA, NMPA, PBS, NPR, and CPB.[5]

NACUBO Joint Proposals

The joint proposals of NACUBO and each of ASCAP, BMI, and SESAC propose to modify the royalty rates set forth in § 381.5. The rates proposed in the NACUBO/BMI and NACUBO/ASCAP submissions reflect a modification of the fees in different rate tiers. NACUBO/BMI Joint Proposal at 5, App. A. NACUBO/ASCAP Joint Proposal at 5, App. A. The NACUBO/SESAC submission retains a flat rate which they propose adjusting, starting in 2018, by the change in the Consumer Price Index or one-and-a-half percent, whichever is greater. NACUBO/SESAC Joint Proposal App. A.

NRBNMLC Joint Proposals

The joint proposals entered into by NRBNMLC and each of HFA/NMPA, ASCAP, BMI, and SESAC propose carrying forward unchanged the current provisions set forth in §§ 381.1 (except to replace ''January 1, 2013'' with ''January 1, 2018'' and ''December 31, 2017'' with ''December 31, 2022''), 381.2, 381.9, and 381.11.

The joint proposal between NMPA/HFA and NRBNMLC states that the rates in § 381.7(b)(4) should be modified. NMPA/HFA and NRBNMLC Joint Proposal at 2–3.

Each of the joint proposals between NRBNMLC and ASCAP, BMI and SESAC propose modifications to § 381.6. ASCAP and NRBNMLC Joint proposal at 3; BMI and NRBNMLC Joint proposal at 5; SESAC and NRBNMLC Joint proposal at 3.

NPR/PBS Joint Proposals

NPR and PBS filed a joint proposal with NMPA and HFA to modify fees in

[1] CMPA's PTP was filed late with permission of the Judges. *See* Order Granting Church Music Publishers' Motion to Accept Late Petition to Participate (May 6, 2016). The Judges received no written direct statement from and no notice of settlement from or regarding CMPA.

[2] Mr. Powell's Petition to Participate was dismissed on August 16, 2016. Order Dismissing Petition to Participate of David Powell.

[3] A ''public broadcasting entity'' is defined as a ''noncommercial educational broadcast station as defined in section 397 of title 47 and any nonprofit institution or organization engaged in the activities described in paragraph (2) of subsection (c)'' of section 118. 17 U.S.C. 118(f).

[4] The Judges received an agreement from BMI on October 24, 2017. They anticipate receiving two others (from ASCAP and SESAC). Submission of NPR and PBS at 1 (Oct. 25, 2017).

[5] The PTP from NPR and PBS covers CPB (the Corporation for Public Broadcasting).

§ 381.7, a change that reflects the same percentage increase made in the prior rate period because such increase ''is fair and reasonable.'' HFA/NMPA and NPR/PBS Joint Proposal at 2.

NPR and PBS filed proposed changes to fees in § 381.4 pursuant to negotiated license agreements with ASCAP, BMI, and SESAC. The changes conform to analogous changes in §§ 381.5 and 381.6.

As noted above, the members of the public and participants in this rate proceeding may comment and object to any or all of the proposed regulations contained in this notice.

List of Subjects in 37 CFR Part 381

Copyright, Music, Radio, Television, Rates.

Proposed Regulations

For the reasons set forth in the preamble, the Copyright Royalty Judges propose to amend part 381 to chapter III of title 37 of the Code of Federal Regulations as set forth below:

PART 381—USE OF CERTAIN COPYRIGHTED WORKS IN CONNECTION WITH NONCOMMERCIAL EDUCATIONAL BROADCASTING

■ 1. The authority citation for part 381 continues to read as follows:

Authority: 17 U.S.C. 118, 801(b)(1) and 803.

§ 381.1 [Amended]

■ 2. In § 381.1 remove ''2013'' and, in its place, add ''2018'', and remove ''2017'' and, in its place, add ''2022''.

■ 3. Amend § 381.4 as follows:

■ a. Revise paragraph (a);

■ b. In paragraph (c) remove ''2013'' and, in its place, add ''2018'', and remove ''2017'' and, in its place, add ''2022''; and

■ c. Remove paragraph (d).

The revision reads as follows:

§ 381.4 Performance of musical compositions by PBS, NPR and other public broadcasting entities engaged in the activities set forth in 17 U.S.C. 118(c).

* * * * *

(a) *Determination of royalty rate.* The following rates and terms shall apply to the performance by PBS, NPR and other public broadcasting entities engaged in activities set forth in 17 U.S.C. 118(c) of copyrighted published nondramatic musical compositions, except for public broadcasting entities covered by §§ 381.5 and 381.6, and except for compositions which are the subject of voluntary license agreements: The royalty shall be $1.

* * * * *

■ 4. Amend § 381.5 by revising paragraph (c) to read as follows:

§ 381.5 Performance of musical compositions by public broadcasting entities licensed to colleges and universities.

* * * * *

(c) *Royalty rate.* A public broadcasting entity within the scope of this section may perform published nondramatic musical compositions subject to the following schedule of royalty rates:

(1) For all such compositions in the repertory of ASCAP, the royalty rates shall be as follows:

(i)

	Number of full-time students	2018	2019	2020	2021	2022
Level 1	<1,000	$352	$359	$366	$373	$380
Level 2	1,000–4,999	407	415	423	431	440
Level 3	5,000–9,999	557	568	579	591	603
Level 4	10,000–19,999	722	736	751	766	781
Level 5	20,000 +	908	926	945	964	983

(ii) Level 1 rates as set forth in paragraph (c)(1)(i) of this section, shall also apply to College Radio Stations with an authorized effective radiated power (ERP), as that term is defined in 47 CFR 73.310(a), of 100 Watts or less, as specified on its current FCC license, regardless of the size of the student population.

(2) For all such compositions in the repertory of BMI, the royalty rates shall be as follows:

(i)

	Number of full-time students	2018	2019	2020	2021	2022
Level 1	<1,000	$352	$359	$366	$373	$380
Level 2	1,000–4,999	407	415	423	431	440
Level 3	5,000–9,999	557	568	579	591	603
Level 4	10,000–19,999	722	736	751	766	781
Level 5	20,000 +	908	926	945	964	983

(ii) Level 1 rates, as set forth in paragraph (c)(2)(i) of this section, shall also apply to College Radio Stations with an authorized effective radiated power (ERP), as that term is defined in 47 CFR 73.310(a), of 100 Watts or less, as specified on its current FCC license, regardless of the size of the student population.

(3) For all such compositions in the repertory of SESAC, the royalty rates shall be as follows:

(i) 2018: The 2017 rate, subject to an annual cost of living adjustment in accordance with paragraph (c)(3)(vi) of this section.

(ii) 2019: The 2018 rate, subject to an annual cost of living adjustment in accordance with paragraph (c)(3)(vi) of this section.

(iii) 2020: The 2019 rate, subject to an annual cost of living adjustment in accordance with paragraph (c)(3)(vi) of this section.

(iv) 2021: The 2020 rate, subject to an annual cost of living adjustment in accordance with paragraph (c)(3)(vi) of this section.

(v) 2022: The 2021 rate, subject to an annual cost of living adjustment in accordance with paragraph (c)(3)(vi) of this section.

(vi) Such cost of living adjustment to be made in accordance with the greater of

(A) The change, if any, in the Consumer Price Index (all consumers, all items) published by the U.S. Department of Labor, Bureau of Labor Statistics during the twelve (12) month period from the most recent Index, published before December 1 of the year

immediately prior to the applicable year, or

(B) One and one-half percent (1.5%).

(4) For the performance of any other such compositions: $1.

* * * * *

■ 5. Amend § 381.6 as follows:

■ a. Remove from the first sentence of paragraph (a) the words ''which are''; and

■ b. Revise paragraph (d).

The revision reads as follows:

§ 381.6 Performance of musical compositions by other public broadcasting entities.

* * * * *

(d) *Royalty rate.* A public broadcasting entity within the scope of this section may perform published nondramatic musical compositions subject to the following schedule of royalty rates:

(1) For all such compositions in the repertory of ASCAP, the royalty rates shall be as follows:

(i) Music Fees (Stations with 20% or more programming containing Feature Music):

	Population count	Calendar years				
		2018	2019	2020	2021	2022
Level 1	0–249,999	$697	$711	$725	$739	$754
Level 2	250,000–499,999	1,243	1,268	1,294	1,319	1,346
Level 3	500,000–999,999	1,864	1,901	1,939	1,978	2,017
Level 4	1,000,000–1,499,999	2,486	2,535	2,586	2,638	2,691
Level 5	1,500,000–1,999,999	3,107	3,169	3,232	3,297	3,363
Level 6	2,000,000–2,499,999	3,728	3,803	3,879	3,956	4,035
Level 7	2,500,000–2,999,999	4,349	4,436	4,525	4,615	4,708
Level 8	3,000,000 and above	6,214	6,338	6,465	6,594	6,726

(ii) Talk Format Station Fees (Stations with <20% Feature Music programming):

	Population count	Calendar years				
		2018	2019	2020	2021	2022
Level 1	0–249,999	$697	$711	$725	$739	$754
Level 2	250,000–499,999	697	711	725	739	754
Level 3	500,000–999,999	697	711	725	739	754
Level 4	1,000,000–1,499,999	870	887	905	923	942
Level 5	1,500,000–1,999,999	1,087	1,109	1,131	1,154	1,177
Level 6	2,000,000–2,499,999	1,305	1,331	1,357	1,384	1,412
Level 7	2,500,000–2,999,999	1,522	1,552	1,583	1,615	1,647
Level 8	3,000,000 and above	2,175	2,218	2,262	2,308	2,354

(2) For all such compositions in the repertory of BMI, the royalty rates shall be as follows:

(i) Music Fees (Stations with 20% or more programming containing Feature Music):

	Population count	Calendar years				
		2018	2019	2020	2021	2022
Level 1	0–249,999	$697	$711	$725	$739	$754
Level 2	250,000–499,999	1,243	1,268	1,294	1,319	1,346
Level 3	500,000–999,999	1,864	1,901	1,939	1,978	2,017
Level 4	1,000,000–1,499,999	2,486	2,535	2,586	2,638	2,691
Level 5	1,500,000–1,999,999	3,107	3,169	3,232	3,297	3,363
Level 6	2,000,000–2,499,999	3,728	3,803	3,879	3,956	4,035
Level 7	2,500,000–2,999,999	4,349	4,436	4,525	4,615	4,708
Level 8	3,000,000 and above	6,214	6,338	6,465	6,594	6,726

(ii) Talk Format Station Fees (Stations with <20% Feature Music programming):

	Population count	Calendar years				
		2018	2019	2020	2021	2022
Level 1	0–249,999	$697	$711	$725	$739	$754
Level 2	250,000–499,999	697	711	725	739	754
Level 3	500,000–999,999	697	711	725	739	754
Level 4	1,000,000–1,499,999	870	887	905	923	942

	Population count	Calendar years				
		2018	2019	2020	2021	2022
Level 5	1,500,000–1,999,999	1,087	1,109	1,131	1,154	1,177
Level 6	2,000,000–2,499,999	1,305	1,331	1,357	1,384	1,412
Level 7	2,500,000–2,999,999	1,522	1,552	1,583	1,615	1,647
Level 8	3,000,000 and above	2,175	2,218	2,262	2,308	2,354

(3) For all such compositions in the repertory of SESAC, the royalty rates shall be as follows:

(i) Music fees for stations with > = 20% Feature Music programming:

	Population count	Calendar years				
		2018	2019	2020	2021	2022
Level 1	0–249,999	$152	$155	$158	$161	$164
Level 2	250,000–499,999	253	258	263	268	274
Level 3	500,000–999,999	380	388	396	403	411
Level 4	1,000,000–1,499,999	507	517	527	538	548
Level 5	1,500,000–1,999,999	634	647	660	673	686
Level 6	2,000,000–2,499,999	760	775	790	806	822
Level 7	2,500,000–2,999,999	887	905	923	941	960
Level 8	3,000,000 and above	1,268	1,293	1,318	1,344	1,371

(ii) Talk fees for stations with <20% Feature Music programming:

	Population count	Calendar years				
		2018	2019	2020	2021	2022
Level 1	0–249,999	$152	$155	$158	$161	$164
Level 2	250,000–499,999	152	155	158	161	164
Level 3	500,000–999,999	152	155	158	161	164
Level 4	1,000,000–1,499,999	177	181	185	188	192
Level 5	1,500,000–1,999,999	222	227	231	236	240
Level 6	2,000,000–2,499,999	266	271	277	282	288
Level 7	2,500,000–2,999,999	311	317	323	330	336
Level 8	3,000,000 and above	444	452	461	470	480

(4) For the performance of any other such compositions, in 2018 through 2022, $1.

* * * * *

■ 6. Amend § 381.7 as follows:

■ a. Revise paragraphs (b)(1)(i)(A) through (D) and (b)(1)(ii)(A) through (D);

■ b. Revise paragraph (b)(2)(i) through (iv); and

■ c. Revise paragraph (b)(4)(i) through (iii).

The revisions read as follows:

§ 381.7 Recording rights, rates and terms.

* * * * *

(b) * * *

(1)(i) * * *

	2018–2022
(A) Feature	$118.70
(B) Concert feature (per minute)	35.65
(C) Background	59.99
(D) Theme:	
(*1*) Single program or first series program	59.99
(*2*) Other series program	24.36

(ii) * * *

	2018–2022
(A) Feature	$9.81
(B) Concert feature (per minute)	2.58
(C) Background	4.26
(D) Theme:	
(*1*) Single program or first series of program	4.26
(*2*) Other series program	1.69

* * * * *

(2) * * *

	2018–2022
(i) Feature	$12.85
(ii) Concert feature (per minute)	18.86
(iii) Background	6.44
(iv) Theme:	
(A) Single program or first series program	6.44
(B) Other series program	2.57

* * * * *

(4) * * *

	2018–2022
(i) Feature	$.81
(ii) Feature (concert) (per half hour)	1.69
(iii) Background	.41

* * * * *

■ 7. Amend § 381.10 as follows:

■ a. In paragraph (a), remove ''2013'' and, in its place, add ''2018'', and remove ''2017'' and, in its place, add ''2022'';

■ b. Revise paragraph (b);

The revision reads as follows:

§ 381.10 Cost of living adjustment.

* * * * *

(b) On the same date of the notices published pursuant to paragraph (a) of this section, the Copyright Royalty Judges shall publish in the **Federal Register** a revised schedule of the rates for § 381.5(c)(3), the rate to be charged for compositions in the repertory of SESAC, which shall adjust the royalty

amounts established in a dollar amount according to the greater of

(1) The change in the cost of living determined as provided in paragraph (a) of this section, or

(2) One-and-a-half percent (1.5%).

(3) Such royalty rates shall be fixed at the nearest dollar.

* * * * *

Dated: October 31, 2017.

Suzanne M. Barnett,

Chief U.S. Copyright Royalty Judge.

[FR Doc. 2017–23991 Filed 11–3–17; 11:15 am]

BILLING CODE 1410–72–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2017–0280; FRL–9969–88–Region 5]

Air Plan Approval; Wisconsin; 2017 Revisions to NR 400 and 406

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Wisconsin State Implementation Plan (SIP) submitted by the Wisconsin Department of Natural Resources (WDNR) to EPA on May 16, 2017. The revision replaces the definition of ''emergency electric generator'' with a broader definition of ''restricted internal combustion engine''. In addition, the revision makes amendments to procedures for revoking construction permits as well as language changes and other administrative updates. Lastly, WDNR is withdrawing two Wisconsin Administrative Code provisions that affect eligibility under general and construction permits. WDNR requested these changes to align state and Federal requirements and ensure consistency. EPA is proposing approval of Wisconsin's May 16, 2017, request because the Agency has made the preliminary determination that this SIP revision is consistent with the Clean Air Act and applicable EPA regulations regarding PSD.

DATES: Comments must be received on or before December 7, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2017–0280 at *http://www.regulations.gov* or via email to *damico.genevieve@epa.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, *etc.*) must be accompanied by a written comment. The written comment is considered the official comment and should include a discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the Web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Radhica Kanniganti, Environmental Engineer, Air Permits Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–8097, *kanniganti.radhica@epa.gov*.

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, this rule will be effective on January 8, 2018. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: October 6, 2017.

Robert A. Kaplan,

Acting Regional Administrator, Region 5.

[FR Doc. 2017–23448 Filed 11–6–17; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 170828822–7822–01]

RIN 0648–XF669

Fisheries of the Northeastern United States; Scup Fishery; 2018 and Projected 2019 Specifications

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes revised scup specifications for the 2018 fishing year and projected specifications for 2019. Updated scientific information regarding the scup stock indicates that higher catch limits may be implemented to achieve optimum yield. This action is intended to inform the public of the proposed specifications for the 2018 fishing year and projected specifications for 2019.

DATES: Comments must be received by 5 p.m. local time, on November 22, 2017.

ADDRESSES: An environmental assessment (EA) was prepared for this action and describes the proposed measures and other considered alternatives, and provides an analysis of the impacts of the proposed measures and alternatives. Copies of the Specifications Document, including 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*.

You may submit comments on this document, identified by NOAA–NMFS–2017–0121, by either of the following methods:

Electronic Submission: Submit all electronic public comments via the Federal e-Rulemaking Portal.

1. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2017-0121,*

2. Click the ''Comment Now!'' icon, complete the required fields, and

3. Enter or attach your comments.

—OR—

Mail: Submit written comments to John Bullard, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope, ''Comments on the Proposed Rule for Revised Scup Specifications.''

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 part of the public record and will generally be posted for public viewing on *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).

FOR FURTHER INFORMATION CONTACT: Emily Gilbert, Fishery Policy Analyst, (978) 281–9244.

SUPPLEMENTARY INFORMATION:

General Background

The Mid-Atlantic Fishery Management Council and the Atlantic States Marine Fisheries Commission cooperatively manage the summer flounder, scup, and black sea bass fisheries. The Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) and its implementing regulations outline the Council's process for establishing specifications. Specifications in these fisheries include various catch and landing subdivisions, such as the commercial and recreational sector annual catch limits (ACLs), annual catch targets (ACTs), and sector-specific landing limits (*i.e.,* the commercial fishery quota and recreational harvest limit). Annual specifications may be proposed for three-year periods, with the Council reviewing the specifications each year to ensure that previously established multi-year specifications remain appropriate. Following review, NMFS announces the final annual specifications in the **Federal Register**. The FMP also contains formulas to divide the specification catch limits into commercial and recreational fishery allocations, state-by-state quotas, and quota periods, depending on the species in question. Rulemaking for measures used to manage the recreational fisheries (minimum fish sizes, open seasons, and bag limits) for these three species occurs separately, and typically takes place in the spring of each year. The summer flounder and black sea bass specifications implemented through previous rulemaking remain unchanged by this action.

On December 28, 2015, NMFS published a final rule implementing the Council's recommended 2016–2018 specifications for the scup fishery (80 FR 80689). The Council intended to reconsider the specifications set for fishing year 2018 following the review of a scup assessment update provided in July 2017.

The assessment update indicated the scup stock is not overfished and overfishing did not occur in 2016, the most recent year for which information is available. The update estimated that the scup spawning stock biomass (SSB) is 2.1 times the proxy reference point for SSB at maximum sustainable yield (MSY), and fishing mortality (F) in 2016 was about 63 percent of the F_{MSY} proxy reference point. In addition, the update estimated that the 2015 year class was about 2.1 times the average recruitment (*i.e.,* number of age 0 scup) from 1984–2016. The 2016 year class was 46 percent below the 1984–2016 recruitment average. Although the 2016 year class was estimated to be below average, the 2015 year class was so large that the assessment update provided higher revised overfishing limit (OFL) recommendations for 2018 and 2019. Compared to the previously implemented 2018 OFL (29.68 million lb, 13,462 mt), the 2018 recommendation is a 52-percent increase.

Proposed Specifications

The Council's Scientific and Statistical Committee (SSC) met on July 19–20, 2017, to discuss the assessment update results and resulting OFL estimates, to identify an updated acceptable biological catch (ABC) level for 2018, and to project an ABC for the 2019 fishing year. To derive the ABC recommendations, the SSC applied the Council's standard risk policy for a species with a typical life history, which produces ABCs estimated to result in a 60-percent probability of not overfishing the stock. The process resulted in ABCs of 39.14 million lb (17,755 metric tons (mt)) for 2018 and 36.43 million lb (16,525 mt) for 2019 (Table 1). The revised 2018 ABC is approximately 45 percent higher than the previously established 2018 ABC. Under the FMP, 22 percent of the ABC is allocated to the recreational fishery, while 78 percent is allocation to the commercial fishery.

Following the SSC meeting, the Monitoring Committee met on July 24, 2017, to discuss ACLs, ACTs, commercial quotas, and recreational harvest limits for the 2018 and 2019 fishing years. In light of the substantial increase in the ABC, the Monitoring Committee recommended a moderate increase for the fishery and suggested setting the 2018 commercial ACT at 25.85 million lb (11,725 mt) and the recreational ACT at 7.29 million lb (3,307 mt). These recommended ACTs were 15 percent lower than those formulaically resulting from the SSC's ABC recommendation, but 22.5 percent higher than what is currently in place for 2018. The Monitoring Committee also recommended setting the 2019 ACTs at the same level as the 2018 ACTs. The Monitoring Committee decided that there was enough management uncertainty around the upcoming adjustments to the commercial quota periods in 2018 and the outcome of the upcoming recreational harvest estimate revisions through the Marine Recreational Information Program to warrant the inclusion of a buffer between the ACLs and ACTs, which would provide for more stability in the fishery by using constant ACTs for both years.

The Council and Commission's Scup Management Board meet jointly on August 8, 2017, to review the SSC's and Monitoring Committee's recommendations. They found merit in the idea of offering stability in the fishery by allowing for a buffer between the ACLs and ACTs, but did not accept the Monitoring Committee's specific recommendations. Instead, the Council and Commission recommended constant sector-specific ACTs across 2018 and 2019, based on the 2019 ABC and setting the ACLs for 2019 equal to the ACTs (*i.e.,* 8.01 million lb (3,636 mt) for the recreational fishery and 23.98 million lb (10,879 mt) for the commercial fishery).

After removing the sector-specific estimated discards from the ACTs, the scup commercial quotas and recreational harvest limits would be those shown in Table 1. These values are approximately 40 percent higher than the current 2018 commercial quota and recreational harvest limit. The Monitoring Committee did not recommend any changes to the current commercial measures, including the 9-inch (22.9-cm) minimum fish size, the mesh size requirements and seasonal possession limit thresholds, and the pot/trap gear requirements.

The Council will revisit its decision on the projected 2019 specifications following the SSC's review next summer. By providing projected specifications for 2019, NMFS hopes to assist fishery participants in planning

ahead. Final 2019 specifications will be published in the **Federal Register** before the start of the 2019 fishing year (January 1, 2019) based on the Council's review.

TABLE 1—COUNCIL-RECOMMENDED SCUP SPECIFICATIONS FOR 2018 AND PROJECTED FOR 2019

	Scup specifications					
	2018 (current)		2018 (revised)		2019 (projected)	
	million lb	mt	million lb	mt	million lb	mt
OFL	29.68	13,462	45.05	20,433	41.03	18,612
ABC	27.05	12,270	39.14	17,755	36.43	16,525
Commercial ACL	21.10	9,571	30.53	13,849	28.42	12,890
Commercial ACT	21.10	9,571	28.42	12,890	28.42	12,890
Commercial Discards	3.76	1,705	4.43	2,011	4.43	2,011
Commercial Quota	17.34	7,866	23.98	10,879	23.98	10,879
Recreational ACL	5.95	2,699	8.61	3,906	8.01	3,636
Recreational ACT	5.95	2,699	8.01	3,636	8.01	3,636
Recreational Discards	0.75	338	0.65	293	0.65	293
Recreational Harvest Limit	5.21	2,361	7.37	3,342	7.37	3,342

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.

This action is exempt from review under E.O. 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 Mid-Atlantic Fishery Management Council conducted an evaluation of the potential socioeconomic impacts of the proposed measures in conjunction with an EA. According to the commercial ownership database, 517 affiliate firms landed scup during the 2014–2016 period, with 513 of those business affiliates categorized as small businesses and 4 categorized as large businesses. Scup represented approximately 3.94 percent of the average receipts of the small entities considered and 0.11 percent of the average receipts of the large entities considered over this time period.

The ownership data for the for-hire fleet indicate that there were 359 for-hire affiliate firms generating revenues from fishing recreationally for various species during the 2014–2016 period, all of which are categorized as small businesses. Although it is not possible to derive what proportion of the overall revenues came from specific fishing activities, given the popularity of scup as a recreational species it is likely that revenues generated from scup are important for some, if not all, of these firms.

The proposed measure would increase both the 2018 commercial quota and the 2018 recreational harvest limit by around 40 percent. However, the scup fishery is a market-limited fishery (*i.e.,* market conditions are typically the limiting factor, not allowable landings) and it is expected that, unless market conditions change drastically, commercial and recreational landings will likely be similar to current landings. As a result, this action is not expected to adversely impact revenues for vessels that fish for scup commercially. The increase in the recreational harvest limit does not directly impact the party/charter fishery. Future regulatory action may be needed to adjust current scup recreational management measures (*i.e.,* bag limits, seasons, and minimum sizes), and consideration of the impact of those potential future measures on small entities engaged in the for-hire fishery will be evaluated at that time, should such a regulatory action become necessary. Because this rule will not have a significant economic impact on a substantial number of small entities, an initial regulatory flexibility analysis is not required and none has been prepared.

There are no new reporting or recordkeeping requirements contained in any of the alternatives considered for this action.

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

Dated: November 2, 2017.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2017–24205 Filed 11–6–17; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 82, No. 214

Tuesday, November 7, 2017

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

November 2, 2017.

The Department of Agriculture has submitted the following information collection requirement(s) to Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by December 7, 2017 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Utilities Service

Title: Electric System Emergency Restoration Plan.

OMB Control Number: 0572–0140.

Summary of Collection: Electric power systems have been identified in Presidential Decision Directive 63, May 1998, as one of the critical infrastructures of the United States. The term ''critical infrastructure'' is defined in section 1016(e) of the USA Patriot Act of 2001 (42 U.S.C. 5195c(e)). To ensure that the electric infrastructure in rural America is adequately protected, Rural Utilities Service (RUS) requires that all current electric borrowers conduct a Vulnerability and Risk Assessment (VRA) of their respective systems and utilize the results of this assessment to enhance an existing Emergency Restoration Plan (ERP) or, create an ERP.

Need and Use of the Information: The ERP provides written procedures detailing response and restoration efforts in the event of a major system outage resulting from a natural or man made disaster. RUS requires each electric borrower to provide annually a self-certification, in writing, that an ERP exists and that an initial VRA has been performed. If this information were not collected, vulnerabilities may exist in the electric system infrastructure. The result would be increased risk to public safety and may affect the Government loan security.

Description of Respondents: Not-for-profit institutions.

Number of Respondents: 625.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 313.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2017–24223 Filed 11–6–17; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Information Collection; Outreach Opportunity Questionnaire

AGENCY: Forest Service, USDA.

ACTION: Notice; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Forest Service is seeking comments from all interested individuals and organizations on the extension with revision of a currently approved information collection, Outreach Opportunity Questionnaire (0596–0207).

DATES: Comments must be received in writing on or before January 8, 2018 to be assured of consideration. Comments received after that date will be considered to the extent practicable.

ADDRESSES: Comments concerning this notice should be addressed to the Northern Research Station, *Attention:* Judy Terrell, Forest Service, USDA, 11 Campus Boulevard, Suite 200, Newtown Square, PA 19073.

Comments also may be submitted via email to: *jterrell@fs.fed.us.* The public may inspect comments received at USDA Forest Service, 11 Campus Boulevard, Suite 200, Newtown Square, PA 19073 during normal business hours. Visitors are encouraged to call ahead to 610–557–4057 to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Judy Terrell, 610–557–4057. Individuals who use telecommunications devices for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339, between 8 a.m. and 8 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION:

Title: Outreach Opportunity Questionnaire.

OMB Number: 0596–0207.

Expiration Date of Approval: February 28, 2018.

Type of Request: Extension with revision.

Abstract: This information collection is proposing to extend the collection of information from students attending local college and university career fairs regarding the effectiveness of the information provided by the Forest Service personnel on career opportunities in the Forest Service. The

collection is necessary to evaluate and determine the effectiveness of the Forest Service Civil Rights Northeastern Service Center (NESC) Outreach Program.

Forest Service, Civil Rights personnel, have utilized the Outreach Opportunity Questionnaire to collect evaluation information from students regarding presentations at career day events as well as at colleges and universities. Data received has appeared in reports provided to the Department of Agriculture, senior Forest Service officials, the Northern Research Station Director, and the Northern Research Station Civil Rights Diversity Committee. This information is a vital component in the analysis of Agency outreach efforts.

Estimate of Annual Burden: 20 hours/year.

Type of Respondents: University/College students.

Estimated Annual Number of Respondents: 675.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 20 hours.

Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) 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 the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the request for Office of Management and Budget approval.

Dated: October 30, 2017.

J. Lenise Lago,

Acting Associate Chief, Forest Service.

[FR Doc. 2017–24179 Filed 11–6–17; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

National Agricultural Statistics Service

Notice of Intent To Request To Conduct a New Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 this notice announces the intention of the National Agricultural Statistics Service (NASS) to seek approval to conduct a new information collection to gather data related to water usage for North Carolina agricultural operations that likely use between 10,000 and 1,000,000 gallons per day.

DATES: Comments on this notice must be received by January 8, 2018 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–NEW, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *E-fax:* (855) 838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW., Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: R. Renee Picanso, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, (202) 720–4333. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at (202) 690–2388 or at *ombofficer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Water Use Survey.

OMB Control Number: 0535–NEW.

Type of Request: Intent to seek approval to conduct a new information collection for a period of three years.

Abstract: The primary objective of the National Agricultural Statistics Service (NASS) is to collect, prepare and issue State and national estimates of crop and livestock production, prices, and disposition; as well as economic statistics, environmental statistics related to agriculture and also to conduct the Census of Agriculture.

The Water Use survey program will collect information on water usage for North Carolina agricultural operations that likely use between 10,000 and 1,000,000 gallons per day. Agricultural operations who use over 1,000,000 gallons in any one day are required to report their water usage directly to North Carolina Department of Environmental Quality (NCDEQ) and are not included in this survey. The program will help the North Carolina Department of Agriculture and Consumer Services (NCDACS) and NCDEQ fulfill the requirements of North Carolina state legislation enacted in 2008 (SL2008–0143). All questionnaires included in this information collection will be voluntary. This project is conducted as a cooperative effort with the North Carolina Department of Agriculture and Consumer Services. Funding for this pilot survey is being provided by NCDACS.

Authority: These data will be collected under authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents. This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–113, 44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at 5 CFR part 1320.

NASS also complies with OMB Implementation Guidance, ''Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),'' **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33362.

Estimate of Burden: Public reporting burden for this information collection is based on similar surveys with expected response time of 30 minutes. The estimated sample size will be approximately 3,300. The frequency of data collection for the different surveys is annual. Estimated number of responses per respondent is 1. Publicity materials and instruction sheets will account for approximately 5 minutes of additional burden per respondent. Respondents who refuse to complete a survey will be allotted 2 minutes of burden per attempt to collect the data.

Respondents: North Carolina operations that likely use between 10,000 and 1,000,000 gallons annually.

Estimated Number of Respondents: 3,300.

Estimated Total Annual Burden on Respondents: 1,614 hours.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological, or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, October 25, 2017.

R. Renee Picanso,

Associate Administrator.

[FR Doc. 2017–24167 Filed 11–6–17; 8:45 am]

BILLING CODE 3410–20–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Alaska Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Alaska Advisory Committee (Committee) to the Commission will be held on December 14, 2017 at 1:00 p.m. (Alaska Time). On Thursday, January 18, 2018; Thursday, February 8, 2018 and Thursday, March 8, 2018 at 12:00 p.m. (Alaska Time). The purpose of the meeting is for the Committee to discuss findings that will be included in an advisory memorandum on Alaska Native voting rights.

DATES: The meeting will be held on Thursday, December 14, 2017 at 1:00 p.m. (AKT) and on Thursday, January 18, 2018; Thursday, February 8, 2018 and Thursday, March 8, 2018 at 12:00 p.m. (AKT).

Public Call Information: Dial: 888–609–5689; Conference ID: 3574845.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 888–609–5689, conference ID number: 3574845. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://facadatabase.gov/committee/meetings.aspx?cid=234.* Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Discuss Advisory Memorandum
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: November 1, 2017.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017–24136 Filed 11–6–17; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Alaska Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Alaska Advisory Committee (Committee) to the Commission will be held at 1:00 p.m. (Alaska Time) Thursday, November 9, 2017. The purpose of the meeting is for the Committee to discuss findings that will be included in an advisory memorandum on Alaska Native voting rights.

DATES: The meeting will be held on Thursday, November 9, 2017, at 1:00 p.m. AKT.

Public Call Information: Dial: 888–609–5689; Conference ID: 3574845.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes (DFO) at *afortes@usccr.gov* or (213) 894–3437.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 888–609–5689, conference ID number: 3574845. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North

Los Angeles Street, Suite 2010, Los Angeles, CA 90012. They may be faxed to the Commission at (213) 894–0508, or emailed Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (213) 894–3437.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://facadatabase.gov/committee/meetings.aspx?cid=234.* Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, *http://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome
II. Discuss Advisory Memorandum
III. Public Comment
IV. Next Steps
V. 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 circumstance of the committee needing to discuss and draft an advisory memorandum focused on Alaska Native voting rights that will be included in the 2018 Statutory Enforcement report.

Dated: November 1, 2017.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2017–24137 Filed 11–6–17; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Proposed Information Collection; Comment Request; Current Population Survey (CPS) Basic Demographic Items

AGENCY: U.S. Census Bureau, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: To ensure consideration, written comments must be submitted on or before January 8, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *PRAcomments@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Karen Woods, U.S. Census Bureau, 7H140F, Washington, DC 20133–8400 at (301) 763–3806.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau plans to request clearance from the Office of Management and Budget (OMB) for the collection of basic demographic information on the Current Population Survey (CPS) beginning in August 2018. The current clearance expires July 31, 2018.

The CPS has been the source of official government statistics on employment and unemployment for over 60 years. The Bureau of Labor Statistics (BLS) and the Census Bureau jointly sponsor the basic monthly survey. The Census Bureau also prepares and conducts all the field work. At the OMB's request, the Census Bureau and the BLS divide the clearance request in order to reflect the joint sponsorship and funding of the CPS program. The BLS submits a separate clearance request for the portion of the CPS that collects labor force information for the civilian noninstitutional population. Some of the information within that portion includes employment status, number of hours worked, job search activities, earnings, duration of unemployment, and the industry and occupation classification of the job held the previous week. The justification that follows is in support of the demographic data.

The demographic information collected in the CPS provides a unique set of data on selected characteristics for the civilian noninstitutional population. Some of the demographic information we collect are age, marital status, sex, Armed Forces status, education, race, origin, and family income. We use these data in conjunction with other data, particularly the monthly labor force data, as well as periodic supplement data. We also use these data independently for internal analytic research and for evaluation of other surveys. In addition, we use these data as a control to produce accurate estimates of other personal characteristics.

II. Method of Collection

The CPS basic demographic information is collected from individual households by both personal visit and telephone interviews each month. All interviews are conducted using computer-assisted interviewing. Households in the CPS are in sample for four consecutive months, and for the same four months the following year. This is called a 4–8–4 rotation pattern; households are in sample for four months, in a resting period for eight months, and then in sample again for four months.

III. Data

OMB Control Number: 0607–0049.

Form Number(s): There are no forms. All interviews are conducted on computers.

Type of Review: Regular submission.

Affected Public: Households.

Estimated Number of Respondents: 59,000 per month.

Estimated Time per Response: 1.5 minutes.

Estimated Total Annual Burden Hours: 17,700.

Estimated Total Annual Cost to Public: There is no cost to the respondents other than their time.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13 U.S.C. Sections 8(b), 141, and 182.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection;

they also will become a matter of public record.

Sheleen Dumas,

Departmental PRA Lead, Office of the Chief Information Officer.

[FR Doc. 2017–24209 Filed 11–6–17; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–810]

Stainless Steel Bar From India: Preliminary Determination of No Shipments and Partial Rescission of the Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In response to requests from interested parties, the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on stainless steel bar (SSB) from India. The period of review (POR) is February 1, 2016, through January 31, 2017. This review covers two producers or exporters of the subject merchandise: Ambica Steels Limited (Ambica), and Bhansali Bright Bars Pvt. Ltd. (Bhansali). We preliminarily determine that Bhansali and Ambica had no shipments of subject merchandise during the POR. Interested parties are invited to comment on these preliminary results.

DATES: Applicable: November 7, 2017.

FOR FURTHER INFORMATION CONTACT: Mark Kennedy, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington DC 20230; telephone: (202) 482–7883.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The merchandise subject to the order is SSB. SSB means articles of stainless steel in straight lengths that have been either hot-rolled, forged, turned, cold-drawn, cold-rolled or otherwise cold-finished, or ground, having a uniform solid cross section along their whole length in the shape of circles, segments of circles, ovals, rectangles (including squares), triangles, hexagons, octagons, or other convex polygons. SSB includes cold-finished SSBs that are turned or ground in straight lengths, whether produced from hot-rolled bar or from straightened and cut rod or wire, and reinforcing bars that have indentations, ribs, grooves, or other deformations produced during the rolling process.

Except as specified above, the term does not include stainless steel semi-finished products, cut-to-length flat-rolled products (*i.e.,* cut-to-length rolled products which if less than 4.75 mm in thickness have a width measuring at least 10 times the thickness, or if 4.75 mm or more in thickness having a width which exceeds 150 mm and measures at least twice the thickness), wire (*i.e.,* cold-formed products in coils, of any uniform solid cross section along their whole length, which do not conform to the definition of flat-rolled products), and angles, shapes, and sections.

Imports of these products are currently classifiable under subheadings 7222.10.00, 7222.11.00, 7222.19.00, 7222.20.00, 7222.30.00 of the Harmonized Tariff Schedule (HTS). Although the HTS subheadings are provided for convenience and customs purposes, our written description of the scope of the *Order* is dispositive.

Background

Carpenter Technology Corporation, Crucible Industries LLC, Electralloy, a Division of G,O, Carlson, Inc., North American Stainless, Universal Stainless & Alloy Products, Inc., and Valbruna Slater Stainless, Inc. (the petitioners) timely requested an administrative review of Ambica, Bhansali, and Ambica Stainless Steel Limited (now known as Aamor Inox Limited) (ASSL).[1] As such, the Department published in the **Federal Register** a notice of initiation of this administrative review of the antidumping duty order on SSB from India for Ambica and Bhansali.[2]

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), the Department will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. The petitioners timely withdrew their request for review of ASSL.[3] No other party requested a review of this producer/exporter. Therefore, in accordance with 19 CFR 351.213(d)(1), the Department is rescinding this review of the AD order on SSB from the PRC with respect to ASSL.

Preliminary Determination of No Shipments

We received timely certifications from Bhansali and Ambica reporting that they had no shipments of the subject merchandise to the United States during the POR and requested that the Department rescind the review with respect to it.[4] As detailed in the Preliminary Decision Memorandum, the Department preliminarily determines that both Bhansali and Ambica had no shipments during the POR.[5]

Consistent with our practice, we will complete the review and issue appropriate instructions to CBP based on the final results of this review.[6]

Public Comment

Interested parties may submit case briefs no later than 30 days after the date of publication of the preliminary results.[7] Rebuttal briefs, limited to the issues raised in the case briefs, may be filed no later than five days after the submission of case briefs.[8] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[9]

All submissions to the Department must be filed electronically using ACCESS, and must also be served on interested parties.[10] An electronically filed document must be received successfully in its entirety by the Department's electronic records system,

[1] *See* Letter to the Department from the petitioners, ''Stainless Steel Bar from India: Petitioners' Request for 2016/17 Administrative Review,'' dated February 28, 2017. Although the petitioners stated that ''Ambica Stainless Steel Limited'' is ''now known as Aamor Inox Limited,'' the Department has not determined that Aamor Inox Limited is the successor in interest to Ambica Stainless Steel Limited.

[2] *See* ''Initiation of Antidumping and Countervailing Duty Administrative Reviews,'' 82 FR 17188 (April 10, 2017) (Initiation Notice).

[3] *See* Letter from the petitioners, ''Stainless Steel Bar from India—Petitioners' Request to Withdraw Request for Administrative Review of Ambica Stainless Steel Limited/Aamor Inox Limited,'' dated April 24, 2017.

[4] *See* Letter from Bhansali, ''Stainless Steel Bar products from India: Request for No Shipment letter during the Period of Review (POR),'' dated March 9, 2017; *see also* Letter from Ambica Steels Limited, ''Stainless Steel Bar—No Shipments In Period of Review (POR),'' dated May 1, 2017.

[5] For additional information and analysis, *see* the Preliminary Decision Memorandum.

[6] *See, e.g.,* Certain Frozen Warmwater Shrimp from Thailand; Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments; 2012–2013, 79 FR 15951, 15952 (March 24, 2014), *unchanged in* Certain Frozen Warmwater Shrimp from Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of Review; 2012–2013, 79 FR 51306, 51306–307 (August 28, 2014).

[7] *See* 19 CFR 351.309(c)(1)(ii); *see also* 19 CFR 351.303 (for general filing requirements).

[8] *See* 19 CFR 351.309(d)(1).

[9] *See* 19 CFR 351.309(c)(2) and (d)(2).

[10] *See* 19 CFR 351.303(f).

ACCESS, by 5:00 p.m. Eastern Time on the date that the document is due.

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, using Enforcement and Compliance's ACCESS system within 30 days of publication of this notice.[11] Requests should contain (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs.

Unless the deadline is extended pursuant to section 751(a)(2)(B)(iv) of the Tariff Act of 1930 (the Act) and 19 CFR 351.213(h)(2), the Department intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their case and rebuttal briefs, within 120 days after the publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Assessment of Antidumping Duties

We are rescinding this review for ASSL; in accordance with Department practice, we will instruct CBP to assess antidumping duties at the rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse for consumption, in accordance with 19 CFR 351.212(c)(1)(i).

Upon issuance of the final results of this review, in accordance with the Department's practice, for entries of subject merchandise during the POR for which Ambica or Bhansali did not know that the merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. We intend to issue instructions to CBP 15 days after the publication date of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Ambica and Bhansali will remain unchanged from the rate assigned to each company in the completed segment for the most recent period for each company; (2) for other producers and exporters covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the completed segment for the most recent period of this proceeding in which that producer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the producer is, then the cash deposit rate will be the rate established for the completed segment for the most recent period of this proceeding for the producer of subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 12.45 percent, the all-others rate established in the investigation.[12] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping 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 preliminary results of administrative review in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: October 31, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2017–24172 Filed 11–6–17; 8:45 am]

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[11] *See* 19 CFR 351.310(c).

[12] *See Notice of Final Determination of Sales at Less Than Fair Value: Stainless Steel Bar from India,* 59 FR 66915, 66921 (December 28, 1994).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–928]

Uncovered Innerspring Units From the People's Republic of China: Preliminary Results and Rescission, in Part, of the Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on uncovered innerspring units (innerspring units) from the People's Republic of China (PRC). The period of review (POR) is February 1, 2016, through January 31, 2017. The Department preliminarily determines that PT Sunhere Buana International (PT Sunhere) failed to cooperate to the best of its ability and is, therefore, basing its margin on facts otherwise available with an adverse inference (AFA). The Department is also rescinding the administrative review with respect to Jietai Machinery Ltd. (HK) (Jietai Machinery). Interested parties are invited to comment on these preliminary results.

FOR FURTHER INFORMATION CONTACT: Kenneth Hawkins, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–6491.

SUPPLEMENTARY INFORMATION:

Background

On February 19, 2009, the Department published an antidumping duty order on innerspring units from the PRC (the *Order*).[1] On February 28, 2017, Leggett & Platt, Inc. (the petitioner) submitted a request for the Department to conduct an administrative review of the *Order* that examines Jietai Machinery and PT Sunhere's exports of subject merchandise made during the POR.[2] On April 10, 2016, the Department published in the **Federal Register** a notice of initiation of this administrative review of the *Order* concerning Jietai Machinery and PT Sunhere's POR

[1] *See Uncovered Innerspring Units from the People's Republic of China: Notice of Antidumping Duty Order,* 74 FR 7661 (February 19, 2009).

[2] *See* Uncovered Innerspring Units from the People's Republic of China: Request for Antidumping Administrative Review, dated February 28, 2017.

exports of subject merchandise.[3] [4] On May 1, 2017 the Department issued its questionnaire to Jietai Machinery and PT Sunhere.[5] The Department's questionnaire to Jietai Machinery was returned as undeliverable.[6] The Department confirmed delivery of its questionnaire to PT Sunhere.[7] On September 6, 2017, based on guidance from U.S. Customs and Border Protection (CBP), we added harmonized tariff schedule (HTS) number 7326.20.0090 to the Scope of the Order.[8]

Scope of the Order

The merchandise subject to the order is uncovered innerspring units composed of a series of individual metal springs joined together in sizes corresponding to the sizes of adult mattresses (*e.g.,* twin, twin long, full, full long, queen, California king and king) and units used in smaller constructions, such as crib and youth mattresses. The product is currently classified under subheading 9404.29.9010 and has also been classified under subheadings 9404.10.0000, 9404.29.9005, 9404.29.9011, 7326.20.0070, 7326.20.0090, 7320.20.5010, 7320.90.5010, or 7326.20.0071 of the Harmonized Tariff Schedule of the United States (HTSUS).[9] The HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of the order is dispositive.[10]

Methodology

The Department is conducting this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). With respect to PT Sunhere, we relied on facts available and, because PT Sunhere did not act to the best of its ability to respond to the Department's requests for information, we drew an adverse inference in selecting from among the facts otherwise available.[11]

For a full description of the methodology underlying our conclusions, please see the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Partial Rescission of Administrative Review

The Department issued its questionnaire to Jietai Machinery but the questionnaire was returned as undeliverable. Despite our request to the petitioner, we received no alternative addresses for Jietai Machinery. Accordingly, consistent with the Department's practice in similar circumstances,[12] the Department is rescinding the administrative review with respect to Jietai Machinery.

Preliminary Results of Review

The Department preliminarily determines that a dumping margin of 234.51 percent exists for PT Sunhere for the period February 1, 2016, through January 31, 2017.

Public Comment [13]

Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs not later than 30 days after the date of publication of this notice in the **Federal Register**. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[14] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[15] Case and rebuttal briefs should be filed using ACCESS.[16]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance within 30 days of the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, the Department intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230, at a date and time to be determined.[17] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Unless extended, the Department intends to issue the final results of this administrative review, which will include the results of our analysis of all issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

As noted above, we are rescinding the review with respect to Jietai Machinery. As such, the Department intends to issue appropriate assessment instructions to U.S. Customs and Border Protection (CBP) 15 days after the date of publication of this notice for Jietai

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 82 FR 17188 (April 10, 2017) (Initiation Notice).

[4] PT Sunhere is located in Indonesia, a market economy country. The Department is examining PT Sunhere's exports of subject merchandise for this administrative review.

[5] *See* the Department's Letter to Jietai Machinery, dated May 1, 2017; *see also,* the Department's Letter to PT Sunhere, dated May 1, 2017 (*Questionnaires*).

[6] *See* Memorandum to the File, re: ''Antidumping Duty Administrative Questionnaire Not Delivered,'' dated August 2, 2017.

[7] *See* Memorandum to the File, re: 2016–2017 Administrative Review of Uncovered Innerspring Units from the People's Republic of China: Delivery Notification of Antidumping Duty Questionnaire to PT Sunhere Buana International, dated August 15, 2017.

[8] *See* Memorandum to the File, through Paul Walker, Program Manager, Antidumping and Countervailing Duty Operations, Office V, from Kenneth Hawkins, Case Analyst, Antidumping and Countervailing Duty Operations, Office V, re: ''Uncovered Innersprings from the People's Republic of China (A–570–928) and South Africa (A–791–821,'' dated September 6, 2017 (Additional HTS Memo).

[9] On September 6, 2017, the Department added HTS 7326.20.0090 to the scope based on a request from CBP. *See* Additional HTS Memo.

[10] For a full description of the scope of the order, see the Department Memorandum, ''Decision Memorandum for Preliminary Results of 2016–2017 Antidumping Duty Administrative Review: Uncovered Innerspring Units from the People's Republic of China,'' dated concurrently with and hereby adopted by this notice (Preliminary Decision Memorandum).

[11] *See* sections 776(a) and (b) of the Act.

[12] *See, e.g., Certain Frozen Warmwater Shrimp from Thailand; Partial Rescission of Antidumping Duty Administrative Review,* 72 FR 50931 (September 5, 2007).

[13] Normally, the Department discloses to interested parties the calculations performed in connection with the preliminary results of review within five days of the date of publication of the notice of preliminary results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because PT Sunhere did not participate and its rate is based solely on AFA, there are no calculations to disclose.

[14] *See* 19 CFR 351.309(d)(1).

[15] *See* 19 CFR 351.309(c)(2) and (d)(2).

[16] *See* 19 CFR 351.303.

[17] *See* 19 CFR 351.310(d).

Machinery. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption in accordance with 19 CFR 351.212(c)(1)(i).

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[18] The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any assessment rate calculated in the final results of this review is above *de minimis.* The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable. Assessment of duties resulting from the final results of this review will pertain only to entries of subject merchandise (*i.e.,* innerspring units from the PRC).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice, as provided by section 751(a)(2)(C) of the Act: (1) For PT Sunhere, the cash deposit rate will be that established in the final results of this review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required) and the Department will collect cash deposits only on PT Sunhere's PRC-origin merchandise; (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate published for the most recently completed period; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 234.51 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213.

Dated: October 31, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Partial Rescission of Administrative Review
5. Discussion of the Methodology
   a. Application of Facts Otherwise Available
   b. Use of Adverse Inference
   c. Selection of the Adverse Facts Available Rate
6. Recommendation

[FR Doc. 2017–24199 Filed 11–6–17; 8:45 am]

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[18] *See* 19 CFR 351.212(b)(1).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–867]

Large Power Transformers From the Republic of Korea: Final Results of the Expedited First Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this sunset review, the Department of Commerce (the Department) finds that revocation of the antidumping duty order on large power transformers (LPTs) from the Republic of Korea (Korea) would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable November 7, 2017.

FOR FURTHER INFORMATION CONTACT: Moses Song, 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) 482–5041.

SUPPLEMENTARY INFORMATION:

Background

On July 3, 2017, the Department published the notice of initiation of the first sunset review of the antidumping duty order on LPTs from Korea, pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[1] On July 18, 2017, the Department received a notice of intent to participate in this review from ABB Inc., (ABB) within the deadline specified in 19 CFR 351.218(d)(1)(i). ABB claimed interested party status under section 771(9)(C) of the Act, as a manufacturer of a domestic like product in the United States.

On August 2, 2017, we received a complete substantive response for this review from ABB within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i). We received no substantive responses from any other interested parties, nor was a hearing requested. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), the Department conducted an expedited (120-day) sunset review of the order.

Scope of the Order

The scope of this order covers large liquid dielectric power transformers (LPTs) having a top power handling capacity greater than or equal to 60,000 kilovolt amperes (60 megavolt amperes), whether assembled or unassembled, complete or incomplete.

Incomplete LPTs are subassemblies consisting of the active part and any other parts attached to, imported with or invoiced with the active parts of LPTs. The ''active part'' of the transformer consists of one or more of the following when attached to or otherwise assembled with one another: The steel core or shell, the windings, electrical insulation between the windings, the mechanical frame for an LPT.

The product definition encompasses all such LPTs regardless of name designation, including but not limited to step-up transformers, step-down transformers, autotransformers, interconnection transformers, voltage regulator transformers, rectifier

[1] *See Initiation of Five-Year (''Sunset'') Reviews,* 82 FR 30844 (July 3, 2017).

transformers, and power rectifier transformers.

The LPTs subject to this order are currently classifiable under subheadings 8504.23.0040, 8504.23.0080 and 8504.90.9540 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Analysis of Comments Received

All issues raised in this review, including the likelihood of continuation or recurrence of dumping in the event of revocation and the magnitude of the margins likely to prevail if the order were revoked, are addressed in the accompanying Issues and Decision Memorandum, which is hereby adopted by 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 to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://enforcement.trade.gov/frn/.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, we determine that revocation of the antidumping duty order on LPTs from Korea would be likely to lead to continuation or recurrence of dumping, and that the magnitude of the dumping margins likely to prevail would be weighted-average dumping margins up to 29.04 percent.

Notification to Interested Parties

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: October 31, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. History of the Order
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Margins Likely to Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2017–24187 Filed 11–6–17; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–900]

Diamond Sawblades and Parts Thereof From the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce is simultaneously initiating and issuing the preliminary results of a changed circumstances review of the antidumping duty order on diamond sawblades and parts thereof from the People's Republic of China to determine whether Chengdu Huifeng New Material Technology Co., Ltd. is the successor-in-interest to Chengdu Huifeng Diamond Tools Co., Ltd. Based on the information on the record, we preliminarily determine that Chengdu Huifeng New Material Technology Co., Ltd. is the successor-in-interest to Chengdu Huifeng Diamond Tools Co., Ltd. for purposes of determining antidumping duty liability. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 7, 2017.

FOR FURTHER INFORMATION CONTACT: Yang Jin Chun, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5760.

SUPPLEMENTARY INFORMATION:

Background

The Department published the antidumping duty order on diamond sawblades and parts thereof from the People's Republic of China on November 4, 2009.[1] In its September 20, 2017, request for a changed circumstances review, Chengdu Huifeng New Material Technology Co., Ltd., informed the Department that, effective August 16, 2016, Chengdu Huifeng Diamond Tools Co., Ltd. (1) changed its legal status from a limited liability company to a joint-stock limited company and (2) changed its name to Chengdu Huifeng New Material Technology Co., Ltd.[2] Chengdu Huifeng Diamond Tools Co., Ltd., is a respondent in the ongoing administrative review of the same order covering the period November 1, 2015, through October 31, 2016.[3] Pursuant to section 751(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.216(c) and 19 CFR 351.221(c)(3), Chengdu Huifeng New Material Technology Co., Ltd. requested that the Department initiate an expedited changed circumstances review and determine that Chengdu Huifeng New Material Technology Co., Ltd. is the successor-in-interest to Chengdu Huifeng Diamond Tools Co., Ltd.

Scope of the Order

The products covered by the order are all finished circular sawblades, whether slotted or not, with a working part that is comprised of a diamond segment or segments, and parts thereof, regardless of specification or size, except as specifically excluded below. Within the scope of the order are semifinished diamond sawblades, including diamond sawblade cores and diamond sawblade segments. Diamond sawblade cores are circular steel plates, whether or not attached to non-steel plates, with slots. Diamond sawblade cores are manufactured principally, but not exclusively, from alloy steel. A diamond sawblade segment consists of a mixture of diamonds (whether natural or

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[1] *See Diamond Sawblades and Parts Thereof from the People's Republic of China and the Republic of Korea: Antidumping Duty Orders,* 74 FR 57145 (November 4, 2009).

[2] *See* Chengdu Huifeng New Material Technology Co., Ltd.'s request for a changed circumstances review dated September 20, 2017 (CCR Request).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 82 FR 4294 (January 13, 2017) (*Initiation Notice*).

synthetic, and regardless of the quantity of diamonds) and metal powders (including, but not limited to, iron, cobalt, nickel, tungsten carbide) that are formed together into a solid shape (from generally, but not limited to, a heating and pressing process).

Sawblades with diamonds directly attached to the core with a resin or electroplated bond, which thereby do not contain a diamond segment, are not included within the scope of the order. Diamond sawblades and/or sawblade cores with a thickness of less than 0.025 inches, or with a thickness greater than 1.1 inches, are excluded from the scope of the order. Circular steel plates that have a cutting edge of non-diamond material, such as external teeth that protrude from the outer diameter of the plate, whether or not finished, are excluded from the scope of the order. Diamond sawblade cores with a Rockwell C hardness of less than 25 are excluded from the scope of the order. Diamond sawblades and/or diamond segment(s) with diamonds that predominantly have a mesh size number greater than 240 (such as 250 or 260) are excluded from the scope of the order. Merchandise subject to the order is typically imported under heading 8202.39.00.00 of the Harmonized Tariff Schedule of the United States (HTSUS). When packaged together as a set for retail sale with an item that is separately classified under headings 8202 to 8205 of the HTSUS, diamond sawblades or parts thereof may be imported under heading 8206.00.00.00 of the HTSUS. On October 11, 2011, the Department included the 6804.21.00.00 HTSUS classification number to the customs case reference file, pursuant to a request by U.S. Customs and Border Protection (CBP).[4] The tariff classification is provided for convenience and customs purposes; however, the written description of the scope of the order is dispositive.

Initiation of Changed Circumstances Review

Pursuant to section 751(b)(1) of the Act and 19 CFR 351.216(d), the Department will conduct a changed circumstances review upon receipt of a request from an interested party or receipt of information concerning an antidumping duty order which shows changed circumstances sufficient to warrant a review of the order. In the past, the Department has used changed circumstances reviews to address the applicability of cash deposit rates after there have been changes in the name or structure of a respondent, such as a merger or spinoff (''successor-in-interest,'' or ''successorship,'' determinations).[5] Based on the request from Chengdu Huifeng New Material Technology Co., Ltd., and in accordance with section 751(b)(1) of Act and 19 CFR 351.216(b), we are initiating a changed circumstances review to determine whether Chengdu Huifeng New Material Technology Co., Ltd. is the successor-in-interest to Chengdu Huifeng Diamond Tools Co., Ltd. for purposes of antidumping duty liability.

Preliminary Results of Changed Circumstances Review

If we conclude that an expedited action is warranted, we may combine the notices of initiation and preliminary results of a changed circumstances review under 19 CFR 351.221(c)(3)(ii). The Department has combined the notice of initiation and preliminary results in successor-in-interest cases when sufficient documentation has been provided supporting the request to make a preliminary determination.[6] In this instance, we have on the record the information necessary to make a preliminary finding. Thus, we find that expedited action is warranted and have combined the notices of initiation and preliminary results pursuant to 19 CFR 351.221(c)(3)(ii).

In making a successor-in-interest determination for purposes of antidumping duty liability, the Department examines several factors including, but not limited to, changes in management, production facilities, supplier relationships, and customer base.[7] While no single factor or combination of these factors will necessarily provide a dispositive indication of a successor-in-interest relationship, the Department will generally consider the new company to be the successor to the previous company if the new company's operations are not materially dissimilar to those of its predecessor.[8] Thus, if the evidence demonstrates that, with respect to the production and sales of the subject merchandise, the new company operates as essentially the same business entity as the former company, the Department will accord the new company the same antidumping treatment as its predecessor.[9]

In its CCR Request and Supplemental Response,[10] Chengdu Huifeng New Material Technology Co., Ltd. has provided evidence for us to preliminarily determine that it is the successor-in-interest to Chengdu Huifeng Diamond Tools Co., Ltd. Chengdu Huifeng New Material Technology Co., Ltd. states that its management, production facilities, and customer/supplier relationships have not changed as a result of changes to the legal status and name of the company.[11] Chengdu Huifeng New Material Technology Co., Ltd., provided documents showing changes to the legal status and name of the company.[12] Further, Chengdu Huifeng New Material Technology Co., Ltd., provided documents demonstrating that its production facilities and their location and domestic and overseas customers and suppliers were the same before and after the changes to the company's legal status and name.[13] Chengdu Huifeng New Material Technology Co., Ltd. also provided a list of members of the management team and supporting documentation indicating that Chengdu Huifeng Diamond Tools Co., Ltd.'s managers hold the same positions in Chengdu Huifeng New Material Technology Co., Ltd., as well as documentation showing nominal changes to the members of the board of directors made as a result of internal

[4] *See Diamond Sawblades and Parts Thereof from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review,* 76 FR 76128, 76130 (December 6, 2011).

[5] *See, e.g., Crystalline Silicon Photovoltaic Celols, Whether or Not Assembled Into Modules, from the People's Republic of China: Final Results of Changed Circumstances Review,* 81 FR 91909 (December 19, 2016).

[6] *See, e.g., Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China,* 81 FR 76561 (November 3, 2016).

[7] *See, e.g., Pressure Sensitive Plastic Tape from Italy: Preliminary Results of Antidumping Duty Changed Circumstances Review,* 75 FR 8925 (February 26, 2010), unchanged in *Pressure Sensitive Plastic Tape from Italy: Final Results of Antidumping Duty Changed Circumstances Review,* 75 FR 27706 (May 18, 2010); and *Brake Rotors from the People's Republic of China: Final Results of Changed Circumstances Antidumping Duty Administrative Review,* 70 FR 69941 (November 18, 2005) (*Brake Rotors*), citing *Brass Sheet and Strip from Canada; Final Results of Antidumping Duty Administrative Review,* 57 FR 20460 (May 13, 1992).

[8] *See, e.g., Brake Rotors.*

[9] *Id. See also, e.g., Notice of Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 77 FR 64953 (October 24, 2012), unchanged in *Final Results of Antidumping Duty Changed Circumstances Review: Certain Frozen Warmwater Shrimp from India,* 77 FR 73619 (December 11, 2012).

[10] *See* CCR Request and Chengdu Huifeng New Material Technology Co., Ltd.'s supplemental response dated October 10, 2017 (Supplemental Response).

[11] *Id.*

[12] *See, e.g.,* CCR Request at Exhibits 1, 2, 8, and 9.

[13] *See* CCR Request at Exhibits 1 through 6, and Supplemental Response at 1 and Exhibits S1–1, S1–2, S1–3, and S1–5.

shifts among existing management and board members.[14]

Based on record evidence, we preliminarily determine that Chengdu Huifeng New Material Technology Co., Ltd. is the successor-in-interest to Chengdu Huifeng Diamond Tools Co., Ltd. for purposes of antidumping duty liability because the changes to the legal status and name of the company resulted in no significant changes to management, production facilities, supplier relationships, or customers. As a result, we preliminarily determine that Chengdu Huifeng New Material Technology Co., Ltd. operates as essentially the same business entity as Chengdu Huifeng Diamond Tools Co., Ltd. Thus, we preliminarily determine that Chengdu Huifeng New Material Technology Co., Ltd. should receive the same antidumping duty cash deposit rate with respect to the subject merchandise as Chengdu Huifeng Diamond Tools Co., Ltd., its predecessor company.

If these preliminary results are adopted in our final results of this changed circumstances review, effective on the publication date of our final results, we will instruct CBP to suspend liquidation of entries of subject merchandise exported by Chengdu Huifeng New Material Technology Co., Ltd. at Chengdu Huifeng Diamond Tools Co., Ltd.'s cash deposit rate.

Public Comment

Interested parties may submit case briefs no later than 14 days after the publication of this notice.[15] Rebuttal briefs, which must be limited to issues raised in case briefs, may be filed not later than five days after the deadline for filing case briefs.[16] Parties who submit case briefs or rebuttal briefs in this changed circumstance review are requested to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Interested parties that wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS, within 14 days of publication of this notice.[17] The hearing request should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230 in a room to be determined. Parties will be notified of the time and date of any hearing, if requested.[18]

All submissions, with limited exceptions, must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* An electronically-filed document must be received successfully in its entirety by no later than 5:00 p.m. Eastern Time on the date the document is due.

Notifications to Interested Parties

Consistent with 19 CFR 351.216(e), we intend to issue the final results of this changed circumstances review no later than 270 days after the date on which this review was initiated, or within 45 days after the publication of the preliminary results if all parties in this review agree to our preliminary results. The final results will include the Department's analysis of issues raised in any written comments.

We are issuing and publishing this initiation and preliminary results notice in accordance with sections 751(b)(1) and 777(i)(1) of the Act, 19 CFR 351.216(b) and (d), and 19 CFR 351.221(c)(3).

Dated: November 1, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2017–24183 Filed 11–6–17; 8:45 am]

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[14] *See* CCR Request at Exhibit 3, 7, and 8, and Supplemental Response at Exhibit S1–4.

[15] *See* 19 CFR 351.309(c)(1)(ii). (''Any interested party may submit a 'case brief' within . . . 30 days after the date of publication of the preliminary results of {a changed circumstances} review, *unless the Secretary alters the time limit.* . . .'') (Emphasis added).

[16] *See* 19 CFR 351.309(d).

[17] *See* 19 CFR 351.310(c) (''Any interested party may request that the Secretary hold a public hearing on arguments to be raised in case or rebuttal briefs within 30 days after the date of publication of the . . . preliminary results of review, *unless the Secretary alters this time limit.* . . .'') (Emphasis added). *See also* 19 CFR 351.303 for general filing requirements.

[18] *See* 19 CFR 351.310.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–904]

Certain Activated Carbon From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2015–2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On May 5, 2017 the Department of Commerce (the Department) published the preliminary results of the 9th administrative review of the antidumping duty order on certain activated carbon from the People's Republic of China (PRC). We gave interested parties an opportunity to comment on the preliminary results. Based on our analysis of the comments received, we made changes to the margin calculations for these final results of the antidumping duty administrative review. The final weighted-average dumping margins are listed below in the ''Final Results of the Review'' section of this notice. The period of review (POR) is April 1, 2015, through March 31, 2016. The two mandatory respondents in this administrative review are Jacobi Carbons AB (Jacobi) and Datong Juqiang Activated Carbon Co. Ltd. (Datong Juqiang).

DATES: Applicable November 7, 2017.

FOR FURTHER INFORMATION CONTACT: Robert Palmer or John Anwesen, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–9068, or (202) 482–0131, respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the *Preliminary Results*[1] on May 5, 2017. For events subsequent to the *Preliminary Results,* see the Department's Issues and Decision

[1] *See Certain Activated Carbon from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2015–2016,* 82 FR 21195 (May 5, 2017), and accompanying Preliminary Decision Memorandum (*Preliminary Results*).

Memorandum.[2] On July 24, 2017,[3] in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (Act), the Department extended the deadline for issuing the final results by 60 days until November 1, 2017.

Scope of the Order

The merchandise subject to the *Order*[4] is certain activated carbon. The products are currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) subheading 3802.1000. Although the HTSUS subheading is provided for convenience and customs purposes, the written description of the scope of the order remains dispositive.[5]

Analysis of Comments Received

In the Issues and Decision Memorandum, we addressed all issues raised in parties' case and rebuttal briefs. In Appendix I to this notice, we provided a list of the issues raised by parties. The Issues and Decision Memorandum is a public document and is on file in the Central Records Unit (CRU), Room B8024 of the main Department of Commerce building, as well as electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and it is available to all parties in the CRU. In addition, parties can directly access a complete version of the Issues and Decision Memorandum on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Verification

Pursuant to section 782(i) of the Act, and 19 CFR 351.307(b)(iv), from May 9–23, 2017, we conducted verification of the questionnaire responses of Datong Juqiang and Jacobi.[6]

Changes Since the Preliminary Results

Based on our review of the record and comments received from interested parties regarding our *Preliminary Results,* we made certain revisions to the margin calculations for Jacobi, Datong Juqiang, and the non-examined, separate rate respondents.[7] Further, the Issues and Decision Memorandum contains descriptions of these revisions.[8]

Final Determination of No Shipments

In the *Preliminary Results,* the Department preliminarily determined that Calgon Carbon (Tianjin) Co., Ltd., Sinoacarbon International Trading Co., Ltd., and Shanxi Dapu International Trade Co., Ltd. had no shipments during the period of review (POR).[9] We received no information to contradict this determination. Therefore, the Department continues to determine that Calgon Carbon (Tianjin) Co., Ltd., Sinoacarbon International Trading Co., Ltd., and Shanxi Dapu International Trade Co., Ltd. had no shipments of subject merchandise during the POR, and will issue appropriate liquidation instructions that are consistent with our ''automatic assessment'' clarification, for these final results.[10]

Separate Rate Respondents

In our *Preliminary Results,* we determined that Jacobi, Datong Juqiang, and 13 other companies demonstrated their eligibility for separate rates.[11] We have received no comments or argument since the issuance of the *Preliminary Results* that provides a basis for reconsideration of these determinations. Therefore, for these final results, we continue to find that the 13 companies listed in the table in the ''Final Results'' section of this notice are eligible for a separate rate.

Rate for Non-Examined Separate Rate Respondents

The statute and the Department's regulations do not address the establishment of a rate to be assigned to respondents not selected for individual examination when the Department limits its examination of companies subject to the administrative review pursuant to section 777A(c)(2)(B) of the Act. Generally, the Department looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for respondents not individually examined in an administrative review. Section 735(c)(5)(A) of the Act articulates a preference for not calculating an all-others rate using rates which are zero, *de minimis,* or based entirely on facts available.[12] Accordingly, the Department's usual practice has been to determine the dumping margin for companies not individually examined by averaging the weighted-average dumping margins for the individually examined respondents, excluding rates that are zero, de minimis, or based entirely on facts available.[13]

In the *Preliminary Results,*[14] the Department calculated rates for Datong Juqiang and Jacobi that were not zero, *de minimis,* or based entirely on facts

[2] *See* Memorandum,''Certain Activated Carbon from the People's Republic of China: Issues and Decision Memorandum for the Final Results of the Ninth Antidumping Duty Administrative Review,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* Memorandum, ''Activated Carbon from the People's Republic of China: Extension of Deadline for Final Results of 2015–2016 Antidumping Duty Administrative Review,'' dated June 13, 2016.

[4] *See Notice of Antidumping Duty Order: Certain Activated Carbon from the People's Republic of China,* 72 FR 20988 (April 27, 2007) (*Order*).

[5] *See* Issues and Decision Memorandum for a complete description of the scope of the *Order.*

[6] *See* Memorandum, ''Verification of the Questionnaire Responses of Datong Juqiang Activated Carbon Co., Ltd. in the Antidumping Administrative Review of Certain Activated Carbon from the People's Republic of China,'' dated June 30, 2017; Memorandum, ''Verification of Questionnaire Responses of Datong Juqiang Activated Carbon Co., Ltd.'s Supplier in the Antidumping Administrative Review of Certain Activated Carbon from the People's Republic of China,'' dated June 30, 2017; Memorandum, ''Verification of the Questionnaire Responses of Ningxia Huahui Activated Carbon Co., Ltd. in the Antidumping Administrative Review of Certain activated Carbon form the People's Republic of China,'' dated June 30, 2017; Memorandum, ''Verification of the Questionnaire Responses of Ningxia Guanghua Activated Carbon Co., Ltd. in the Antidumping Administrative Review of Certain Activated Carbon from the People's Republic of China,'' dated June 30, 2017; and Memorandum, ''Verification of the Questionnaire Responses of Jacobi Carbons Industry (Tianjin) Company Limited in the Antidumping Administrative Review of Certain Activated Carbon from the People's Republic of China,'' dated June 30, 2017.

[7] *See* Memoranda, ''Antidumping Duty Administrative Review of Certain Activated Carbon from the People's Republic of China: Final Determination Calculation Memorandum for Jacobi Carbons AB,'' and ''Antidumping Duty Administrative Review of Certain Activated Carbon the People's Republic of China: Final Determination Calculation Memorandum for Datong Juqiang Activated Carbon Co., Ltd., '' dated concurrently with this memorandum.

[8] *See* Issues and Decisions Memorandum at 4–5 for a summary of these revisions.

[9] *See Preliminary Results* at 21195.

[10] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 4, 2011) (*Assessment Practice Refinement*).

[11] *See Preliminary Results,* 82 FR 21196, and accompanying Preliminary Decision Memorandum at 7–9.

[12] *See Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews and Rescission of Reviews in Part,* 73 FR 52823, 52824 (September 11, 2008), and accompanying Issues and Decision Memorandum(IDM) at Comment 16.

[13] *See, e.g., Preliminary Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 71 FR 77373, 77377 (December 26, 2006), unchanged in *Final Determination of Sales at Less Than Fair Value and Partial Affirmative Determination of Critical Circumstances: Certain Polyester Staple Fiber from the People's Republic of China,* 72 FR 19690 (April 19, 2007).

[14] *See* Preliminary Decision Memorandum at 10–11.

available. However, for these final results, the calculated rate for Datong Juqiang is zero, and the calculated rate for Jacobi continues to be above *de minimis.* Therefore, the Department has assigned to the companies that have not been individually examined, but have demonstrated their eligibility for a separate rate, Jacobi's calculated rate for these final results.

Final Results of the Review

For companies subject to this review, which established their eligibility for a separate rate, the Department determines that the following weighted-average dumping margins exist for the POR from April 1, 2015, through March 31, 2016:

Exporter	Weighted-average dumping margin (USD/kg) [15]
Jacobi Carbons AB [16]	0.22
Datong Juqiang Activated Carbon Co., Ltd.	0.00
Beijing Pacific Activated Carbon Products Co., Ltd.	0.22
Carbon Activated Tianjin Co., Ltd.	0.22
Datong Municipal Yunguang Activated Carbon Co., Ltd.	0.22
Jilin Bright Future Chemicals Company, Ltd.	0.22
Ningxia Guanghua Cherishmet Activated Carbon Co., Ltd.	0.22
Ningxia Huahui Activated Carbon Co., Ltd.	0.22
Ningxia Mineral and Chemical Limited	0.22
Shanxi Industry Technology Trading Co., Ltd.	0.22
Shanxi Sincere Industrial Co., Ltd.	0.22
Shanxi Tianxi Purification Filter Co., Ltd.	0.22
Tancarb Activated Carbon Co., Ltd.	0.22
Tianjin Channel Filters Co., Ltd.	0.22
Tianjin Maijin Industries Co., Ltd.	0.22

In the *Preliminary Results,* the Department found that 186 companies for which a review was requested did not establish eligibility for a separate rate because they did not file a separate rate application or a separate rate certification, as appropriate. No interested party commented on the Department's preliminary determination with respect to these 186 companies. Therefore, for these final results we determine these companies, listed in Appendix II of this notice, to be part of the PRC-wide entity. Because no party requested a review of the PRC-wide entity, and the Department no longer considers the PRC-wide entity as an exporter conditionally subject to administrative reviews,[17] we did not conduct a review of the PRC-wide entity. Thus, the weighted-average dumping margin for the PRC-wide entity (*i.e.,* 2.42 USD/kg) [18] is not subject to change as a result of this review.

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b), the Department has determined, and U.S Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. The Department intends to issue assessment instructions to CBP 15 days after the publication date of these final results of review.

For each individually-examined respondent in this review which has a final weighted-average dumping margin that is not zero or *de minimis* (*i.e.,* less than 0.5 percent), we will calculate importer- (or customer-) specific per-unit duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's (or customer's) examined sales to the total sales quantity associated with those sales, in accordance with 19 CFR 351.212(b)(1).[19] The Department will also calculate (estimated) *ad valorem* importer-specific assessment rates with which to assess whether the per-unit assessment rates are *de minimis.* Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer- (or customer-) specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[20]

For the respondents which were not selected for individual examination in this administrative review and which qualified for a separate rate, the assessment rate will be equal to the rate assigned to them for the final results (*i.e.* the 0.22 USD/kg rate for Jacobi).

For the companies identified in Appendix II as part of the PRC-wide entity, we will instruct CBP to apply a per-unit assessment rate of 2.42 USD/kg to all entries of subject merchandise during the POR which were produced or exported by those companies.

Pursuant to a refinement in the Department's non-market economy practice, for sales that were not reported in the U.S. sales data submitted by companies individually examined during this review, the Department will instruct CBP to liquidate entries associated with those sales at the rate for the PRC-wide entity. Furthermore, where the Department found that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's cash deposit rate) will be liquidated at the rate for the PRC-wide entity.[21]

Cash Deposit Requirements

The following per-unit cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For Jacobi, Datong Juqiang, and the non-examined, separate rate respondents, the cash deposit rate will be equal to their weighted-average dumping margins established in the final results of this review; (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding in which they were reviewed; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate,

[15] In the second administrative review of the *Order,* the Department determined that it would calculate per-unit weighted-average dumping margins and assessment rates for all future reviews. *See Certain Activated Carbon from the People's Republic of China: Final Results and Partial Rescission of Second Antidumping Duty Administrative Review,* 75 FR 70208, 70211 (November 17, 2010) (*AR2 Carbon*), and accompanying IDM at Comment 3.

[16] In the third administrative review of the *Order,* the Department found that Jacobi Carbons AB, Tianjin Jacobi International Trading Co. Ltd., and Jacobi Carbons Industry (Tianjin) are a single entity and, because there were no facts presented on the record of this review which would call into question our prior finding, we continue to treat these companies as part of a single entity for this administrative review, pursuant to sections 771(33)(E), (F), and (G) of the Act and 19 CFR 351.401(f). *See Certain Activated Carbon from the People's Republic of China: Final Results and Partial Rescission of Third Antidumping Duty Administrative Review,* 76 FR 67142, 67145 n.25 (October 31, 2011); *See also* Preliminary Decision Memorandum at n.8.

[17] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65969–70 (November 4, 2013).

[18] *See, e.g., Certain Activated Carbon from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2012–2013,* 79 FR 70163, 70165 (November 25, 2014).

[19] *See AR2 Carbon,* and accompanying IDM at Comment 3.

[20] *See* 19 CFR 351.106(c)(2).

[21] For a full discussion of this practice, *see Assessment Practice Refinement,* 76 FR at 65694.

the cash deposit rate will be equal to the weighted-average dumping margin for the PRC-wide entity (*i.e.,* 2.42 USD/kg); and (4) for all non-PRC exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These per-unit cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Notification to Importers Regarding the Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of double antidumping duties.

Notification Regarding 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(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these final results of administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: November 1, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Issues and Decision Memorandum

Summary

Background

Scope of the Order

Changes Since the *Preliminary Results*

Discussion of the Issues

- Comment 1: Value Added Tax and Entered Value
- Comment 2: Inflator Calculation
- Comment 3: Anthracite Coal Surrogate Value
- Comment 4: Coal Tar Surrogate Value
- Comment 5: Carbonized Material Surrogate Value
- Comment 6: Hydrochloric Acid Surrogate Value
- Comment 7: Whether To Use IndustrySpecific Thai Labor Data
- Comment 8: Whether To Continue to Use the Thai Financial Statements
- Comment 9: Whether To Apply Partial Adverse Facts Available for Datong Juqiang's Wood Input
- Comment 10: Whether To Revise Ningxia Guanghua Activated Carbon Co., Ltd.'s Water Consumption
- Comment 11: Jacobi Tianjin New Packing Variable
- Comment 12: Whether To Adjust Jacobi Tianjin's Packing Variance
- Comment 13: Jacobi Tianjin's Fiberboard Consumption
- Comment 14: Whether To Apply Adverse Facts Available to Jacobi Tianjin's Factors of Production Allocation

Recommendation

Appendix II

Companies Not Eligible for a Separate Rate and To Be Treated as Part of PRC-Wide Entity

Company

1. AmeriAsia Advanced Activated Carbon Products Co., Ltd.
2. Anhui Handfull International Trading (Group) Co., Ltd.
3. Anhui Hengyuan Trade Co. Ltd.
4. Anyang Sino-Shon International Trading Co., Ltd.
5. Baoding Activated Carbon Factory
6. Beijing Broad Activated Carbon Co., Ltd.
7. Beijing Embrace Technology Co., Ltd.
8. Beijing Haijian Jiechang Environmental Protection Chemicals
9. Beijing Hibridge Trading Co., Ltd,
10. Bengbu Jiutong Trade Co, Ltd.
11. Changji Hongke Activated Carbon Co., Ltd.
12. Chengde Jiayu Activated Carbon Factory
13. China National Building Materials and Equipment Import and Export Corp.
14. China National Nuclear General Company Ningxia Activated Carbon Factory
15. China Nuclear Ningxia Activated Carbon Plant
16. China SDIC International Trade Co., Ltd.
17. Chongqing Feiyang Active Carbon Manufacture Co., Ltd.
18. Da Neng Zheng Da Activated Carbon Co., Ltd.
19. Datong Carbon Corporation
20. Datong Changtai Activated Carbon Co., Ltd.
21. Datong City Zuoyun County Activated Carbon Co., Ltd.
22. Datong Fenghua Activated Carbon
23. Datong Forward Activated Carbon Co., Ltd.
24. Datong Fuping Activated Carbon Co. Ltd.
25. Datong Guanghua Activated Co., Ltd.
26. Datong Hongtai Activated Carbon Co., Ltd.
27. Datong Huanqing Activated Carbon Co., Ltd.
28. Datong Huaxin Activated Carbon
29. Datong Huibao Active Carbon Co., Ltd.
30. Datong Huibao Activated Carbon Co., Ltd.
31. Datong Huiyuan Cooperative Activated Carbon Plant
32. Datong Kaneng Carbon Co. Ltd.
33. Datong Locomotive Coal & Chemicals Co., Ltd.
34. Datong Tianzhao Activated Carbon Co., Ltd.
35. DaTong Tri-Star & Power Carbon Plant
36. Datong Weidu Activated Carbon Co., Ltd.
37. Datong Xuanyang Activated Carbon Co., Ltd.
38. Datong Zuoyun Biyun Activated Carbon Co., Ltd.
39. Datong Zuoyun Fu Ping Activated Carbon Co., Ltd.
40. Dezhou Jiayu Activated Carbon Factory
41. Dongguan Baofu Activated Carbon
42. Dongguan SYS Hitek Co., Ltd.
43. Dushanzi Chemical Factory
44. Fu Yuan Activated Carbon Co., Ltd.
45. Fujian Jianyang Carbon Plant
46. Fujian Nanping Yuanli Activated Carbon Co., Ltd.
47. Fujian Xinsen Carbon Co., Ltd.
48. Fujian Yuanli Active Carbon Co., Ltd.
49. Fujian Active Carbon Industrial Co., Ltd.
50. Fujian Yuanli Active Carbon Industrial Co., Ltd.
51. Fujian Zhixing Activated Carbon Co., Ltd.
52. Fuzhou Taking Chemical
53. Fuzhou Yihuan Carbon
54. Great Bright Industrial
55. Hangzhou Hengxing Activated Carbon
56. Hangzhou Hengxing Activated Carbon Co., Ltd.
57. Hangzhou Linan Tianbo Material (HSLATB)
58. Hangzhou Nature Technology
59. Hangzhou Waterland Environmental Technologies Co., Ltd.
60. Hebei Foreign Trade and Advertising Corporation
61. Hebei Luna Trading Co., Ltd.
62. Hebei Shenglun Import & Export Group Company
63. Hegongye Ninxia Activated Carbon Factory
64. Heilongjiang Provincial Hechang Import & Export Co., Ltd.
65. Hongke Activated Carbon Co., Ltd.
66. Huaibei Environment Protection Material Plant
67. Huairen Huanyu Purification Material Co., Ltd.
68. Huairen Jinbei Chemical Co., Ltd.
69. Huaiyushan Activated Carbon Group
70. Huatai Activated Carbon
71. Huzhou Zhonglin Activated Carbon
72. Inner Mongolia Taixi Coal Chemical Industry Limited Company
73. Itigi Corp. Ltd.
74. J&D Activated Carbon Filter Co. Ltd.
75. Jiangle County Xinhua Activated Carbon Co., Ltd.
76. Jiangsu Taixing Yixin Activated Carbon Technology Co., Ltd.

77. Jiangxi Hanson Import Export Co.
78. Jiangxi Huaiyushan Activated Carbon
79. Jiangxi Huaiyushan Activated Carbon Group Co.
80. Jiangxi Huaiyushan Suntar Active Carbon Co., Ltd.
81. Jiangxi Jinma Carbon
82. Jiangxi Yuanli Huaiyushan Active Carbon Co., Ltd.
83. Jianou Zhixing Activated Carbon
84. Jiaocheng Xinxin Purification Material Co., Ltd.
85. Jilin Province Bright Future Industry and Commerce Co., Ltd.
86. Jing Mao (Dongguan) Activated Carbon Co., Ltd.
87. Kaihua Xingda Chemical Co., Ltd.
88. Kemflo (Nanjing) Environmental Tech
89. Keyun Shipping (Tianjin) Agency Co., Ltd.
90. Kunshan Actview Carbon Technology Co., Ltd.
91. Langfang Winfield Filtration Co.
92. Link Shipping Limited
93. Longyan Wanan Activated Carbon
94. Meadwestvaco (China) Holding Co., Ltd.
95. Mindong Lianyi Group
96. Nanjing Mulinsen Charcoal
97. Nantong Ameriasia Advanoed Activated Carbon Product Co., Ltd.
98. Ningxia Baiyun Carbon Co., Ltd.
99. Ningxia Baota Activated Carbon Co., Ltd.
100. Ningxia Baota Active Carbon Plant
101. Ningxia Guanghua A/C Co., Ltd.
102. Ningxia Blue-White-Black Activated Carbon (BWB)
103. Ningxia Fengyuan Activated Carbon Co., Ltd.
104. Ningxia Guanghua Chemical Activated Carbon Co., Ltd.
105. Ningxia Haoqing Activated Carbon Co., Ltd.
106. Ningxia Henghui Activated Carbon
107. Ningxia Honghua Carbon Industrial Corporation
108. Ningxia Huinong Xingsheng Activated Carbon Co., Ltd.
109. Ningxia Jirui Activated Carbon
110. Ningxia Lingzhou Foreign Trade Co., Ltd.
111. Ningxia Luyuangheng Activated Carbon Co., Ltd.
112. Ningxia Pingluo County Yaofu Activated Carbon Plant
113. Ningxia Pingluo Xuanzhong Activated Carbon Co., Ltd.
114. Ningxia Pingluo Yaofu Activated Carbon Factory
115. Ningxia Taixi Activated Carbon
116. Ningxia Tianfu Activated Carbon Co., Ltd.
117. Ninxia Tongfu Coking Co., Ltd.
118. Ningxia Weining Active Carbon Co., Ltd.
119. Ningxia Xingsheng Coal and Active Carbon Co., Ltd.
120. Ningxia Xingsheng Coke & Activated Carbon Co., Ltd.
121. Ningxia Yinchuan Lanqiya Activated Carbon Co., Ltd.
122. Ningxia Yirong Alloy Iron Co., Ltd.
123. Ningxia Zhengyuan Activated
124. Nuclear Ningxia Activated Carbon Co., Ltd.
125. OEC Logistic Qingdao Co., Ltd.
126. OEC Logistics Co., Ltd. (Tianjin)
127. Panshan Import and Export Corporation
128. Pingluo Xuanzhong Activated Carbon Co., Ltd.
129. Pingluo Yu Yang Activated Carbon Co., Ltd.
130. Shanghai Activated Carbon Co., Ltd.
131. Shanghai Astronautical Science Technology Development Corporation
132. Shanghai Coking and Chemical Corporation
133. Shanghai Goldenbridge International
134. Shanghai Jiayu International Trading (DezhouJiayu and Chengde Jiayu)
135. Shanghai Jinhu Activated Carbon (Xingan Shenxin and Jiangle Xinhua)
136. Shanghai Light Industry and Textile Import & Export Co., Ltd.
137. Shanghai Mebao Activated Carbon
138. Shanghai Xingchang Activated Carbon
139. Shanxi Blue Sky Purification Material Co., Ltd.
140. Shanxi Carbon Industry Co., Ltd.
141. Shanxi DMD Corporation
142. Shanxi Newtime Co., Ltd.
143. Shanxi Qixian Foreign Trade Corporation
144. Shanxi Qixian Hongkai Active Carbon Goods
145. Shanxi Supply and Marketing Cooperative
146. Shanxi Tianli Ruihai Enterprise Co.
147. Shanxi U Rely International Trade
148. Shanxi Xiaoyi Huanyu Chemicals Co., Ltd.
149. Shanxi Xinhua Activated Carbon Co., Ltd.
150. Shanxi Xinhua Chemical Co., Ltd. (formerly Shanxi Xinhua Chemical Factory)
151. Shanxi Xinhua Protective Equipment
152. Shanxi Xinshidai Import Export Co., Ltd.
153. Shanxi Xuanzhong Chemical Industry Co., Ltd.
154. Shanxi Zuoyun Yunpeng Coal Chemistry
155. Shenzhen Sihaiweilong Technology Co.
156. Shijiazhuang Xinshuang Trade Co., Ltd.
157. Sincere Carbon Industrial Co. Ltd.
158. Taining Jinhu Carbon
159. Tangshan Solid Carbon Co., Ltd.
160. Tianchang (Tianjin) Activated Carbon
161. Tianjin Century Promote International Trade Co., Ltd.
162. Taiyuan Hengxinda Trade Co., Ltd,
163. Tonghua Bright Future Activated Carbon Plant
164. Tonghua Xinpeng Activated Carbon Factory
165. Top One International Trading Co., Ltd.
166. Triple Eagle Container Line
167. Uniclear New-Material Co., Ltd.
168. United Manufacturing International (Beijing) Ltd.
169. Valqua Seal Products (Shanghai) Co.
170. VitaPac (HK) Industrial Ltd.
171. Wellink Chemical Industry
172. Xi Li Activated Carbon Co., Ltd.
173. Xi'an Shuntong International Trade & Industrials Co., Ltd.
174. Xiamen All Carbon Corporation
175. Xingan County Shenxin Activated Carbon Factory
176. Xinhua Chemical Company Ltd.
177. Xuanzhong Chemical Industry
178. Yangyuan Hengchang Active Carbon
179. Yicheng Logistics
180. Yinchuan Lanqiya Activated Carbon Co., Ltd.
181. Zhejiang Topc Chemical Industry Co.
182. Zhejiang Quizhou Zhongsen Carbon
183. Zhejiang Xingda Activated Carbon Co., Ltd.
184. Zhejiang Yun He Tang Co., Ltd.
185. Zhuxi Activated Carbon
186. Zuoyun Bright Future Activated Carbon Plant

[FR Doc. 2017–24184 Filed 11–6–17; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–932]

Certain Steel Threaded Rod From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2015–2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On May 5, 2017, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on certain steel threaded rod from the People's Republic of China (PRC) for the period of review (POR), April 1, 2015, through March 31, 2016. For the final results of this review, the Department finds that Jiaxing Brother Fastener Co., Ltd., RMB Fasteners Ltd., and IFI & Morgan Ltd. (RMB/IFI) had a single shipment, and Tianjin Port Free Trade Zone and Star Pipe International Trade Co., Ltd. (Tianjin Star) is eligible for a separate rate.

DATES: Applicable November 7, 2017.

FOR FURTHER INFORMATION CONTACT: Courtney Canales or Matthew Renkey, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4997 or (202) 482–2312, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 5, 2017, the Department published the *Preliminary Results* of the antidumping duty order on certain steel threaded rod from the PRC.[1] On June 12,

[1] *See Certain Steel Threaded Rod from the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review, and Rescission of Antidumping Duty Administrative Review; 2014–2015,* 82 FR 21189 (May 5, 2017) (*Preliminary Results*) and accompanying Preliminary Decision Memorandum.

2017, the petitioner submitted case briefs.[2] On June 16, 2017 the Department released draft U.S. Customs and Border Protection (CBP) instructions.[3] On June 21, 2017, RMB/IFI and Tianjin Star submitted rebuttal briefs.[4] On September 1, 2017, the Department extended the deadline for the final results to November 1, 2017.[5]

We note that no party submitted comments on the Department's preliminary determination to treat Zhejiang New Oriental Fastener Co., Ltd. (New Oriental), Zhejiang Heiter Industries Co., Ltd. (Heiter Industries), and Zhejiang Heiter Mfg. & Trade Co. Ltd. (Heiter Mfg. as part of the PRC-wide entity. Therefore, for these final results, we continue to find that New Oriental, Heiter Industries, and Heiter Mfg. are part of the PRC-wide entity. We also note that no party submitted comments on the draft CBP instructions.

The Department conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The merchandise covered by the order includes steel threaded rod. The subject merchandise is currently classifiable under subheading 7318.15.5051, 7318.15.5056, 7318.15.5090, and 7318.15.2095 of the United States Harmonized Tariff Schedule (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the order, which is contained in the accompanying Issues and Decision Memorandum (I&D Memo), is dispositive.[6]

Analysis of Comments Received

We addressed all issues raised in the case and rebuttal briefs by parties in this review in the I&D Memo dated concurrently with, and hereby adopted by, this notice. A list of the issues which parties raised is attached in the Appendix to this notice. The I&D Memo is a public document and is on file in the Central Records Unit (CRU), Room B8024 of the main Department of Commerce building, as well as electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov* and in the CRU. In addition, a complete version of the I&D Memo can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed I&D Memo and the electronic versions of the I&D Memo are identical in content.

Final Results

The final weighted-average dumping margins are as follows:

Exporter/producer	Weighted-average dumping margin (percent)
RMB Fasteners Ltd. and IFI & Morgan Ltd. (RMB/IFI)	0.00
Tianjin Port Free Trade Zone Tianjin Star International Trade Co., Ltd	5.40

Because no party requested a review of the PRC-wide entity, and the Department no longer considers the PRC-wide entity as an exporter conditionally subject to administrative reviews,[7] we did not conduct a review of the PRC-wide entity. Thus, the weighted-average dumping margin for the PRC-wide entity (*i.e.,* 206.00 percent)[8] is not subject to change as a result of this review.

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act, and 19 CFR 351.212(b), the Department has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of this administrative review.

Where the respondent reported reliable entered values, we calculated importer (or customer)-specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer).[9] Where the Department calculated a weighted-average dumping margin by dividing the total amount of dumping for reviewed sales to that party by the total sales quantity associated with those transactions, the Department will direct CBP to assess importer-specific assessment rates based on the resulting per-unit rates.[10] Where an importer- (or customer-) specific *ad valorem* or per-unit rate is greater than *de minimis,* the Department will instruct CBP to collect the appropriate duties at the time of liquidation.[11] Where an importer- (or customer-) specific *ad valorem* or per-unit rate is zero or *de minimis,* the Department will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[12]

Pursuant to the Department's assessment practice, for entries that were not reported in the U.S. sales data submitted by companies individually examined during this review, the Department will instruct CBP to liquidate such entries at the rate for the PRC-wide entity.[13]

For the one suspended AD/CVD entry for which RMB/IFI had knowledge of sale in the United States, the Department will direct CBP to liquidate that entry without regard to antidumping duties. For all other entries claiming RMB/IFI as the exporter or producer, the Department will direct CBP to liquidate such entries and to assess antidumping duties pursuant to the *Reseller Policy, i.e.,* at the rate for the PRC-wide entity. For all suspended AD/CVD entries by Tianjin Star, the Department will direct CBP to liquidate such entries and to assess antidumping duties at the rate identified in the Final Results section above.

[2] *See* the petitioner's June 12, 2017 submission.

[3] *See* Memo to the File, from Courtney Canales, International Trade Compliance Analyst, ''Certain Steel Threaded Rod from the People's Republic of China: Cash Deposit and Liquidation Instructions for the Preliminary Results,'' dated June 16, 2017.

[4] *See* RMB/IFI's June 21, 2017 submission; Tianjin Star's June 21, 2017 submission.

[5] *See* Memorandum to Scot T. Fullerton, Director, Office VI, from Courtney Canales, International Trade Compliance Analyst, ''Certain Steel Threaded Rod from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated September 1, 2017.

[6] For a full description of the scope of the order, *see* Memorandum from James Maeder Senior Director, performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, ''Certain Steel Threaded Rod from the People's Republic of China: Issues and Decision Memorandum for the Final Results of the Seventh Administrative Review'' (November 1, 2017) (I&D Memo).

[7] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65969–70 (November 4, 2013).

[8] The rate for the PRC-wide entity was originally set in the original investigation, *see Certain Steel Threaded Rod from the People's Republic of China: Final Determination of Sales at Less than Fair Value,* 74 FR 8907 (February 27, 2009). This rate has been applied in each subsequent administrative review in which there was a party being considered as part of the PRC-wide entity.

[9] *See* 19 CFR 351.212(b)(1).

[10] *Id.*

[11] *Id.*

[12] *See* 19 CFR 351.106(c)(2).

[13] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011) (*Reseller Policy*).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be the rate established in the final results of review (except, if the rate is zero or *de minimis, i.e.,* less than 0.5 percent, a zero cash deposit rate will be required for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-Wide rate of 206 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporters that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

Normally, the Department discloses to interested parties the calculations performed in connection with the final results within five days of its public announcement, or if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). However, because the Department has not calculated a weighted-average dumping margin for either of the mandatory respondents, there are no calculations to disclose.

Notification to Importers

This notice also 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 Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

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 the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a violation subject to sanction.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h) and 351.221(b)(5).

Dated; November 1, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties for the Assistant Secretary for Enforcement and Compliance.

Appendix

Issues and Decision Memorandum

I. Summary
II. Scope
III. Background
IV. Discussion of the Issues
  Comment 1: Circumvention Concerns and Treatment of RMB/IFI
  Comment 2: Proper Classification and Collection of Antidumping Duties on Tianjin Star's Entries
V. Conclusion

[FR Doc. 2017–24178 Filed 11–6–17; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–836, A–580–891, A–469–816, A–489–831, A–412–826]

Carbon and Alloy Steel Wire Rod From Italy, the Republic of Korea, Spain, Turkey, and the United Kingdom: Postponement of Final Determinations of Less-Than-Fair-Value Investigation and Extension of Provisional Measures

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) is postponing the deadline for issuing the final determinations in the less-than-fair-value (LTFV) investigations of carbon and alloy steel wire rod (wire rod) from Italy, the Republic of Korea (Korea), Spain, Turkey, and the United Kingdom (the UK) until no later than March 15, 2018, and is extending the provisional measures from a four-month period to a period of not more than six months. As the deadline for the final determinations of the countervailing duty (CVD) investigations of wire rod from Italy and Turkey have been aligned with the deadline for the final determinations of the LTFV investigations, the final CVD determinations shall also be postponed.

DATES: Applicable November 7, 2017.

FOR FURTHER INFORMATION CONTACT: Victoria Cho (Italy) at 202–482–5075, Lingjun Wang (Korea) at 202–482–2316, Davina Freidmann (Spain) at 202–482–0698, Ryan Mullen (Turkey) at 202–482–5260, or Alice Maldonado (the UK) at 202–482–4682, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On April 26, 2017, the Department of Commerce (the Department) published the notice of initiation of the LTFV investigations of imports of wire rod from Italy, Korea, Spain, Turkey, and the UK in the **Federal Register**.[1] The period of investigations is January 1, 2016, through December 31, 2016, for the CVD investigations on imports from Italy and Turkey as well as for the LTFV investigations on imports from Italy, Korea, Spain, Turkey, and the UK. On September 5, 2017, and October 31, 2017, respectively, the Department published its preliminary determinations in the CVD and LTFV investigations.[2] On September 18, 2017,

[1] *See Carbon and Alloy Steel Wire Rod from Belarus, Italy, the Republic of Korea, the Russian Federation, South Africa, Spain, the Republic of Turkey, Ukraine, United Arab Emirates, and United Kingdom: Initiation of Less-Than-Fair-Value Investigations,* 82 FR 19207 (April 26, 2017) (*LTFV Initiation Notice*).

[2] *See Carbon and Alloy Steel Wire Rod from Italy: Preliminary Affirmative Countervailing Duty Determination,* 82 FR 41931 (September 5, 2017); *Carbon and Alloy Steel Wire Rod from the Republic of Turkey: Preliminary Affirmative Countervailing Duty Determination and Preliminary Affirmative Critical Circumstances Determination, in Part,* 82 FR 41929 (September 5, 2017) (collectively *CVD Preliminary Determinations*). *See also, Carbon and Alloy Steel Wire Rod from Italy: Preliminary Affirmative Determination of Sales at Less Than Fair Value,* 82 FR 50381 (October 31, 2017); *Carbon and Alloy Steel Wire Rod from the Republic of Korea: Preliminary Affirmative Determination of Sales at Less Than Fair Value, and Preliminary Negative Determination of Critical Circumstance,* 82 FR 50386 (October 31, 2017); *Carbon and Alloy Steel Wire Rod from Spain: Preliminary Affirmative Determination of Sales at Less Than Fair Value and Preliminary Determination of Critical Circumstance, in Part,* 82 FR 50389 (October 31, 2017); *Carbon and Alloy Steel Wire Rod from Turkey: Preliminary Affirmative Determination of*

Continued

the Department aligned the final deadline for the CVD investigations with the final determination of the LTFV investigations.[3]

Postponement of Final LTFV Determinations and Aligned Final CVD Determinations

Section 735(a)(2) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.210(b)(2) provide that a final determination may be postponed until not later than 135 days after the date of the publication of the preliminary determination if, in the event of an affirmative preliminary determination, a request for such postponement is made by the exporters or producers who account for a significant proportion of exports of the subject merchandise, or in the event of a negative preliminary determination, a request for such postponement is made by the petitioners. Further, 19 CFR 351.210(e)(2) requires that such postponement requests by exporters be accompanied by a request for extension of provisional measures from a four-month period to a period of not more than six months, in accordance with section 733(d) of the Act.

Between September 14, 2017, and October 10, 2017, Ferriere Nord S.p.A. (Ferriere Nord); POSCO; Global Steel Wire SA (GSW), CELSA Atlantic SA (CELSA Atlantic) and Compania Espanola de Laminacion (CELSA Barcelona) (collectively, CELSA); Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi A.S. (Habas); Icdas Celik Enerji Tersane ve Ulasim Sanayi A.S. (Icdas); and British Steel Limited (British Steel), mandatory respondents in these investigations, requested that the Department fully extend the deadline for the final LTFV determinations, and extend the application of the provisional measures from a four-month period to a period of not more than six months.[4]

On October 27, 2017, Gerdau Ameristeel US Inc., Nucor Corporation, Keystone Consolidated Industries, Inc., and Charter Steel (collectively, the Petitioners), requested that the Department grant the requests of the respondents in these investigations and fully extend the deadline for the final LTFV determinations.[5]

In accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii), because: (1) The preliminary determination was affirmative; (2) the request was made by the exporters and producers who account for a significant proportion of exports of the subject merchandise; and (3) no compelling reasons for denial exist, the Department is postponing the final determinations until no later than 135 days after the date of the publication of of the *LTFV Preliminary Determinations,* and extend the provisional measures from a four-month period to a period of not more than six months. Because the CVD investigations covering Italy and Turkey are aligned with the LTFV investigations as noted above, the Department will issue its final determinations in the CVD and LTFV investigations no later than March 15, 2018.

This notice is issued and published pursuant to 19 CFR 351.210(g).

Dated: November 1, 2017.

Gary Taverman,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2017–24175 Filed 11–6–17; 8:45 am]

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Sales at Less Than Fair Value, and Preliminary Negative Determination of Critical Circumstance, 82 FR 50377 (October 31, 2017); and *Carbon and Alloy Steel Wire Rod from the United Kingdom: Preliminary Affirmative Determination of Sales at Less Than Fair Value and Preliminary Determination of Critical Circumstance,* 82 FR 50394 (October 31, 2017).

[3] *See Carbon and Alloy Steel Wire Rod from Italy and Turkey: Alignment of Final Countervailing Duty Determinations With Final Antidumping Duty* Determinations, 82 FR 43516 (September 18, 2017).

[4] *See* Letters from Ferriere Nord, POSCO, CELSA, Habas, Icdas, and British Steel dated September 19, 2017, October 10, 2017, October 10, 2017, September 28, 2017, September 14, 2017, and September 18, 2017, respectively.

[5] *See* Letters from the Petitioners dated October 27.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

United States Global Change Research Program (USGCRP) To Announce the Availability of a Draft Fourth National Climate Assessment Report for Public Comment

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of availability for public comment.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) is publishing this notice on behalf of the United States Global Change Research Program (USGCRP) to announce the availability of a draft Fourth National Climate Assessment report for public comment. Following revision and further review (including by the National Academy of Sciences), a revised draft will undergo final Federal interagency clearance.

DATES: Comments on this draft scientific assessment must be received by January 31, 2018.

ADDRESSES: The draft Fourth National Climate Assessment can be accessed via the USGCRP Open Notices page (*http://www.globalchange.gov/notices*) or directly at the USGCRP Review and Comment System (*https://review.globalchange.gov/*). Registration details can be found on the review site home page, and review instructions are located on the dedicated report page. Comments may be submitted only via this online mechanism.

All comments received through this process will be considered by the relevant chapter authors without knowledge of the commenters' identities. When the final assessment is issued, the comments and the commenters' names, along with the authors' responses, will become part of the public record and made available on *http://www.globalchange.gov.* No information submitted by a commenter as part of the registration process (such as an email address) will be disclosed publicly.

Response to this notice is voluntary. Responses to this notice may be used by the government for program planning on a non-attribution basis. NOAA therefore requests that no business proprietary information or copyrighted information be submitted in response to this notice. Please note that the U.S. Government will not pay for response preparation, or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT: David Dokken, (202) 419–3473, *ddokken@usgcrp.gov,* U.S. Global Change Research Program.

SUPPLEMENTARY INFORMATION: The U.S. Global Change Research Program (USGCRP) is mandated under the Global Change Research Act (GCRA) of 1990 to conduct a quadrennial National Climate Assessment (NCA) to evaluate scientific findings and uncertainties related to global change, analyze the effects of global change, and analyze the current and projected trends in global change, both human-induced and natural.

The Fourth NCA fulfills this mandate by synthesizing and assessing the science and impacts of climate change across 15 sectors and 10 regions of the United States, and considers options to reduce present and future risk, in a policy-relevant, but not policy-prescriptive manner. The Fourth NCA is a product of the USGCRP, and is overseen by an interagency Federal

Steering Committee. Non-Federal Regional Chapter Leads were identified via an Open Call for nominations (*https://www.federalregister.gov/d/2016-20982*). The draft assessment was written by teams of Federal and non-Federal authors selected for their demonstrated subject matter expertise and publications relevant to the chapter topics outlined in the prospectus (*https://www.federalregister.gov/d/2016-15807*) and was informed by an array of technical inputs, many gathered through an Open Call (*https://www.federalregister.gov/d/2016-20982*).

The report adheres to the Information Quality Act requirements (*http://www.cio.noaa.gov/services_programs/info_quality.html*) for quality, transparency, and accessibility as appropriate for a Highly Influential Scientific Assessment (HISA).

Dan Barrie, Program Manager, Assessments Program, NOAA Climate Program Office.

Dated: October 10, 2017.

David Holst,

Chief Financial Officer/CAO, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration

[FR Doc. 2017–24221 Filed 11–6–17; 8:45 am]

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DEPARTMENT OF EDUCATION

Authorization of Subgrants for the High School Career and Technical Education Teacher Pathway Initiative

AGENCY: Office of Career, Technical, and Adult Education, Department of Education.

ACTION: Notice.

SUMMARY: Pursuant to the Education Department General Administrative Regulations, this notice authorizes grantees receiving awards under the High School Career and Technical Education (CTE) Teacher Pathway Initiative (CFDA 84.051D) to make subgrants, subject to the limitations described in this notice.

DATES: Grantees may begin making subgrants on November 7, 2017.

FOR FURTHER INFORMATION CONTACT: Laura Messenger, U.S. Department of Education, 400 Maryland Avenue SW., Potomac Center Plaza (PCP), Room 11028, Washington, DC 20202–7241. Telephone: (202) 245–7840 or by fax at (202) 245–7170.

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:

Purpose of Program: The purpose of the High School CTE Teacher Pathway Initiative is to improve CTE programs assisted under the Carl D. Perkins Career and Technical Education Act of 2006 (the Perkins Act) by increasing the supply of high school CTE teachers available to teach students in CTE programs that align to in-demand industry sectors or occupations in States and communities where shortages of such teachers exist.

Program Authority: 20 U.S.C. 2324.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 79, 81, 82, 84, 86, 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. (d) The priorities and requirements in the notice inviting applications for this program, published June 13, 2017, in the **Federal Register** (82 FR 27047).

Eligible Entities for Subgrants: The following entities are eligible to apply under this competition:

(a) A State board designated or created consistent with State law as the sole State agency responsible for the administration of CTE in the State or for the supervision of the administration of CTE in the State;

(b) A local educational agency (LEA) (including a public charter school that operates as an LEA), an area CTE school, an educational service agency, or a consortium of such entities, in each case, that receives assistance under section 131 of the Perkins Act; and

(c) An eligible institution or consortium of eligible institutions that receives assistance under section 132 of the Perkins Act.

Discussion: Recognizing that creating sustainable, new, or expanded pathways to recruit and retain CTE teachers will require collaborative approaches and coordination among several entities, the Department of Education has required that the applicants to the High School CTE Teacher Pathway Initiative create partnerships to carry out the activities proposed in the applications. The Office of Career, Technical, and Adult Education has determined that for some of the partnerships, subgranting may be appropriate and necessary to meet the purposes of the High School CTE Teacher Pathway Initiative, particularly for State eligible agencies that receive a High School CTE Teacher Pathway Initiative grant award, because many of the allowable activities are decided and implemented at the school district level. The current absence of subgranting authority limits the extent to which the program grantees and partners can most effectively collaborate to conduct the activities described in funded applications.

Requirements: If the grantee uses this subgranting authority, the subgrants, consistent with 34 CFR 75.708(b)(2), must be used only to carry out directly those project activities described in the grantee's approved application. Consistent with 34 CFR 75.708(d), grantees must ensure that subgrants are awarded on the basis of the approved budget that is consistent with the grantee's approved application and all applicable Federal statutory, regulatory, and other requirements. Grantees have the authority to award subgrants to entities that have been identified in their applications as well as to those that are awarded a subgrant through a competitive award process. Grantees under the High School CTE Teacher Pathway Initiative must ensure that every subgrant includes any conditions required by Federal statutes and Executive orders and their implementing regulations. Grantees must ensure that subgrantees are aware of the requirements imposed upon them by Federal statutes and regulations, including the Federal anti-discrimination laws listed in 34 CFR 75.500, and enforced by the Department.

Note: This notice does not solicit applications.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site. You may also access documents of the Department published in the **Federal Register** by using the article search feature at:

www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: November 2, 2017.

Michael E. Wooten,

Deputy Assistant Secretary, Delegated the Duties of the Assistant Secretary for Career, Technical, and Adult Education.

[FR Doc. 2017–24218 Filed 11–6–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2017–ICCD–0111]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Corrective Action Plan (CAP)

AGENCY: Department of Education (ED), Office of Special Education and Rehabilitative Services (OSERS).

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 December 7, 2017.

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–2017–ICCD–0111. 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. *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, 400 Maryland Avenue SW., LBJ, Room 216–44, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Edward West, 202–245–6145.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Corrective Action Plan (CAP).

OMB Control Number: 1820–0694.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 60.

Total Estimated Number of Annual Burden Hours: 975.

Abstract: Pursuant to the Rehabilitation Act of 1973 as amended by the Workforce Innovation and Opportunity Act, the Rehabilitation Services Administration (RSA) must conduct periodic monitoring of the Vocational Rehabilitation (VR) programs in each state. As a result of this monitoring, RSA may require that VR agencies to develop a Corrective Action Plan (CAP) in order to resolve findings of non-compliance. The CAP must contain the specific steps that the agency will take to resolve each finding, timelines for the completion of each step and methods for evaluating that the findings have been resolved. RSA requires the agency to report progress toward completion of the CAP on a quarterly basis.

Dated: November 2, 2017.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–24185 Filed 11–6–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

[Docket Number: EERE 2017–VT–00XX]

Proposed Agency Information Collection Extension

AGENCY: Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy (DOE).

ACTION: Notice and request for comments.

SUMMARY: The Department of Energy pursuant to the Paperwork Reduction Act of 1995, intends to extend for three years an information collection request with the Office of Management and Budget.

DATES: Comments regarding this proposed information collection must be received on or before January 8, 2018. If you anticipate difficulty in submitting comments within that period, contact the person listed in **ADDRESSES** as soon as possible.

ADDRESSES: Written comments should include DOCKET # EERE–2017–VT–00XX in the subject line of the message and may be sent to: Mr. Dana V. O'Hara, Office of Energy Efficiency and Renewable Energy (EE–3V), U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–0121, or by email at *Dana.O'Hara@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Mr. Dana V. O'Hara, Office of Energy Efficiency and Renewable Energy (EE–3V), U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585–0121, (202) 586–8063, *Dana.O'Hara@ee.doe.gov.* The information collection instrument is completed online, via a password protected Web page; for review purposes, the same instrument is available online at *http://www1.eere.energy.gov/vehiclesandfuels/epact/docs/reporting_spreadsheet.xls.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the extended collection of information is necessary for the proper performance of the functions of DOE, including whether the information shall have practical utility; (b) the accuracy of DOE's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the

burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

This information collection request contains: (1) OMB No. 1910–5101; (2) Information Collection Request Title: Annual Alternative Fuel Vehicle Acquisition Report for State Government and Alternative Fuel Provider Fleets; (3) Type of Review: Renewal; (4) Purpose: The information is required so that DOE can determine whether alternative fuel provider and State government fleets are in compliance with the alternative fueled vehicle acquisition mandates of sections 501 and 507(o) of the Energy Policy Act of 1992, as amended, (EPAct), whether such fleets should be allocated credits under section 508 of EPAct, and whether fleets that opted into the alternative compliance program under section 514 of EPAct are in compliance with the applicable requirements; (5) Annual Estimated Number of Respondents: Approximately 303; (6) Annual Estimated Number of Total Responses: 335; (7) Annual Estimated Number of Burden Hours: 1,970; (8) Annual Estimated Reporting and Recordkeeping Cost Burden: $120,000.

Statutory Authority: 42 U.S.C. 13251 *et seq.*

Issued in Washington, DC on: November 1, 2017.

Michael Berube,

Director, Vehicle Technologies Office, Energy Efficiency and Renewable Energy.

[FR Doc. 2017–24180 Filed 11–6–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP17–808–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: Report Filing: RP17–808 Supplemental Filing.

Filed Date: 10/30/17.

Accession Number: 20171030–5005.

Comments Due: 5 p.m. ET 11/8/17.

Docket Numbers: RP18–70–000.

Applicants: Trunkline Gas Company, LLC.

Description: Compliance filing Annual Interruptible Storage Revenue Credit filed 10–31–17.

Filed Date: 10/30/17.

Accession Number: 20171030–5085.

Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–71–000.

Applicants: Trailblazer Pipeline Company LLC.

Description: § 4(d) Rate Filing: Neg Rate 2017–10–30 Morgan Stanley to be effective 11/1/2017.

Filed Date: 10/30/17.

Accession Number: 20171030–5106.

Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–72–000.

Applicants: Southern Star Central Gas Pipeline, Inc.

Description: § 4(d) Rate Filing: Vol. 2 Negotiated and Non-Conforming PLS—Tenaska November Amendment to be effective 11/1/2017.

Filed Date: 10/30/17.

Accession Number: 20171030–5135.

Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–73–000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: Neg Rate 2017–10–30 Encana to be effective 10/28/2017.

Filed Date: 10/30/17.

Accession Number: 20171030–5144.

Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–74–000.

Applicants: Kern River Gas Transmission Company.

Description: § 4(d) Rate Filing: 2018 P2/AltP2 Rates, 15-Year 2003 Expansion to be effective 5/1/2018.

Filed Date: 10/30/17.

Accession Number: 20171030–5145.

Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–75–000.

Applicants: Algonquin Gas Transmission, LLC.

Description: § 4(d) Rate Filing: AGT FRQ 2017 Filing to be effective 12/1/2017.

Filed Date: 10/30/17.

Accession Number: 20171030–5160.

Comments Due: 5 p.m. ET 11/13/17.

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 October 31, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–24149 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2363–088]

Notice of Application Accepted for Filing, Soliciting Comments, Protests and Motions To Intervene; Sappi Cloquet LLC

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Proceeding:* Extension of License Term.

b. *Project No.:* P–2363–088.

c. *Date Filed:* October 23, 2017.

d. *Licensee:* Sappi Cloquet LLC.

e. *Name and Location of Project:* Cloquet Hydroelectric Project, located on the St. Louis River in Carlton County, Minnesota.

f. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

g. *Licensee Contact Information:* Mr. Robert Schilling, Sappi North America, 2201 Avenue B, P.O. Box 511, Cloquet, MN 55720, Phone: (218) 879–0638, Email: *Robert.Schilling@SAPPI.com* and Ms. Nancy J. Skancke, NJS Law PLC, 1025 Connecticut Avenue NW., Suite 1000, Washington, DC 20036, Phone: (202) 327–5460, Email: *njskancke@njs-law.com.*

h. *FERC Contact:* Mr. Ashish Desai, (202) 502–8370, *Ashish.Desai@ferc.gov.*

i. Deadline for filing comments, motions to intervene and protests, is 30 days from the issuance date of this notice by the Commission. The Commission strongly encourages electronic filing. Please file motions to intervene, protests, comments, and recommendations, using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance,

please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, 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–2363–088.

j. *Description of Proceeding:* The licensee, Sappi Cloquet LLC, requests that the Commission extend the term of the license for the Cloquet Hydroelectric Project 10 years, from June 30, 2025 to June 30, 2035. The licensee is requesting the extension to align the license expiration date of the project with that of the St. Louis River Hydroelectric Project No. 2360. The Cloquet Project is located between the Knife Falls and Scanlon developments of the St. Louis River Project. The licensee states that the extension would allow it to coordinate its relicensing efforts with those of the St. Louis River Project to increase efficiency and evaluate the operational and environment impacts of the two projects in a comprehensive manner. The licensee's request includes comments from the U.S. Fish and Wildlife Service and the National Park Service supporting the license extension.

k. This notice is available for review and reproduction at the Commission in the Public Reference Room, Room 2A, 888 First Street NE., Washington, DC 20426. The filing may also be viewed on the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the Docket number (P–2363–088) excluding the last three digits in the docket number field to access the notice. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call toll-free 1–866–208–3676 or email *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659.

l. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

m. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, 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.

n. *Filing and Service of Responsive Documents:* Any filing must (1) bear in all capital letters the title COMMENTS, PROTEST, or MOTION TO INTERVENE as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to the request to extend the license term. 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. If an intervener 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. 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.

Dated: November 1, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–24153 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11175–025]

Crown Hydro, LLC; Notice of Teleconference To Discuss Section 106 Consultation for an Application To Amend the Crown Mill Project

a. *Project Name and Number:* Crown Mill Hydroelectric Project No. 11175.

b. *Project licensee:* Crown Hydro, LLC.

c. *Date and Time of Teleconference:* Wednesday, December 6, 2017, from 9:00 a.m. to 11:00 a.m. Central Standard Time.

d. *FERC Contact:* Jennifer Polardino, (202) 502–6437 or *jennifer.polardino@ferc.gov*

e. *Purpose of Meeting:* Commission staff will hold a teleconference to discuss the status of consultation under section 106 of the National Historic Preservation Act for an application to amend the license of the unconstructed Crown Mill Hydroelectric Project. Crown Mill, LLC (licensee) proposes to move the location of the project's powerhouse about 250 feet north to U.S. Army Corps of Engineers (Corps) lands within the campus of the Upper St. Anthony Falls Lock and Dam. Crown Mill, LLC also proposes to construct a new tailrace tunnel instead of connecting to an existing tunnel. The project would be located on the Mississippi River, in the downtown area of the City of Minneapolis, Hennepin County, Minnesota.

f. All local, state, and federal agencies, Indian tribes, and other interested entities are invited to participate in the teleconference. Please call or email Jennifer Polardino at (202) 502–6437 or *Jennifer.polardino@ferc.gov* by Thursday, November 30, 2017, to RSVP and to receive the teleconference call-in information.

Dated: October 31, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–24142 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC18–12–000.

Applicants: Public Service Company of New Hampshire, Granite Shore Power LLC.

Description: Joint Application of Public Service Company of NH, et al. for Approval of the Disposition of Jurisdictional Facilities Under Section 203 of the FPA, Request for Waivers, Request for Shortened Notice Period and Expedited Consideration.

Filed Date: 10/27/17.

Accession Number: 20171027–5272.

Comments Due: 5 p.m. ET 12/11/17.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG18–12–000.

Applicants: EGP Stillwater Solar PV II, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of EGP Stillwater Solar PV II, LLC.
Filed Date: 10/31/17.
Accession Number: 20171031–5257.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: EG18–13–000.
Applicants: EGP Stillwater Solar, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of EGP Stillwater Solar, LLC.
Filed Date: 10/31/17.
Accession Number: 20171031–5260.
Comments Due: 5 p.m. ET 11/21/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3297–010.
Applicants: Powerex Corp.
Description: Notice of Change in Status of Powerex Corp.
Filed Date: 10/30/17.
Accession Number: 20171030–5227.
Comments Due: 5 p.m. ET 11/20/17.

Docket Numbers: ER17–1712–002.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Tariff Amendment: 2017–10–31_Amended Compensation for Manual Redispatch Filing to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5201.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER17–2218–001.
Applicants: PJM Interconnection, L.L.C.
Description: Tariff Amendment: Response to Deficiency Letter Issued September 28, 2017 in Docket No. ER17–2218 to be effective 10/3/2017.
Filed Date: 10/30/17.
Accession Number: 20171030–5208.
Comments Due: 5 p.m. ET 11/20/17.

Docket Numbers: ER17–2220–001.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Tariff Amendment: 2017–10–30_Deficiency response re MISO–PJM JOA pseudo-tie revisions to be effective 10/1/2017.
Filed Date: 10/30/17.
Accession Number: 20171030–5193.
Comments Due: 5 p.m. ET 11/20/17.

Docket Numbers: ER17–2449–001.
Applicants: Public Service Company of New Hampshire.
Description: Tariff Amendment: Amendment ? Rate Schedule No. IA–ES–37 Interconnect Agreement PSNH and Pontook to be effective 12/16/2016.
Filed Date: 10/31/17.
Accession Number: 20171031–5258.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–127–001.
Applicants: Virginia Electric and Power Company, PJM Interconnection, L.L.C.
Description: Tariff Amendment: VEPCO submits Amendment to WDSA, Service Agreement No. 4817 to be effective 10/1/2017.
Filed Date: 10/30/17.
Accession Number: 20171030–5209.
Comments Due: 5 p.m. ET 11/20/17.

Docket Numbers: ER18–183–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Revisions to OATT re: Proposed Pro Forma Dynamic Schedule Agreement to be effective 12/29/2017.
Filed Date: 10/30/17.
Accession Number: 20171030–5192.
Comments Due: 5 p.m. ET 11/20/17.

Docket Numbers: ER18–184–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: 2018 RSBAA Update Filing to be effective 1/1/2018.
Filed Date: 10/31/17.
Accession Number: 20171031–5015.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–186–000.
Applicants: New England Power Pool Participants Committee.
Description: § 205(d) Rate Filing: Nov 2017 Membership Filing to be effective 10/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5172.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–187–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original Cost Responsibility Agreement No. 4829—NQ155 to be effective 10/19/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5176.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–188–000.
Applicants: Jordan Creek Wind Farm LLC.
Description: Petition for Waiver of Jordan Creek Wind Farm LLC.
Filed Date: 10/30/17.
Accession Number: 20171030–5248.
Comments Due: 5 p.m. ET 11/20/17.

Docket Numbers: ER18–189–000.
Applicants: California Power Exchange Corporation.
Description: § 205(d) Rate Filing: Rate Filing for Rate Period 32 to be effective 1/1/2018.
Filed Date: 10/31/17.
Accession Number: 20171031–5213.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–190–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: NCMPA1 RS No 318 Amendment (2018) to be effective 1/1/2018.
Filed Date: 10/31/17.
Accession Number: 20171031–5223.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–191–000.
Applicants: DATC Path 15, LLC.
Description: § 205(d) Rate Filing: Revised Appendix I 2018 to be effective 1/1/2018.
Filed Date: 10/31/17.
Accession Number: 20171031–5270.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–192–000.
Applicants: Dynegy Oakland, LLC.
Description: § 205(d) Rate Filing: Annual RMR Section 205 Filing and RMR Schedule F Informational Filing to be effective 1/1/2018.
Filed Date: 10/31/17.
Accession Number: 20171031–5288.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–193–000.
Applicants: Midcontinent Independent System Operator, Inc., Dairyland Power Cooperative.
Description: § 205(d) Rate Filing: 2017–10–31_Dairyland Power Coop request for rate incentive treatment to be effective 1/1/2018.
Filed Date: 10/31/17.
Accession Number: 20171031–5290.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–194–000.
Applicants: American Electric Power Service Corporation, Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: AEP Transcos Formula Rate Revisions to be effective 1/1/2018.
Filed Date: 10/31/17.
Accession Number: 20171031–5305.
Comments Due: 5 p.m. ET 11/21/17.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES17–10–000.
Applicants: NSTAR Electric Company.
Description: Supplement to January 13, 2017 Application of NSTAR Electric Company under Section 204 of the FPA for Authority to Assume Short-Term Debt Obligations of its affiliate, Western Mass Electric Company.
Filed Date: 9/19/17.
Accession Number: 20170919–5171.
Comments Due: 5 p.m. ET 11/13/17.

Take notice that the Commission received the following PURPA 210(m)(3) filings:

Docket Numbers: QM18–1–000.
Applicants: Missouri River Energy Services.

Description: Application to Terminate Mandatory PURPA Purchase Obligation of Missouri River Energy Services, on behalf of itself and member Marshall, Minnesota.

Filed Date: 10/31/17.

Accession Number: 20171031–5298.

Comments Due: 5 p.m. ET 11/28/17.

Docket Numbers: QM18–2–000.

Applicants: Missouri River Energy Services.

Description: Application to Terminate Mandatory PURPA Purchase Obligation of Missouri River Energy Services, on behalf of itself and thirty-three members.

Filed Date: 10/31/17.

Accession Number: 20171031–5300.

Comments Due: 5 p.m. ET 11/28/17.

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: October 31, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–24145 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket No.	File date	Presenter or requester
Prohibited		
1. CP17–101–000	10–16–2017	Lower Raritan Watershed Partnership.
2. CP15–554–000	10–17–2017	William S. Moore, Carol M. Moore.
3. P–2100–000	10–17–2017	Pacific Fishery Management Council.
4. P–2082–000	10–23–2017	Copco Lake Fire Protection District.
5. P–2082–000	10–23–2017	Copco Lake Fire Protection District.
6. CP15–558–000	10–25–2017	Chamber of Commerce Southern New Jersey.
7. CP15–554–000, CP16–10–000	10–27–2017	Bert Carlson.
Exempt		
1. CP15–93–000	10–19–2017	U.S. House Representative Alex X. Mooney.
2. CP16–38–000	10–19–2017	U.S. House Representative Alex X. Mooney.
3. CP15–514–000	10–19–2017	U.S. House Representative Alex X. Mooney.
4. CP16–10–000	10–19–2017	U.S. House Representative Alex X. Mooney.
5. CP16–357–000	10–19–2017	U.S. House Representative Alex X. Mooney.
6. CP16–22–000	10–19–2017	U.S. House Representative Alex X. Mooney.
7. CP16–361–000	10–19–2017	U.S. House Representative Alex X. Mooney.
8. CP15–555–000	10–19–2017	U.S. House Representative Alex X. Mooney.
9. CP15–138–000	10–19–2017	U.S. House Representative Alex X. Mooney.
10. P–2305–000	10–19–2017	U.S. House Representative Mike Johnson.
11. CP17–41–000	10–19–2017	FERC Staff.[1]
12. CP16–22–000	10–23–2017	City of Waterville, Ohio, Mayor Lori A. Brodie.
13. CP17–101–000	10–24–2017	New Jersey Senator Bob Smith.

Docket No.	File date	Presenter or requester
14. CP16–38–000	10–24–2017	U.S. House Representative David B. McKinley, P.E.

[1] Telephone Call Summary for call on October 18, 2017 with U.S. Fish and Wildlife Service representatives.

Dated: October 31, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–24141 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP18–100–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Petrohawk 41455 to various eff 11–1–2017) to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5221.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–101–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Methanex 42805 to BP 48730) to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5222.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–102–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Neg Rate Agmt Filing (Indianapolis Power & Light 34015) to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5230.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–103–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (RE Gas 35433, 34955 to BP 36710, 36712) to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5233.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–104–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Kaiser 35448 to Kaiser 36730) to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5235.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–105–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: Neg Rate 2017–10–31 CP to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5245.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–106–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate—IDT To BP—contract 795292 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5286.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–107–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (EOG 34687 to various eff 11–1–17) to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5294.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–108–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Volume No. 2—Connecticut Exp Project—Amendment to Gas Trans Agmt to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5297.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–109–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: § 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—Nov 2017 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5303.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–110–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Piedmont to Emera 8948562 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5307.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–111–000.
Applicants: Kern River Gas Transmission Company.
Description: § 4(d) Rate Filing: 2017 November Negotiated Rates to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5310.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–112–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—EQT Releases to Pacific Summit to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5340.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–113–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—City of Dalton to Centerpoint 8948517 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5352.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–114–000.
Applicants: Guardian Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Update Statement of Negotiated Rates—November 2017 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5353.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–115–000.
Applicants: Guardian Pipeline, L.L.C.
Description: § 4(d) Rate Filing: Update Non-Conforming and Negotiated Rate Agreements—November 2017 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5354.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–116–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: TETLP ASA DEC 2017 FILING to be effective 12/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5363.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–117–000.
Applicants: Rockies Express Pipeline LLC.
Description: § 4(d) Rate Filing: Neg Rate (7 new) 10–31–2017 to be effective 11/1/2017.

Filed Date: 10/31/17.
Accession Number: 20171031–5365.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–118–000.
Applicants: Tennessee Gas Pipeline Company, L.L.C.
Description: § 4(d) Rate Filing: Section 311 Filing to be effective 12/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5371.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–119–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Pathing to Off-System Locations to be effective 12/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5372.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–120–000.
Applicants: Wyoming Interstate Company, L.L.C.
Description: § 4(d) Rate Filing: Firm Daily Balancing Service to be effective 12/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5374.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–76–000.
Applicants: Equitrans, L.P.
Description: Compliance filing Operational Purchases and Sales Report for 2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5067.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–77–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Con Ed Ramapo Releases eff 11–1–2017 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5068.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–78–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Rate Service Agreements—BP MEA J Aron to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5069.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–79–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—BUG Ramapo Releases eff 11–1–2017 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5074.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–80–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Con Ed NJNY Releases eff 11–1–2017 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5096.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–81–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—KeySpan Ramapo Releases eff 11–1–2017 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5099.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–82–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rate—Direct Energy—contract 795251 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5100.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–83–000.
Applicants: Rager Mountain Storage Company LLC.
Description: § 4(d) Rate Filing: URL Update to be effective 12/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5101.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–84–000.
Applicants: Rover Pipeline LLC.
Description: § 4(d) Rate Filing: Non-Conforming Agreements—1 in compliance with CP15–93 Order to be effective 12/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5102.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–85–000.
Applicants: Rover Pipeline LLC.
Description: § 4(d) Rate Filing: Non-Conforming Agreement List Update—1 to be effective 12/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5103.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–86–000.
Applicants: ETC Tiger Pipeline, LLC.
Description: § 4(d) Rate Filing: Fuel Filing on 10–31–17 to be effective 12/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5104.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–87–000.
Applicants: Fayetteville Express Pipeline LLC.
Description: § 4(d) Rate Filing: Fuel Filing on 10–31–17 to be effective 12/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5105.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–88–000.
Applicants: Florida Southeast Connection, LLC.
Description: § 4(d) Rate Filing: Re-Collation of Tariffs to be effective 10/31/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5142.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–89–000.
Applicants: Alliance Pipeline L.P.
Description: § 4(d) Rate Filing: Contract Extension Direct Energy to be effective 10/31/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5149.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–90–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—KeySpan Ramapo Releases 2 eff 11–1–2017 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5165.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–91–000.
Applicants: Transcontinental Gas Pipe Line Company.
Description: § 4(d) Rate Filing: Rate Schedules GSS & LSS Tracker—eff 11–1–2017 to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5174.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–92–000.
Applicants: Wyoming Interstate Company, L.L.C.
Description: § 4(d) Rate Filing: FLU Update Filing to be effective 12/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5180.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–93–000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20171031 Negotiated Rate to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5183.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–94–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: § 4(d) Rate Filing: Amendment to Neg Rate Agmt (BP 37–25) to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5197.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–95–000.
Applicants: Gulf South Pipeline Company, LP.

Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (FPL 41618 to DTE 48614) to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5198.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–96–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Amendment to Neg Rate Agmt (Sequent 34693–41) to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5199.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–97–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Atmos 45527 to CenterPoint 48643) to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5200.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–98–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Atlanta 8438 to various eff 11–1–17) to be effective 11/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5202.
Comments Due: 5 p.m. ET 11/13/17.

Docket Numbers: RP18–99–000.
Applicants: BNP Paribas Energy Trading GP, Morgan Stanley Capitol Group Inc.
Description: Joint Petition of BNP Paribas Energy Trading GP, et al. for Waiver of Commission Capacity Release Regulations and Policies, Related Natural Gas Pipeline Tariff Provisions, et al.
Filed Date: 10/31/17.
Accession Number: 20171031–5215.
Comments Due: 5 p.m. ET 11/13/17.

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: November 1, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–24193 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR18–2–000]

Notice of Petition for Declaratory Order; Permian Express Terminal LLC; Permian Express Partners LLC

Take notice that on October 27, 2017, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2016), Permian Express Terminal LLC (PET) and Permian Express Partners LLC (PEP), filed a petition for a declaratory order seeking approval of specific rate structures, terms of service, and prorationing methodology for the proposed Permian Express 3 crude oil pipeline, as more fully explained in the petition.

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. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

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 Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on November 20, 2017.

Dated: October 31, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–24154 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL18–26–000]

EDF Renewable Energy, Inc. v. Midcontinent Independent System Operator, Inc.; Southwest Power Pool, Inc.; PJM Interconnection, L.L.C.; Notice of Complaint

Take notice that on October 30, 2017, pursuant to sections 206 and 306 of the Federal Power Act, 16 U.S.C. 824e and 825e and Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206 (2017), EDF Renewable Energy, Inc. (Complainant) filed a formal complaint against Midcontinent Independent System Operator, Inc., Southwest Power Pool, Inc., and PJM Interconnection, L.L.C. (Respondents) alleging that Respondents' current Affected System coordination procedures and practices are unjust, unreasonable and unduly discriminatory, all as more fully explained in the complaint.

Complainant certifies that a copy of the Complaint was served on the contacts for Respondents as listed on the Commission's list of Corporate Officials.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and

interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on November 20, 2017.

Dated: November 1, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–24151 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP18–10–000]

Notice of Application; Texas Eastern Transmission, LP

Take notice that on October 19, 2017, Texas Eastern Transmission, LP (Texas Eastern), 5400 Westheimer Court, Houston, Texas 77056, filed in Docket No. CP18–10–000, an application under section 7(c) of the Natural Gas Act for the proposed Texas Industrial Market Expansion and Louisiana Market Expansion Projects (Projects). Specifically, Texas Eastern requests authorization to: (i) Construct and operate facility upgrades at its existing Gillis Compressor Station in Beauregard Parish, Louisiana; (ii) implement rolled-in rate treatment for firm service on the Projects; and (iii) charge an incremental electric power cost rate applicable to firm service on the Texas Industrial Market Expansion Project. The Projects will provide an additional 157,500 dekatherms per day of firm capacity for two customers from receipt points in Louisiana to delivery points in Louisiana and Texas, all as more fully set forth in the application which is on file with the Commission and open to public inspection. This filing may be viewed on the web at *http://www.ferc.gov* using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding this Application should be directed to Berk Donaldson, Director, Rates and Certificates, Texas Eastern Transmission, LP., P.O. Box 1642, Houston, Texas 77251–1642; Phone: 713–627–4488, or Fax: (713) 627–5947.

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 7 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. 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 commenter's will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenter's will not be required to serve copies of filed documents on all other parties. However, the non-party commentary, will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the e-Filing link.

Comment Date: 5:00 p.m. Eastern Time on November 21, 2017.

Dated: October 31, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–24146 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC18–12–000.
Applicants: Public Service Company of New Hampshire, Granite Shore Power LLC.
Description: Supplement to October 27, 2017 Joint Application of Public Service Company of New Hampshire, et al. for Approval of the Disposition of Jurisdictional Facilities Under Section 203 of the FPA.
Filed Date: 10/31/17.
Accession Number: 20171031–5384.
Comments Due: 5 p.m. ET 12/11/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–206–000.
Applicants: Southern Partners, INC.
Description: Baseline eTariff Filing: Southern Partners, INC MBR Application to be effective 11/1/2017.
Filed Date: 11/1/17.
Accession Number: 20171101–5099.
Comments Due: 5 p.m. ET 11/22/17.

Docket Numbers: ER18–207–000.
Applicants: Duke Energy Progress, LLC.
Description: § 205(d) Rate Filing: DEP-City of Camden First Amended and Restated RS No. 197 to be effective 1/1/2017.
Filed Date: 11/1/17.
Accession Number: 20171101–5114.
Comments Due: 5 p.m. ET 11/22/17.

Docket Numbers: ER18–208–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 2891R3 AECC and Entergy Arkansas Attachment AO to be effective 1/1/2018.
Filed Date: 11/1/17.
Accession Number: 20171101–5118.
Comments Due: 5 p.m. ET 11/22/17.

Docket Numbers: ER18–211–000.
Applicants: San Diego Gas & Electric Company.
Description: § 205(d) Rate Filing: 2018 SDGE TACBAA Update to Transmission Owner Tariff Filing to be effective 1/1/2018.
Filed Date: 11/1/17.
Accession Number: 20171101–5161.
Comments Due: 5 p.m. ET 11/22/17.

Docket Numbers: ER18–213–000.
Applicants: Pittsfield Generating Company, L P.
Description: Compliance filing: Re-file Baseline Tariff to be effective 12/31/9998.
Filed Date: 11/1/17.
Accession Number: 20171101–5168.
Comments Due: 5 p.m. ET 11/22/17.

Docket Numbers: ER18–214–000.
Applicants: Consolidated Edison Company of New York, Inc.
Description: § 205(d) Rate Filing: Con Edison VDER filing 11–1–2017 to be effective 11/1/2017.
Filed Date: 11/1/17.
Accession Number: 20171101–5185.
Comments Due: 5 p.m. ET 11/22/17.

Docket Numbers: ER18–215–000.
Applicants: Interstate Power and Light Company.
Description: § 205(d) Rate Filing: Interstate Power and Light Company Changes in Wholesale Formula Rates to be effective 1/1/2018.
Filed Date: 11/1/17.
Accession Number: 20171101–5198.
Comments Due: 5 p.m. ET 11/22/17.

Docket Numbers: ER18–216–000.
Applicants: Wisconsin Power and Light Company.
Description: § 205(d) Rate Filing: Wisconsin Power and Light Company Wholesale Formula Rate Changes to be effective 1/1/2018.
Filed Date: 11/1/17.
Accession Number: 20171101–5199.
Comments Due: 5 p.m. ET 11/22/17.

Docket Numbers: ER18–217–000.
Applicants: New York State Electric & Gas Corporation.
Description: § 205(d) Rate Filing: NYSEG–DCEC Attachment C Annual Update to be effective 1/1/2018.
Filed Date: 11/1/17.
Accession Number: 20171101–5203.
Comments Due: 5 p.m. ET 11/22/17.

Docket Numbers: ER18–218–000.
Applicants: Wisconsin Public Service Corporation.
Description: § 205(d) Rate Filing: Filing of a Wholesale Distribution Agreement w/Stratford to be effective 1/1/2018.
Filed Date: 11/1/17.
Accession Number: 20171101–5218.
Comments Due: 5 p.m. ET 11/22/17.

Docket Numbers: ER18–219–000.
Applicants: Wisconsin Public Service Corporation.
Description: § 205(d) Rate Filing: Filing of a Wholesale Distribution Agreement w/ WEPCo to be effective 1/1/2018.
Filed Date: 11/1/17.
Accession Number: 20171101–5232.
Comments Due: 5 p.m. ET 11/22/17.

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: November 1, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–24150 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR18–3–000]

Notice of Petition for Declaratory Order; BridgeTex Pipeline Company, LLC

Take notice that on October 30, 2017, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2016), BridgeTex Pipeline Company, LLC (BridgeTex), filed a petition for a declaratory order seeking approval of expansion of BridgeTex pipeline systems overall tariff rate structure and terms of service, for transportation of crude oil and condensate from new origin in Midland, Texas to Houston, Texas (to be known as the BridgeTex II Expansion Project), as more fully explained in the petition.

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. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

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 Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern time on November 21, 2017.

Dated: November 1, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–24152 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–185–000.
Applicants: Enerwise Global Technologies, Inc.
Description: Request for Limited Waiver of ISO New England, Inc. Tariff of Enerwise Global Technologies, Inc.
Filed Date: 10/30/17.
Accession Number: 20171030–5220.
Comments Due: 5 p.m. ET 11/20/17.

Docket Numbers: ER18–195–000.
Applicants: American Electric Power Service Corporation, Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: AEP Formula Rate Revisions to be effective 1/1/2018.
Filed Date: 10/31/17.
Accession Number: 20171031–5311.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–196–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: DEC-Central Electric Fifth Amended and Restated RS No. 336 to be effective 1/1/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5321.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–197–000.
Applicants: Alabama Power Company.
Description: § 205(d) Rate Filing: FPU NITSA Amendment Filing to be effective 1/1/2018.
Filed Date: 10/31/17.
Accession Number: 20171031–5334.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–198–000.
Applicants: Pacific Gas and Electric Company.
Description: § 205(d) Rate Filing: Q3 2017 Quarterly Filing of City and County of San Francisco's WDT SA (SA 275) to be effective 9/30/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5336.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–199–000.
Applicants: Otter Tail Power Company.
Description: § 205(d) Rate Filing: Revisions to CASOT Service Agreement No. 4 with East River Electric Power Cooper to be effective 1/1/2018.
Filed Date: 10/31/17.
Accession Number: 20171031–5362.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–200–000.
Applicants: Otter Tail Power Company.
Description: § 205(d) Rate Filing: Notice of Termination of Rate Schedule No. 168, East River ITSA to be effective 12/31/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5373.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–201–000.
Applicants: Arizona Public Service Company.
Description: § 205(d) Rate Filing: Rate Schedule No. 33—WAPA Triangle Agreement, Exhibit A Revision No. 52 to be effective 12/31/2017.
Filed Date: 10/31/17.
Accession Number: 20171031–5376.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–202–000.
Applicants: Startrans IO, LLC.
Description: § 205(d) Rate Filing: TRBAA 2018 Update to be effective 1/1/2018.
Filed Date: 10/31/17.
Accession Number: 20171031–5379.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–203–000.
Applicants: Appalachian Power Company.
Description: § 205(d) Rate Filing: APCo-Radford PSA Cancellation to be effective 9/30/2017.
Filed Date: 11/1/17.
Accession Number: 20171101–5036.
Comments Due: 5 p.m. ET 11/22/17.

Docket Numbers: ER18–204–000.
Applicants: PacifiCorp.
Description: Notice of Termination of PacifiCorp (Rate Schedule No. 607) Lease Agreement.
Filed Date: 10/31/17.
Accession Number: 20171031–5387.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ER18–205–000.
Applicants: Pacific Gas and Electric Company.
Description: Notice of Termination of Pacific Gas and Electric Company (Rate Schedule No. 240) Lease Agreement.
Filed Date: 10/31/17.
Accession Number: 20171031–5388.
Comments Due: 5 p.m. ET 11/21/17.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES18–5–000.
Applicants: Baltimore Gas and Electric Company.
Description: Application of Baltimore Gas and Electric Company under Section 204 of the Federal Power Act for Authorization of the Issuance of Securities.
Filed Date: 10/31/17.
Accession Number: 20171031–5382.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ES18–6–000.
Applicants: Commonwealth Edison Company.
Description: Application of Commonwealth Edison Company under Section 204 of the Federal Power Act for Authorization of the Issuance of Securities.
Filed Date: 10/31/17.
Accession Number: 20171031–5383.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ES18–7–000.
Applicants: PECO Energy Company.
Description: Application of PECO Energy Company under Section 204 of the Federal Power Act for Authorization of the Issuance of Securities.
Filed Date: 10/31/17.
Accession Number: 20171031–5385.
Comments Due: 5 p.m. ET 11/21/17.

Docket Numbers: ES18–8–000.
Applicants: Delmarva Power & Light Company, Potomac Electric Power Company.
Description: Joint Application of Delmarva Power & Light Company and Potomac Electric Power Company under Section 204 of the Federal Power Act for Authorization to Issue Securities.
Filed Date: 10/31/17.
Accession Number: 20171031–5386.
Comments Due: 5 p.m. ET 11/21/17.

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: November 1, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–24148 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP17–1073–000.
Applicants: Natural Gas Pipeline Company of America.
Description: Penalty Revenue Crediting Report of Natural Gas Pipeline Company of America LLC.
Filed Date: 9/22/17.
Accession Number: 20170922–5035.
Comments Due: 5 p.m. ET 11/2/17.

Docket Numbers: RP17–1080–000.
Applicants: LA Storage, LLC.
Description: Annual Penalty Disbursement Report of LA Storage, LLC.
Filed Date: 9/22/17.
Accession Number: 20170922–5173.
Comments Due: 5 p.m. ET 11/3/17.

Docket Numbers: RP17–1081–000.
Applicants: Mississippi Hub, LLC.
Description: Annual Penalty Disbursement Report of Mississippi Hub, LLC.
Filed Date: 9/22/17.
Accession Number: 20170922–5174.
Comments Due: 5 p.m. ET 11/3/17.

Docket Numbers: RP18–56–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: Negotiated Rates—Conoco 911441 to be effective 11/1/2017.
Filed Date: 10/25/17.
Accession Number: 20171025–5156.
Comments Due: 5 p.m. ET 11/6/17.

Docket Numbers: RP18–57–000.
Applicants: Alliance Pipeline L.P.
Description: § 4(d) Rate Filing: Housekeeping Sheet No. 18 to be effective 11/1/2017.
Filed Date: 10/25/17.
Accession Number: 20171025–5167.
Comments Due: 5 p.m. ET 11/6/17.

Docket Numbers: RP18–58–000.
Applicants: Southern LNG Company, L.L.C.
Description: § 4(d) Rate Filing: SLNG Electric Power Cost Adjustment—2017 to be effective 12/1/2017.
Filed Date: 10/26/17.
Accession Number: 20171026–5040.
Comments Due: 5 p.m. ET 11/7/17.

Docket Numbers: RP18–59–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: ConocoPhillips K910882 eff. 11–1–2017 to be effective 11/1/2017.
Filed Date: 10/26/17.
Accession Number: 20171026–5279.
Comments Due: 5 p.m. ET 11/7/17.

Docket Numbers: RP18–60–000.
Applicants: Texas Eastern Transmission, LP.
Description: § 4(d) Rate Filing: PCB TETLP DEC 2017 FILING to be effective 12/1/2017.
Filed Date: 10/26/17.
Accession Number: 20171026–5302.
Comments Due: 5 p.m. ET 11/7/17.

Docket Numbers: RP18–61–000.
Applicants: Dauphin Island Gathering Partners.
Description: 2017 Cash Out Report of Dauphin Island Gathering Partners.
Filed Date: 10/26/17.
Accession Number: 20171026–5319.
Comments Due: 5 p.m. ET 11/7/17.

Docket Numbers: RP18–62–000.
Applicants: Midwestern Gas Transmission Company.
Description: Compliance filing 2016–2017 Cashout Report.
Filed Date: 10/27/17.
Accession Number: 20171027–5079.
Comments Due: 5 p.m. ET 11/8/17.

Docket Numbers: RP18–63–000.
Applicants: Midwestern Gas Transmission Company.
Description: Compliance filing 2016–2017 Gas Sales and Purchases Report.
Filed Date: 10/27/17.
Accession Number: 20171027–5080.
Comments Due: 5 p.m. ET 11/8/17.

Docket Numbers: RP18–64–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Negotiated Rate Filing Tenaska Marketing Ventures to be effective 11/1/2017.
Filed Date: 10/27/17.
Accession Number: 20171027–5092.
Comments Due: 5 p.m. ET 11/8/17.

Docket Numbers: RP18–65–000.
Applicants: Guardian Pipeline, L.L.C.
Description: Compliance filing 2016–2017 Gas Sales and Purchases Report.
Filed Date: 10/27/17.
Accession Number: 20171027–5093.
Comments Due: 5 p.m. ET 11/8/17.

Docket Numbers: RP18–66–000.
Applicants: Natural Gas Pipeline Company of America.
Description: § 4(d) Rate Filing: Shell Energy North Negotiated Rate to be effective 11/1/2017.
Filed Date: 10/27/17.
Accession Number: 20171027–5096.
Comments Due: 5 p.m. ET 11/8/17.

Docket Numbers: RP18–67–000.
Applicants: OkTex Pipeline Company, L.L.C.
Description: Compliance filing 2016–2017 Gas Sales and Purchases Report.
Filed Date: 10/27/17.
Accession Number: 20171027–5100.
Comments Due: 5 p.m. ET 11/8/17.

Docket Numbers: RP18–68–000.
Applicants: Viking Gas Transmission Company.
Description: Compliance filing 2016–2017 Gas Sales and Purchases Report.
Filed Date: 10/27/17.
Accession Number: 20171027–5110.
Comments Due: 5 p.m. ET 11/8/17.

Docket Numbers: RP18–69–000.
Applicants: Texas Eastern Transmission, LP.
Description: Compliance filing TETLP OFO October 2017 Penalty Disbursement Report.
Filed Date: 10/27/17.
Accession Number: 20171027–5161.
Comments Due: 5 p.m. ET 11/8/17.

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: October 30, 2017.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2017–24147 Filed 11–6–17; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9970–30–Region 3]

Clean Air Act Operating Permit Program; Petition To Object to Title V Permit for Wheelabrator Frackville Energy; Pennsylvania

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final action.

SUMMARY: Pursuant to the Clean Air Act (CAA), the Environmental Protection Agency (EPA) Administrator signed an Order, dated October 6, 2017, denying a petition to object to a title V operating permit, issued by the Pennsylvania Department of Environmental Protection (PADEP) to the Wheelabrator Frackville Energy facility in Schuylkill County, Pennsylvania. The Order responds to an October 15, 2016 petition. The petition was submitted by the Environmental Integrity Project (EIP) and the Sierra Club (Petitioners). This Order constitutes final action on that petition requesting that the Administrator object to the issuance of the proposed CAA title V permit.

ADDRESSES: Copies of the final Order, the petition, and all pertinent information relating thereto are on file at the following location: EPA, Region III, Air Protection Division (APD), 1650 Arch St., Philadelphia, Pennsylvania 19103. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view copies of the final Order, petition, and other supporting information. You may view the hard copies Monday through Friday, from 9 a.m. to 3 p.m., excluding Federal holidays. If you wish to examine these documents, you should make an appointment at least 24 hours before the visiting day. The final Order is also available electronically at the following Web site: *https://www.epa.gov/title-v-operating-permits/title-v-petition-database.*

FOR FURTHER INFORMATION CONTACT: David Talley, Air Protection Division, EPA Region III, telephone (215) 814–2117, or by email at *talley.david@epa.gov.*

SUPPLEMENTARY INFORMATION: The CAA affords EPA a 45-day period to review and object to, as appropriate, operating permits proposed by state permitting authorities. Section 505(b)(2) of the CAA authorizes any person to petition the EPA Administrator within 60 days after the expiration of this review period to object to a state operating permit if EPA has not done so. Petitions must be based only on objections raised with reasonable specificity during the public comment period, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or that the grounds for objection or other issue arose after the comment period.

The October 15, 2016 petition requested that the Administrator object to the proposed title V operating permit issued by PADEP (Permit No. 54–00005), on the grounds that the proposed permit did not contain adequate monitoring and testing requirements to demonstrate compliance with the particulate matter emission limits contained in the permit.

The Order denying the petition to object to the state operating permit to the Wheelabrator Frackville Energy facility explains the reasons behind EPA's decision to deny the petition for objection.

Dated: October 18, 2017.

Cosmo Servidio,

Regional Administrator, Region III.

[FR Doc. 2017–24215 Filed 11–6–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Federal Advisory Committee Act; Meeting of Technological Advisory Council

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's (FCC) Technological Advisory Council will hold a meeting.

DATES: Wednesday, December 6, 2017 in the Commission Meeting Room, from 10:00 a.m. to 4:00 p.m.

ADDRESSES: Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Walter Johnston, Chief, Electromagnetic Compatibility Division, 202–418–0807; *Walter.Johnston@FCC.gov.*

SUPPLEMENTARY INFORMATION: At the December 6, meeting, which is the final meeting of the calendar year, the FCC Technological Advisory Council will discuss recommendations to the FCC Chairman on its work program agreed to at its initial meeting on June 8, 2017. The FCC will attempt to accommodate as many people as possible. However, admittance will be limited to seating availability. Meetings are also broadcast live with open captioning over the Internet from the FCC Live Web page at *http://www.fcc.gov/live/.* The public may submit written comments before the meeting to: Walter Johnston, the FCC's Designated Federal Officer for Technological Advisory Council by email: *Walter.Johnston@fcc.gov* or U.S. Postal Service Mail (Walter Johnston, Federal Communications Commission, Room 2–A665, 445 12th Street SW., Washington, DC 20554). Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Office of Engineering and Technology at 202–418–2470 (voice), (202) 418–1944 (fax). Such requests should include a detailed description of the accommodation needed. In addition, please include your contact information. Please allow at least five days advance notice; last minute requests will be accepted, but may not be possible to fill.

Federal Communications Commission.

Julius P. Knapp,

Chief, Office of Engineering and Technology.

[FR Doc. 2017–24157 Filed 11–6–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION NOTICE OF PREVIOUS ANNOUNCEMENT: 82 FR 51253.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Wednesday, November 8, 2017 at 10:00 a.m.

CHANGES IN THE MEETING: The following matter will also be considered: FEC Email Management Policy.

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Dayna C. Brown,

Secretary and Clerk of the Commission.

[FR Doc. 2017–24338 Filed 11–3–17; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than November 21, 2017.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Director of Applications) 1000 Peachtree Street NE., Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Gaylon M. Lawrence, Nashville, Tennessee;* to retain 10 percent or more of the outstanding voting shares of CapStar Financial Holdings, Inc., and thereby indirectly retain voting shares of CapStar Bank, both in Nashville, Tennessee.

Board of Governors of the Federal Reserve System, November 1, 2017.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2017–24210 Filed 11–6–17; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

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

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 1, 2017.

A. Federal Reserve Bank of Minneapolis (Brendan S. Murrin, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Dakota Financial, Inc., Marietta, Minnesota;* to acquire 63.23 percent of the voting shares of Milan Agency, Inc., and thereby indirectly acquire shares of Prairie Sun Bank, both in Milan, Minnesota.

Board of Governors of the Federal Reserve System, November 1, 2017.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2017–24211 Filed 11–6–17; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the World Trade Center Health Program Scientific/Technical Advisory Committee (STAC)

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) is seeking nominations for membership on the STAC. The STAC consists of 17 members including experts in fields associated with occupational medicine, environmental medicine, environmental health, industrial hygiene, epidemiology, toxicology, mental health, and representatives of World Trade Center (WTC) responders as well as representatives of certified-eligible WTC survivors. Members may be invited to serve for three-year terms. Selection of members is based on candidates' qualifications to contribute to the accomplishment of STAC objectives *https://www.cdc.gov/wtc/stac.html.*

DATES: Nominations for membership on the STAC must be received no later than January 26, 2018. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be mailed to NIOSH Docket 229–F, c/o Mia Wallace, Committee Management Specialist, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1600 Clifton Rd. NE., MS: E–20, Atlanta, Georgia 30333, or emailed (recommended) to *nioshdocket@cdc.gov.*

FOR FURTHER INFORMATION CONTACT: Paul Middendorf, Deputy Associate Director for Science, 1600 Clifton Rd. NE., MS: E–20, Atlanta, GA 30333; telephone (404) 498–2500 (this is not a toll-free number); email *pmiddendorf@cdc.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of points of view represented, and the committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning and annually during their terms. NIOSH identifies potential candidates and provides a slate of nominees for consideration to the Director of CDC for STAC membership each year, CDC reviews the proposed slate of candidates, and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in October, or as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to

the accomplishments of the committee's objectives. The Administrator is seeking nominations for members fulfilling the following categories:

- Environmental medicine or Environmental health specialist;
- Epidemiologist;
- Occupational physician who has experience treating WTC rescue and recovery workers;
- Occupational physician;
- Representative of WTC responders; and
- Toxicologist.

Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address);
- The category of membership (environmental medicine or environmental health specialist, occupational physician, pulmonary physician, representative of WTC responders, certified-eligible WTC survivor representative, industrial hygienist, toxicologist, epidemiologist, or mental health professional) that the candidate is qualified to represent);
- A summary of the background, experience, and qualifications that demonstrates the nominee's suitability for the nominated membership category; and
- At least one letter of recommendation from person(s) not employed by the U.S. Department of Health and Human Services. (Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (*e.g.,* CDC, NIH, FDA, etc.).

Nominations may be submitted by the candidate him- or herself, or by the person/organization recommending the candidate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2017–24155 Filed 11–6–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10656 and CMS–10455]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 8, 2018.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10656 Evaluation of the Partnership for Patients (PfP) 3.0

CMS–10455 Report of a Hospital Death Associated with Restraint or Seclusion

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* New collection of information request; *Title of Information Collection:* Evaluation of the Partnership for Patients (PfP) 3.0; *Use:* In the summer of 2015, the Centers for Medicare & Medicaid Services (CMS) Administrator approved the plans for integration of the Partnership for Patients (PfP) Hospital Engagement Network (HEN) model test with the Quality Improvement Network-Quality Improvement Organization (QIN–QIO) program. This is consistent

with the Agency's intention for further integration to maximize the strengths of the QIO program and PfP HENs to sustain and expand current national reductions in in-patient harm and 30-day readmissions. The alignment of the two programs permits the systematic use of innovative patient safety practices at a national scale.

Under this initiative, CMS has awarded multiple contracts to Hospital Improvement Innovation Networks (HIINs), formerly known as HENs, to engage the hospital, provider, and broader caregiver communities to implement well-tested and measured best practices. The end result of the overall initiative is the anticipated reduction in preventable hospital-based harm and readmissions for patients.

The PfP initiative is a public-private partnership dedicated to the improvement of health care quality, safety, and affordability. CMS, working with hospitals, providers, and the broader caregiver community, aims to implement and disseminate best practices on a national scale to reduce hospital acquired conditions (HACs) and all-cause readmissions. Through the PfP model, which was initiated in April 2011, CMS fostered rapid learning among a nationwide community of practice, resulting in major strides in patient safety and engagement by patients and families.

A mixed methods approach to answering the PfP HIIN evaluation questions includes three primary data collection activities, as follows: Hospital Survey on Prevention of Adverse Events and Reduction of Readmissions, HIIN Data Quality Assurance (QA) Survey and Qualitative Discussions with HIIN leaders and Other Support Contractors. The data collected will provide us feedback to focus efforts to improve the effectiveness and efficiency of the HIIN initiative. As we draft future HIIN and QIO contracts, information from hospitals about HIIN influence on their care processes will be used together with follow-up input from stakeholders about the survey results. *Form Number:* CMS–10656 (OMB Control Number: 0938–NEW); *Frequency:* Annually; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 835; Total *Annual Responses:* 854; *Total Annual Hours:* 392. (For policy questions regarding this collection contact Israel Cross at 410–786–0619.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Report of a Hospital Death Associated with Restraint or Seclusion; *Use:* The regulation that was published on May, 16, 2012 (77 FR 29074) included a reduction in the reporting requirement related to hospital deaths associated with the use of restraint or seclusion, § 482.13(g). Hospitals must use Form CMS–10455 to report those deaths associated with restraint and/or seclusion directly to the Centers for Medicare & Medicaid Services (CMS) Regional Office (RO). This requirement also applies to rehabilitation or psychiatric distinct part units (DPUs) in Critical Access Hospitals (CAHs). The RO must provide hospitals with instructions for submitting the form fax and/or email, based on RO preference. Hospitals are no longer required to report to CMS those deaths where there was no use of seclusion and the only restraint was 2-point soft wrist restraints beginning in May 9, 2014. This reporting requirement change resulted in no necessary edits to the form CMS–10455 as soft wrist restraints may be used in combination with other types of restraints. It was estimated that this would reduce the volume of reports that must be submitted by 90 percent for hospitals. In addition, the final rule replaced the previous requirement for reporting via telephone to CMS, which proved to be cumbersome for both CMS and hospitals, with a requirement that allows submission of reports via telephone, facsimile or electronically, as determined by CMS.

Form CMS–10455 is being revised in order to obtain the necessary information for the ROs to make a determination whether or not to authorize an on-site investigation related to the details surrounding the death of individuals associated with restraint and/or seclusion. *Form Number:* CMS–10455 (OMB control number: 0938–1210); *Frequency:* Occasionally; *Affected Public:* Private Sector; *Number of Respondents:* 6,389; *Number of Responses:* 6,389; *Total Annual Hours:* 2,619. (For policy questions regarding this collection contact Karina Meushaw at 410–786–1000.)

Dated: *November 1, 2017.*

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–24134 Filed 11–6–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0529]

Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery; 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 guidance for industry entitled ''Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery.'' The guidance is intended to promote the safe use of nonprescription (also referred to as over-the-counter or OTC) aspirin drug products by encouraging drug manufacturers, packagers, and labelers marketing aspirin drug products with cardiovascular-related imagery to include a statement that reminds consumers to talk to their health care provider before using aspirin for their heart.

DATES: The announcement of the guidance is published in the **Federal Register** on November 7, 2017.

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

Electronic Submissions

Submit electronic comments in the following way:

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

do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2012–D–0529 for ''Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery; Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

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

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

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

Submit written requests for single copies of the guidance to the 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Emily Baker, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51 Rm. 5203, Silver Spring, MD 20993–0002, 301–796–7524.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery.'' Aspirin is a common active ingredient in many prescription and OTC drug products. Most OTC aspirin drug products are currently marketed pursuant to the Tentative Final Monograph (TFM) for Internal Analgesic, Antipyretic, and Antirheumatic (IAAA) Drug Products (53 FR 46204, November 16, 1988) for the temporary relief of minor aches and pains associated with a cold, headache, backache, toothache, premenstrual and menstrual cramps, minor pain of arthritis, and reduction in fever.

In addition to the OTC conditions of use in the IAAA TFM, FDA regulations at § 343.80 (21 CFR 343.80) also contain professional labeling about cardiovascular uses of aspirin directed at health care practitioners (63 FR 56802, October 23, 1998). After publication of the professional labeling regulation for aspirin, some OTC aspirin labels were modified to include cardiovascular-related imagery (*e.g.,* heart image, electrocardiography graphic, stethoscope around a heart image). However, the final rule for IAAA products at § 343.80 authorizes labeling for cardiovascular events only in professional labeling directed to health care professionals.

Because of the potential side effects associated with long-term aspirin therapy, FDA recommends that any cardiovascular-related imagery on OTC aspirin labels be accompanied by a statement that reminds consumers to talk to their health care provider before using aspirin for the professional indication of secondary prevention of cardiovascular events. Therefore, this guidance provides that FDA does not intend to take action against manufacturers of single-ingredient aspirin, buffered aspirin, and aspirin in combination with an antacid, marketed pursuant to the TFM for IAAA Drug Products because the product label includes cardiovascular-related imagery (*e.g.,* heart image, electrocardiography graphic, stethoscope around a heart image) if the label also includes language as described in the guidance recommending that patients talk to a health care professional before taking aspirin for cardiovascular uses and the product is otherwise marketed in accordance with the TFM.

In the **Federal Register** of January 11, 2017 (82 FR 3335), FDA published a draft guidance entitled ''Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery; Guidance for Industry.'' We have made changes to the guidance in response to comments received and revised the recommended statement to make it more consumer friendly.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Recommended Statement for Over-the-Counter Aspirin-Containing Drug Products Labeled With Cardiovascular-Related Imagery.'' 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

The recommendations in this guidance are not subject to review by the Office of Management and Budget because they do not constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the labeling statements are a ''public disclosure of

information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

III. Electronic Access

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

Dated: November 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24192 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1129]

Medical Devices; Exemptions From Premarket Notification: Class II Devices; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing its intent to exempt a list of class II devices from premarket notification requirements, subject to certain limitations. The Agency has determined that, based on established factors, these devices no longer require premarket notification to provide reasonable assurance of safety and effectiveness. FDA is publishing this notice to obtain comments regarding the proposed exemptions, in accordance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on the notice by January 8, 2018.

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 January 8, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 8, 2018. 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–2017–N–1129 for ''Medical Devices; Exemptions from Premarket Notification: Class II Devices; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

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

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

FOR FURTHER INFORMATION CONTACT: Bryce Bennett, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5244, Silver Spring, MD 20993, 301–348–1446, *Gregory.Bennett@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION :

I. Statutory Background

Section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and the implementing regulations, 21 CFR part 807 subpart E, require persons who intend to market a new device to submit and obtain clearance of a premarket notification (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law on December 13, 2016. Section 3054 of the Cures Act amended section 510(m) of the FD&C Act. As amended,

section 510(m)(1)(A) of the FD&C Act requires FDA to publish in the **Federal Register** a notice containing a list of each type of class II device that FDA determines no longer requires a report under section 510(k) of the FD&C Act to provide reasonable assurance of safety and effectiveness. FDA is required to publish this notice within 90 days of the date of enactment of the Cures Act and at least once every 5 years thereafter, as FDA determines appropriate. Additionally, FDA must provide at least a 60-day comment period for any such notice required to be published under section 510(m)(1)(A) of the FD&C Act. FDA published this notice in the **Federal Register** of March 14, 2017 (82 FR 13609). Under section 510(m)(1)(B) of the FD&C Act, FDA must publish in the **Federal Register**, within 210 days of enactment of the Cures Act, a list representing its final determination regarding the exemption of the devices that were contained in the list published under section 510(m)(1)(A). FDA published that list in the **Federal Register** of July 11, 2017 (82 FR 31976).

As amended, section 510(m)(2) of the FD&C Act provides that, 1 day after the date of publication of the final list under section 510(m)(1), FDA may exempt a class II device from the requirement to submit a report under section 510(k) of the FD&C Act upon its own initiative or a petition of an interested person, if FDA determines that a report under section 510(k) is not necessary to assure the safety and effectiveness of the device. To do so, FDA must publish in the **Federal Register** a notice of its intent to exempt the device, or of the petition, and provide a 60-day period for public comment. Within 120 days after the issuance of this notice, FDA must publish an order in the **Federal Register** that sets forth its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under section 510(m)(2) of the FD&C Act within 180 days of receiving it, the petition shall be deemed granted.

II. Factors FDA May Consider for Exemption

There are a number of factors FDA may consider to determine whether a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the January 21, 1998, **Federal Register** notice (63 FR 3142) and subsequently in the guidance the Agency issued on February 19, 1998, entitled ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff'' (''Class II 510(k) Exemption Guidance'') (Ref. 1). Accordingly, FDA generally considers the following factors to determine whether premarket notification is necessary for class II devices: (1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device; (2) characteristics of the device necessary for its safe and effective performance are well established; (3) changes in the device that could affect safety and effectiveness will either (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm, or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (4) any changes to the device would not be likely to result in a change in the device's classification. FDA may also consider that, even when exempting devices, these devices would still be subject to the limitations on exemptions.

III. Limitations on Exemptions

FDA has determined that premarket notification is not necessary to assure the safety and effectiveness of the class II devices listed in table 1. This determination is based, in part, on the Agency's knowledge of the device, including past experience and relevant reports or studies on device performance (as appropriate), the applicability of general and special controls, and the Agency's ability to limit an exemption.

A. General Limitations of Exemptions

FDA's proposal to grant an exemption from premarket notification for class II devices listed in table 1 applies only to those devices that have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type, or, in the case of in vitro diagnostic devices, for which a misdiagnosis, as a result of using the device, would not be associated with high morbidity or mortality. FDA proposes that a manufacturer of a listed device would still be required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into commercial distribution when the device meets any of the conditions described in 21 CFR 862.9 to 21 CFR 892.9.

B. Partial Limitations of Exemptions

In addition to the general limitations, FDA may also partially limit an exemption from premarket notification requirements to specific devices within a listed device type when initial Agency assessment determines that the factors laid out in the Class II 510(k) Exemption Guidance (Ref. 1) do not weigh in favor of exemption for all devices in a particular group. In such situations where a partial exemption limitation has been identified, FDA has determined that premarket notification is necessary to provide a reasonable assurance of safety and effectiveness for these devices. In table 1, for example, FDA is listing the proposed exemption of the genetic health risk assessment system, but limits the exemption to such devices that have received a first-time FDA marketing authorization (*e.g.,* 510(k) clearance) for the genetic health risk assessment system (a ''one-time FDA reviewed genetic health risk assessment system''). FDA believes that a one-time FDA review (*e.g.,* premarket notification) of a genetic health risk assessment system is necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA believes that a one-time FDA review of a genetic health risk assessment system is necessary to mitigate the risk of false negatives and false positives by ensuring that certain information be submitted to FDA to allow the Agency to assess the safety and effectiveness of the devices and the regulatory controls necessary to address those issues as well as to ensure the devices perform to acceptable standards.

IV. List of Class II Devices

FDA is identifying the following list of class II devices that, if finalized, would no longer require premarket notification under section 510(k) of the FD&C Act, subject to the general limitations to the exemptions found in §§ 862.9 to 892.9:

TABLE 1—CLASS II DEVICES

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
862.1840	Total 25-hydroxyvitamin D Mass Spectrometry Test System.	PSL	

TABLE 1—CLASS II DEVICES—Continued

21 CFR section	Device type	Product code	Partial exemption limitation (if applicable)
866.5950	Genetic Health Risk Assessment System	PTA	Exemption is limited to a genetic health risk assessment system that has received a first-time FDA marketing authorization (e.g., 510(k) clearance) for the genetic health risk assessment system (a ''one-time FDA reviewed genetic health risk assessment system'').
876.1500	Endoscopic Maintenance System	PUP	
880.6710	Purifier, Water, Ultraviolet, Medical	KMG	
884.5960	Vibrator for Therapeutic Use, Genital	KXQ	

V. Reference

The following reference is on display in the Dockets Management Staff (see **ADDRESSES**) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the Web site address, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA Guidance, ''Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff,'' February 19, 1998, available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080199.pdf.*

Dated: October 31, 2017.

Lauren Silvis,

Chief of Staff.

[FR Doc. 2017–24163 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0618; FDA–2013–N–1155; FDA–2010–N–0118; FDA–2011–N–0655; FDA–2014–N–0086; FDA–2011–N–0144; FDA–2016–N–2836]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* 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.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Reporting and Recordkeeping for Electronic Products—General Requirements	0910–0025	7/31/2020
Food Labeling Regulations	0910–0381	7/31/2020
Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–0520	7/31/2020
Animal Generic Drug User Fee Act Cover Sheet	0910–0632	7/31/2020
Potential Tobacco Product Violations Reporting Form	0910–0716	7/31/2020
Voluntary Qualified Importer Program Guidance for Industry	0910–0840	7/31/2020
Donor Risk Assessment Questionnaire for the FDA/National Heart, Lung, and Blood Institute—Sponsored Transfusion-Transmissible Infectious Monitoring System	0910–0841	7/31/2020

Dated: November 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24189 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1170]

Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment; 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 guidance for industry entitled ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment.'' The purpose of this guidance is to assist sponsors in all phases of development of direct-acting antiviral (DAA) drugs for the treatment of chronic hepatitis C. This guidance finalizes the draft guidance of the same name issued on May 4, 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on November 7, 2017.

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

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2013–D–1170 for ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment; Guidance for Industry; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

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

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

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

Submit written requests for single copies of this 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. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jeffrey Murray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6360, Silver Spring, MD 20993–0002, 301–796–1500.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral Drugs for Treatment.'' This guidance addresses nonclinical development, early phases of clinical development, and phase 3 protocol designs. Important issues addressed in this guidance include: trial design options, choice of noninferiority margins for active-controlled phase 3 trials in the evaluation of interferon (IFN)-free regimens, and trial design options and safety evaluations for specific populations including patients with decompensated cirrhosis, patients either pre- or post-liver transplant, and patients with chronic kidney disease and clinical virology considerations. This guidance finalizes the draft guidance of the same name issued on May 4, 2016 (81 FR 26805). Changes made to the guidance took into consideration comments received. In addition to editorial changes primarily for clarification, the major changes are as follows:

• Modification of several sections to focus on IFN-free DAA regimens.

• Additional clarification on trial designs for combinations of investigational DAAs with or without ribavirin.

• Additional clarification on the recommended trial population to

include patients with clinical or laboratory evidence of chronic hepatitis C disease, such as the presence of fibrosis by biopsy or noninvasive tests.

• Additional details on DAA drug development in patients with decompensated cirrhosis, including recommendations for a review by an independent adjudication committee for all serious hepatic events, deaths, liver transplantations, and changes in prespecified alanine transaminase, aspartate transaminase, and bilirubin parameters and a recommendation for long-term followup to characterize clinical outcomes such as progression or regression of liver disease, liver-related mortality, occurrence of hepatocellular carcinoma, or liver failure requiring liver transplantation.

• Additional clarification on efficacy endpoints, specifically additional post-treatment followup (*e.g.,* 1 year or longer) may be needed if one or more drugs in the regimen has a long plasma or intracellular half-life or prolonged antiviral activity.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Chronic Hepatitis C Virus Infection: Developing Direct-Acting Antiviral 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

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

Dated: November 2, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–24195 Filed 11–6–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following Heart, Lung, & Blood Program Project Review Committee 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: Heart, Lung, and Blood Initial Review Group; Heart, Lung, and Blood Program Project Review Committee.

Date: December 1, 2017.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton BWI (Baltimore), 1100 Old Elkridge Landing Road, Baltimore, MD 21090.

Contact Person: Jeffrey H. Hurst, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7208, Bethesda, MD 20892, 301–435–0303, *hurstj@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 1, 2017.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–24144 Filed 11–6–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Synthetic Psychoactive Drugs and Strategic Approaches to Counteract their Deleterious Effects.

Date: November 30, 2017.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jasenka Borzan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892–7814, 301–435–1787, *borzanj@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neuroimmunology, Neuroinflammation and Brain Tumor.

Date: December 6, 2017.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Nataliya Gordiyenko, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5202, MSC 7846, Bethesda, MD 20892, 301–435–1265, *gordiyenkon@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Retinal Synapses and Circuitry.

Date: December 6, 2017.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Afia Sultana, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 4189, Bethesda, MD 20892, (301) 827–7083, *sultanaa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 1, 2017.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–24143 Filed 11–6–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6045–N–01]

Annual Indexing of Basic Statutory Mortgage Limits for Multifamily Housing Programs

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: In accordance with Section 206A of the National Housing Act, HUD has adjusted the Basic Statutory Mortgage Limits for Multifamily Housing Programs for Calendar Year 2017.

DATES: January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Daniel J. Sullivan, Deputy Director, Office of Multifamily Development, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410–8000, telephone (202) 402–6130 (this is not a toll-free number). Hearing or speech-impaired individuals may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: The FHA Down Payment Simplification Act of 2002 (Pub. L. 107–326, approved December 4, 2002) amended the National Housing Act by adding a new Section 206A (12 U.S.C. 1712a). Under Section 206A, the following are affected:

I. Section 207(c)(3)(A) (12 U.S.C. 1713(c)(3)(A));
II. Section 213(b)(2)(A) (12 U.S.C. 1715e(b)(2)(A));
III. Section 220(d)(3)(B)(iii)(I) (12 U.S.C. 1715k(d)(3)(B)(iii)(I));
IV. Section 221(d)(4)(ii)(I) (12 U.S.C. 1715l(d)(4)(ii)(I));
V. Section 231(c)(2)(A) (12 U.S.C. 1715v(c)(2)(A)); and
VI. Section 234(e)(3)(A) (12 U.S.C. 1715y(e)(3)(A)).

The Dollar Amounts in these sections are the base per unit statutory limits for FHA's multifamily mortgage programs collectively referred to as the 'Dollar Amounts.' They are adjusted annually (commencing in 2004) on the effective date of the Consumer Financial Protection Bureau's adjustment of the $400 figure in the Home Ownership and Equity Protection Act of 1994 (HOEPA) (Pub. L. 103–325, approved September 23, 1994). The adjustment of the Dollar Amounts shall be calculated using the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U) as applied by the Bureau of Consumer Financial Protection for purposes of the above-described HOEPA adjustment.

HUD has been notified of the percentage change in the CPI–U used for the HOEPA adjustment and the effective date of the HOEPA adjustment. The percentage change in the CPI–U is 2.1 percent and the effective date of the HOEPA adjustment is January 1, 2017. The Dollar Amounts have been adjusted correspondingly and have an effective date of January 1, 2017.

These revised statutory limits, high cost areas and per unit cost thresholds for substantial rehabilitation may be applied to FHA multifamily mortgage insurance applications submitted or amended on or after July 1, 2017, so long as the loan has not been initially endorsed.

The adjusted Dollar Amounts for Calendar Year 2017 are shown below:

Basic Statutory Mortgage Limits for Calendar Year 2017

Multifamily Loan Program

Section 207—Multifamily Housing

Section 207 pursuant to Section 223(f)—Purchase or Refinance Housing

Section 220—Housing in Urban Renewal Areas

Bedrooms	Non-elevator	Elevator
0	$51,575	$60,158
1	57,133	66,657
2	68,244	81,734
3	84,116	102,368
4+	95,228	115,749

Section 213—Cooperatives

Bedrooms	Non-elevator	Elevator
0	$55,894	$59,515
1	64,447	67,428
2	77,725	81,993
3	99,489	106,073
4+	110,837	116,438

Section 234—Condominium Housing

Bedrooms	Non-elevator	Elevator
0	$57,035	$60,021
1	65,762	68,806
2	79,311	83,667
3	101,521	108,239
4+	113,098	118,812

Section 221(d)(4)—Moderate Income Housing

Bedrooms	Non-elevator	Elevator
0	$51,328	$55,445
1	58,266	63,562
2	70,429	77,291
3	88,400	99,988
4+	99,890	109,758

Section 231—Housing for the Elderly

Bedrooms	Non-elevator	Elevator
0	$48,800	$55,445
1	54,555	63,562
2	65,147	77,291
3	78,401	99,988
4+	92,173	109,758

Section 207—Manufactured Home Parks Per Space—$23,678

Per Unit Limit for Substantial Rehabilitation for Calendar Year 2017

The 2016 Multifamily Accelerated Processing (MAP) Guide established a base amount of $15,000 per unit to define substantial rehabilitation for FHA insured loan programs. Section 5.1.D.2 of the MAP guide requires that this base amount be adjusted periodically based on the percentage change published by the Consumer Financial Protection Bureau or other inflation cost index published by HUD. Accordingly, the 2017 base amount per dwelling unit to determine substantial rehabilitation for FHA insured loan programs is $15,315.

Environmental Impact

This issuance establishes mortgage and cost limits that do not constitute a development decision affecting the physical condition of specific project areas or building sites. Accordingly, under 24 CFR 50.19(c)(6), this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Dated: October 31, 2017.

Dana T. Wade,

General Deputy Assistant Secretary for Housing.

[FR Doc. 2017–24171 Filed 11–6–17; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5997–N–72]

30-Day Notice of Proposed Information Collection: Transfer and Consolidation of Public Housing Programs and Public Housing Agencies

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date: December 7, 2017.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806, Email: *OIRA Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email *Colette.Pollard@hud.gov,* or telephone 202–402–3400. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A. The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on June 27, 2017 at 82 FR 29091.

A. Overview of Information Collection

Title of Information Collection: Transfer and Consolidation of Public Housing Programs and Public Housing Agencies.

OMB Approval Number: 2577–0280.

Type of Request: Reinstatement, without change, of a previously approved collection for which approval has expired.

Form Number: No form is used to collect this information. Forms collected with information incidental to this collection are: HUD–52190–A, HUD–53012–A, HUD 53012–B, HUD–52722, HUD–52723, HUD–51999, SF–1199A, HUD–27056, HUD–27054A, HUD–52540.

Description of the Need for the Information and Proposed Use: State legislatures or other local governing bodies may from time to time direct or agree that the public interest is best served if one Public Housing Agency (PHA) cedes its public housing program to another PHA, or that two or more PHAs should be combined into one multijurisdictional PHA. This proposed information collection serves to protect HUD's several interests in either transaction: (1) Insuring the continued use of the property as Public Housing; (2) that HUD's interests are secured; and (3) that the Operating and Capital subsidies that HUD pays to support the operation and maintenance of Public Housing is properly paid to the correct PHA on behalf of the correct properties. In addition to submitting documentation to HUD, PHAs are required to make conforming changes to HUD's Public Housing Information Center (PIC).

Total Estimated Burdens:

TOTAL BURDEN HOUR ESTIMATES FOR PHAS

Number of transfer or consolidation actions	Number of respondents	Frequency of requirement *	×	Estimated average time for requirement (hours)	=	Estimated annual burden (hours)
3 Transfers	6	1		120		720
2 Consolidations	4	1		200		800
Subtotals	10			320		1520

* The frequency shown assumes that the receiving or consolidated PHA makes one submission for all other PHAs involved in either the transfer or consolidation.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

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

(4) Ways to minimize the burden of the collection of information on those who are to respond: Including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: November 1, 2017.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2017–24213 Filed 11–6–17; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5997–N–71]

30-Day Notice of Proposed Information Collection: Housing Opportunities for Persons With AIDS (HOPWA) Program

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of

information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* December 7, 2017

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax:202–395–5806, Email: *OIRA Submission@omb.eop.gov*

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Anna P. Guido at *Anna. P. Guido@ hud.gov* or telephone 202–402–5535. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339. Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on June 16, 2017 at 82 FR 27716.

A. Overview of Information Collection

Title of Information Collection: Housing Opportunities for Persons With AIDS (HOPWA) Program.

OMB Approval Number: 2506–0133.

Type of Request: Revision of a currently approved collection.

Form Number: HUD–40110–B, HUD–40110–C, HUD–40110–D, SF–424, SF–LLL, and HUD–2991.

Description of the need for the information and proposed use: The current paperwork reduction act approval under OMB Control No. 2506–0133 covers both the HOPWA formula and competitive grant programs. The competitive grant program includes new competitive grants and renewal grants. The information collection requirements pertain to grant application submission requirements which will be used to rate applications, determine eligibility, and establish grant amounts. HOPWA plans to continue using form HUD–40110–B, HOPWA Competitive Application & Renewal of Permanent Supportive Housing Project Budget Summary, as a component of determining applicant eligibility and establishing grant amounts for competitive grants. Limited technical edits are proposed for form HUD–40110–B. HOPWA competitive and renewal application submission also require submission of the following forms: SF424; SFLLL; and HUD–2991. Form HUD–2991 is currently covered under OMB approval number 2506–0112.

The addition of narratives to address the five HUD standard rating factors will allow HUD to rate application and further determine eligibility and establish grant amounts. Applicants applying for HUD competitive funds are required to respond to these five rating factors in narrative form. These narratives will complement the currently approved budget summary form, and allow HUD to determine if applicants are proposing projects within statutory and regulatory limitations. The five HUD standard rating factors include: Factor 1: Capacity of the Applicant and Relevant Organizational Staff; Factor 2: Need/Extent of the Problem; Factor 3: Soundness of Approach; Factor 4: Leveraging Resources; and Factor 5: Achieving Results and Program Evaluation. New HOPWA competitive applicants will be required to respond to each rating factor within the page limits establish in the grant solicitation. HOPWA renewal applicants will also be required to respond with narratives, but the information will be more limited and focused on continued compliance with the HOPWA program activities originally awarded until their initial grant application.

The reporting and recordkeeping for both HOPWA formula and competitive grant programs are also included in this approval. Technical edits are proposed for forms HUD–40110–C and HUD–40110–D, and are limited to updating outdated references and information currently contained in the forms. Grantees provide annual information on program accomplishments that supports program evaluation and the ability to measure program beneficiary outcomes related to: maintaining housing stability; preventing homelessness; and improving access to care and support. Competitive grantees report through HUD–40110–C, the HOPWA Annual Performance Report (APR); Formula grantees report through HUD–40110–D, the HOPWA Consolidated Annual Performance and Evaluation Report (CAPER). Grantees are required to report on the activities undertaken only. HUD systematically reviews and conducts data analysis in order to prepare national and individual grantee performance profiles that are not only used to measure program performance against benchmark goals and objectives, but also to communicate the program's achievement and contributions towards Departmental strategic goals.

Completed technical edits incorporated into forms covered by this proposed information collection, as discussed above.

I. HUD–40110–B, HOPWA Competitive Application & Renewal of Permanent Supportive Housing Project Budget Summary

a. *Cover page description.* The statement, ''Selections of applications for funding under the HOPWA Program are based on the rating factors set forth in the SuperNOFA for Housing and Community Development Programs and the criteria established in the annual HOPWA renewal notice for those permanent supportive housing grantee's seeking renewal funding.'' changed to, ''Selections of applications for funding under the HOPWA Program are based on the rating factors set forth in the published Notice of Funding Award (NOFA) and the criteria established in the annual HOPWA renewal notice for eligible permanent supportive housing grantees seeking renewal funding.'' This edit reflects a change in Departmental process that now each program office releases a NOFA when funding is available to be awarded.

b. *Cover page description.* The public reporting burden was updated on the budget form to show the number of hours it would take to complete the renewal grant application versus the new competitive grant application.

c. *Transparency Act Compliance.* This section of the form was removed. All grantees are required to enter this information into Federal Funding Accountability and Transparency Act (FFATA) Federal Subaward Reporting System (FSRS) so it is no longer necessary to collect this information here.

d. *Applicant Certifications.* Language from Appendix A of 24 CFR part 87 was added to cover the certification regarding lobbying for all applicants.

II. HUD–40110–C, HOPWA Annual Performance Report (APR)

a. Cover page and Overview pages.

i. *Descriptive paragraph.* The number of burden hours was updated.

ii. *Recordkeeping.* HMIS overview of HOPWA elements were updated to reflect current HMIS elements.

iii. *Filing Requirements.* The physical address was updated to include the correct room number.

iv. *Program Income.* The citation was updated to reflect new 2 CFR 200 requirements.

b. Part 2: Grantee Narrative and Assessment

i. E. *Unmet Housing Need.* This section was removed. Grantees are no longer required to report on local unmet need.

c. Part 3: Summary Overview of Grant Activities

i. *Section 3: Households.* The link to HUD-published area median income was updated.

III. HUD–40110–D, HOPWA Consolidated Annual Performance and Evaluation Report (CAPER)

a. Cover page and Overview pages.

i. *Descriptive paragraph.* The number of burden hours was updated.

ii. *Recordkeeping.* HMIS overview of HOPWA elements were updated to reflect current HMIS elements.

iii. *Filing Requirements.* The physical address was updated to include the correct room number.

iv. *Program Income.* The citation was updated to reflect new 2 CFR 200 requirements.

b. Part 1: 5. Grantee Narrative and Performance Assessment

i. d. *Unmet Housing Need.* This section was removed. Grantees are no longer required to report on local unmet need.

c. Part 3. Accomplishment Data

i. *Opening paragraph.* References to reporting in IDIS were removed. Grantees are no longer required to use IDIS for the reporting of Accomplishment Data.

d. Part 7: Summary Overview of Grant Activities

Section 3: Households. The link to HUD-published area median income was updated *Respondents* (*i.e.* affected public): HOPWA competitive and renewal grant applicants, and all HOPWA formula, competitive, and renewal grantees.

Information collection	Number of respondents	Responses per year	Total annual responses	Hours per response	Total hours	Hourly cost	Annualized cost
HOPWA Renewal Application (including HUD–40110–B, narratives, and other requirements listed in the renewal notice)	28.00	1.00	28.00	15.00	420.00	$23.85	$10,017.00
HOPWA Competitive Application (including HUD–40110–B, narratives, and other requirements listed in the NOFA)	40.00	1.00	40.00	45.00	1,800.00	23.85	42,930.00
HUD–40110–C Annual Progress Report (APR)	99.00	1.00	99.00	55.00	5,445.00	23.85	129,863.25
HUD–40110–D Consolidated Annual Performance and Evaluation Report (CAPER)	128.00	1.00	128.00	41.00	5,248.00	23.85	125,164.80
Recordkeeping for Competitive, Renewal, and Formula Grantees	227.00	1.00	227.00	60.00	13,620.00	23.85	324,837.00
Grant Amendments (budget change, extension, or early termination)	30.00	1.00	30.00	6.00	180.00	23.85	4,293.00
Total	552.00	–	552.00	–	26,713.00	–	637,105.05

Renewal grants are awarded for a three-year operating period. Currently, there are 82 eligible renewal grantees. The number of respondents listed for HOPWA renewal applications represents one-third of the renewal grantees, or the estimated number of grantees projected to renew HOPWA grants each year. The number of respondents listed for HOPWA competitive applications represents the number of respondents expected to submit an application if funding becomes available in the next three years. Form HUD–40110–C, the APR is submitted by all renewal and competitive grantees on an annual basis. The number of respondents for the APR include 82 renewal grantees, eight (8) current HOPWA competitive grantees, and nine (9) potential competitive grantees, if funding becomes available.

HOPWA grantees and applicants may be required to respond to more than one piece of information collection. The total number of respondents include: 82 renewal grantees, eight (8) current HOPWA competitive grantees, 40 potential competitive applicants, and 128 current HOPWA formula grantees. The total of 552 total annual responses captures each unique response from the 258 respondents. All annualized costs reflect staff time spent on tasks in the table. The hourly rate is based on a GS–9 for Rest of United States. 26,713 hours * $23.85 = $637,105.05

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

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

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: October 31, 2017.

Anna P. Guido,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2017–24170 Filed 11–6–17; 8:45 am]

BILLING CODE 4210–67–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–442 and 731–TA–1095–1096 (Second Review)]

Lined Paper School Supplies From China and India; Amended Schedule for Expedited Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: October 27, 2017.

FOR FURTHER INFORMATION CONTACT: Calvin Chang (202–205–3062), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: On October 6, 2017, the Commission established a schedule for conducting expedited reviews on lined paper school supplies from China and India. On October 26, 2017, the schedule was published in the **Federal Register** (82 FR 49659). This notice corrects several dates in the previously-published schedule. In particular, the staff report containing information concerning the subject matter of the review will be placed in the nonpublic record on January 3, 2018 and made available to persons on the Administrative Protective Order service list for this review. Comments pursuant to section 207.62(d) of the Commission's rules are due on or before January 9, 2018.

The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

For further information concerning these investigations see the Commission's notice cited above.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.
Issued: November 1, 2017.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2017–24174 Filed 11–6–17; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Cambrex Charles City

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 in accordance with on or before January 8, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. Comments and requests for hearings on applications to import raw material are not appropriate. 72 FR 3417 (January 25, 2007).

SUPPLEMENTARY INFORMATION: The Attorney General has delegated his authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Assistant Administrator of the DEA Diversion Control Division (''Assistant Administrator'') pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on June 12, 2017, Cambrex Charles City, 1205 11th Street, Charles City, Iowa 50616 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid	2010	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
4-Anilino-N-phenethyl-4-piperidine (ANPP)	8333	II
Phenylacetone	8501	II
Cocaine	9041	II
Codeine	9050	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Morphine	9300	II
Oripavine	9330	II
Thebaine	9333	II
Opium extracts	9610	II
Opium fluid extract	9620	II
Opium tincture	9630	II
Opium, powdered	9639	II
Oxymorphone	9652	II
Noroxymorphone	9668	II
Fentanyl	9801	II

The company plans to manufacture the listed controlled substances in bulk for sale to its customers, for dosage form development, for clinical trials, and for use in stability qualification studies.

Dated: October 30, 2017.

Demetra Ashley,

Acting Assistant Administrator.

[FR Doc. 2017–24201 Filed 11–6–17; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1110–0060]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection—CJIS Name Check Form (1–791)

AGENCY: Criminal Justice Information Services Division, Federal Bureau of Investigation, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Federal Bureau of Investigation (FBI), Criminal Justice Information Services (CJIS) Division, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until January 8, 2018.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Gerry Lynn Brovey, Supervisory Information Liaison Specialist, FBI, CJIS, Resources Management Section, Administrative Unit, Module C–2, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306 (facsimile: 304–625–5093) or email *glbrovey@ic.fbi.gov.* Written comments and/or suggestions can also be sent to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503. Additionally, comments may be submitted via email to *OIRA_submission@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Revision of a currently approved collection in use without an OMB control number.

(2) *The Title of the Form/Collection:* CJIS Name Check Request.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* 1–791.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Agencies authorized to submit applicant fingerprints into the Next Generation Identification (NGI) system for noncriminal justice purposes such as employment, benefits, and licensing. This form is completed to obtain a name check for an applicant when the fingerprints have been rejected twice for quality to ensure eligible individuals are not denied employment, benefits, or licensing.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 77,816 respondents will complete each form within approximately 5 minutes.

(6) *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 6,485 total annual burden hours associated with this collection.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405A, Washington, DC 20530.

Dated: November 2, 2017.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2017–24208 Filed 11–6–17; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On October 31, 2017, the Department of Justice lodged a proposed consent decree with the United States District Court for the Southern District of Texas in the lawsuit entitled *United States and the Louisiana Department of Environmental Quality* v. *Exxon Mobil Corp. and ExxonMobil Oil Corp.,* Civil Action No. 4:17-cv-03302.

The United States and Louisiana Department of Environmental Quality filed this lawsuit under the Clean Air Act and Louisiana Environmental Quality Act. The complaint seeks injunctive relief and civil penalties based on violations of the Clean Air Act's New Source Review requirements, New Source Performance Standards, National Emissions Standards for Hazardous Air Pollutants, ''Title V'' program requirements and operating permits, and related Texas and Louisiana state implementation plan requirements. The alleged violations involve flares used at petrochemical manufacturing plants owned and operated by the defendants, Exxon Mobil Corp. and ExxonMobil Oil Corp., in Baytown and Beaumont, Texas, and Baton Rouge, Louisiana. The consent decree requires the defendants to perform injunctive relief, pay a $2,500,000 civil penalty, perform a Supplemental Environmental Project in Baytown, Texas, and two Beneficial Environmental Projects in Louisiana.

The publication of this notice opens a period for public comment on the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and the Louisiana Department of Environmental Quality* v. *Exxon Mobil Corp. and ExxonMobil Oil Corp.,* D.J. Ref. No. 90–5–2–1–10128. All comments must be submitted no later than thirty (30) days after the publication date of this notice.

Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General; U.S. DOJ–ENRD; P.O. Box 7611; Washington, DC. 20044–7611.

During the public comment period, the proposed consent decree may be examined and downloaded at this Justice Department Web site: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed consent decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $36.75 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $23.50.

Thomas P. Carroll,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2017–24125 Filed 11–6–17; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employment and Training Administration

Federal-State Unemployment Compensation Program: Certifications for 2017 Under the Federal Unemployment Tax Act

AGENCY: Employment and Training Administration, DOL.

ACTION: Notice.

SUMMARY: The Secretary of Labor signed the annual certifications under the Federal Unemployment Tax Act, 26 U.S.C. 3301 *et seq.,* thereby enabling employers who make contributions to state unemployment funds to obtain certain credits against their liability for the federal unemployment tax. By letter, the certifications were transmitted to the Secretary of the Treasury. The letter and certifications are printed below.

Signed in Washington, DC, October 31, 2017.

Nancy M. Rooney,

Deputy Assistant Secretary, Employment and Training Administration.

The Honorable Steven T. Mnuchin
Secretary of the Treasury
Department of the Treasury
1500 Pennsylvania Avenue NW.,
Washington, DC 20220

Dear Secretary Mnuchin:

Transmitted herewith are an original and one copy of the certifications of the states and their unemployment compensation laws for the 12-month period ending on October 31, 2017. One certification is required with respect to the normal federal unemployment tax credit by Section 3304 of the Internal Revenue Code of 1986 (IRC), and the other certification is required with respect to the additional tax credit by Section 3303 of the IRC. Both certifications list all 53 jurisdictions.

Sincerely,
R. Alexander Acosta

UNITED STATES DEPARTMENT OF LABOR

OFFICE OF THE SECRETARY

WASHINGTON, DC

CERTIFICATION OF STATES TO THE SECRETARY OF THE TREASURY PURSUANT TO SECTION 3304(c) OF THE INTERNAL REVENUE CODE OF 1986

In accordance with the provisions of Section 3304(c) of the Internal Revenue Code of 1986 (26 U.S.C. 3304(c)), I hereby certify the following named states to the Secretary of the Treasury for the 12-month period ending on October 31, 2017, in regard to the unemployment compensation laws of those states, which heretofore have been approved under the Federal Unemployment Tax Act:

Alabama
Alaska
Arizona
Arkansas
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Georgia
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
Puerto Rico
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Virgin Islands
Washington
West Virginia
Wisconsin
Wyoming

This certification is for the maximum normal credit allowable under Section 3302(a) of the Code.

Signed at Washington, DC, on October 31, 2017.

R. Alexander Acosta

UNITED STATES DEPARTMENT OF LABOR

OFFICE OF THE SECRETARY

WASHINGTON, DC

CERTIFICATION OF STATE UNEMPLOYMENT COMPENSATION LAWS TO THE SECRETARY OF THE TREASURY PURSUANT TO SECTION 3303(b)(1) OF THE INTERNAL REVENUE CODE OF 1986

In accordance with the provisions of paragraph (1) of Section 3303(b) of the Internal Revenue Code of 1986 (26 U.S.C. 3303(b)(1)), I hereby certify the unemployment compensation laws of the following named states, which heretofore have been certified pursuant to paragraph (3) of Section 3303(b) of the Code, to the Secretary of the Treasury for the 12-month period ending on October 31, 2017:

Alabama
Alaska
Arizona
Arkansas
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Georgia

Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Maine
Maryland
Massachusetts
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Pennsylvania
Puerto Rico
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Virgin Islands
Washington
West Virginia
Wisconsin
Wyoming

This certification is for the maximum additional credit allowable under Section 3302(b) of the Code, subject to the limitations of Section 3302(c) of the Code.

Signed at Washington, DC, on October 31, 2017.

R. Alexander Acosta

[FR Doc. 2017–24177 Filed 11–6–17; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Report on Current Employment Statistics

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) revision titled, ''Report on Current Employment Statistics,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995. Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before December 7, 2017.

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* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201706-1220-004* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *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.* 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.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: This ICR seeks approval under the PRA for revisions to the Report on Current Employment Statistics (CES) information collection. The Congress has charged the BLS with the responsibility of collecting and publishing monthly information on employment, average wages received, and the hours worked, by area and by industry. *See* 29 U.S.C. 2. The CES program provides current monthly statistics on employment, hours, and earnings, by industry. The statistics are fundamental inputs in economic decision processes at all levels of government, private enterprise, and organized labor. This information collection has been classified as a revision, because the agency has added additional foreign language versions of the forms. The BLS Authorizing Statute authorizes this information collection. *See* 29 U.S.C. 1, 2.

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 it is approved by the OMB under the PRA 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 1220–0011. The current approval is scheduled to expire on November 30, 2017; however, the DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on June 19, 2017 (82 FR 27874).

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 1220–0011. 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: Report on Current Employment Statistics.

OMB Control Number: 1220–0011.

Affected Public: Private Sector—businesses or other for-profits and not-for-profit institutions; State, Local, and Tribal Governments; and Federal Government.

Total Estimated Number of Respondents: 297,683.

Total Estimated Number of Responses: 3,572,196.

Total Estimated Annual Time Burden: 538,240 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: October 31, 2017.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2017–24176 Filed 11–6–17; 8:45 am]

BILLING CODE 4510–24–P

DEPARTMENT OF LABOR

Office of the Secretary

Office of the Assistant Secretary for Administration and Management; Request for Comments on the Draft DOL FY 2018–2022 Strategic Plan

AGENCY: Office of the Secretary, Labor.

ACTION: Request for comments on the draft DOL FY 2018–2022 strategic plan.

SUMMARY: The Department of Labor (DOL) is seeking public comment on its Draft FY 2018–2022 Strategic Plan.

DATES: Comments must be received by December 7, 2017.

ADDRESSES: Comments can be provided by email to *dolstratplan@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Steve Richardson, Office of the Assistant Secretary for Administration and Management, Performance Management Center, (202) 693–7122.

SUPPLEMENTARY INFORMATION: The Department of Labor's Draft FY 2018–2022 Strategic Plan is provided to satisfy a requirement of the Government Performance and Results Modernization Act (GPRMA) that agency stakeholders have an opportunity to comment. This plan presents the Secretary's vision, the Department's mission, and a description of how component agencies will achieve supporting goals and strategic objectives in the next four years. We look forward to receiving your comments. The text of the draft strategic plan is available in pdf on the Department of Labor Web site at *https://www.dol.gov/agencies/osec/stratplan.*

Dated: November 1, 2017.

Bryan Slater,

Assistant Secretary for Administration and Management.

[FR Doc. 2017–24212 Filed 11–6–17; 8:45 am]

BILLING CODE 4510–04–P

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0212]

Biweekly Notice; Applications and Amendments to Facility Operating Licenses and Combined Licenses Involving No Significant Hazards Considerations

AGENCY: Nuclear Regulatory Commission.

ACTION: Biweekly notice.

SUMMARY: Pursuant to Section 189a. (2) of the Atomic Energy Act of 1954, as amended (the Act), the U.S. Nuclear Regulatory Commission (NRC) is publishing this regular biweekly notice. The Act requires the Commission to publish notice of any amendments issued, or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding the pendency before the Commission of a request for a hearing from any person.

This biweekly notice includes all notices of amendments issued, or proposed to be issued, from October 7 to October 23, 2017. The last biweekly notice was published on October 24, 2017.

DATES: Comments must be filed by December 7, 2017. A request for a hearing must be filed by January 8, 2018.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0212. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* May Ma, Office of Administration, Mail Stop: OWFN–2–A13, 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: Beverly A. Clayton, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3475, email: *beverly.clayton@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2017–0212, facility name, unit number(s), plant docket number, application date, and subject 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 Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0212.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents*'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *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.

B. Submitting Comments

Please include Docket ID NRC–2017–0212, facility name, unit number(s), plant docket number, application date, and subject in your comment submission.

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

comment submissions to remove identifying or contact information.

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

II. Notice of Consideration of Issuance of Amendments to Facility Operating Licenses and Combined Licenses and Proposed No Significant Hazards Consideration Determination

The Commission has made a proposed determination that the following amendment requests involve no significant hazards consideration. Under the Commission's regulations in § 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is shown below.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest.

In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding.

The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or federally recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562, August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public Web site at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some

instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to these license amendment applications, see the application for amendment which is available for public inspection in ADAMS and at the NRC's PDR. For additional direction on accessing information related to this document, see the ''Obtaining Information and Submitting Comments'' section of this document.

DTE Electric Company, Docket No. 50–341, Fermi 2, Monroe County, Michigan

Date of amendment request: August 31, 2017. A publicly-available version is in ADAMS under Accession No. ML17243A422.

Description of amendment request: The proposed amendment would replace existing technical specifications (TS) requirements related to ''operations with a potential for draining the reactor vessel'' (OPDRVs) with new requirements on reactor pressure vessel water inventory control (RPV WIC) to protect Safety Limit 2.1.1.3, which requires reactor vessel water level to be greater than the top of active irradiated fuel.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change replaces existing TS requirements related to OPDRVs with new requirements on RPV WIC that will protect Safety Limit 2.1.1.3. Draining of RPV water inventory in Mode 4 (*i.e.,* cold shutdown) and Mode 5 (*i.e.,* refueling) is not an accident previously evaluated and, therefore, replacing the existing TS controls to prevent or mitigate such an event with a new set of controls has no effect on any accident previously evaluated. RPV water inventory control in Mode 4 or Mode 5 is not an initiator of any accident previously evaluated. The existing OPDRV controls or the proposed RPV WIC controls are not mitigating actions assumed in any accident previously evaluated.

The proposed change reduces the probability of an unexpected draining event (which is not a previously evaluated accident) by imposing new requirements on the limiting time in which an unexpected draining event could result in the reactor vessel water level dropping to the top of the active fuel (TAF). These controls require cognizance of the plant configuration and control of configurations with unacceptably short drain times. These requirements reduce the probability of an unexpected draining event. The current TS requirements are only mitigating actions and impose no requirements that reduce the probability of an unexpected draining event.

The proposed change reduces the consequences of an unexpected draining event (which is not a previously evaluated accident) by requiring an Emergency Core Cooling System (ECCS) subsystem to be operable at all times in Modes 4 and 5. The current TS requirements do not require any water injection systems, ECCS or otherwise, to be Operable in certain conditions in Mode 5. The change in requirement from two ECCS subsystems to one ECCS subsystem in Modes 4 and 5 does not significantly affect the consequences of an unexpected draining event because the proposed Actions ensure equipment is available within the limiting drain time that is as capable of mitigating the event as the current requirements. The proposed controls provide escalating compensatory measures to be established as calculated drain times decrease, such as verification of a second method of water injection and additional confirmations that containment and/or filtration would be available if needed.

The proposed change reduces or eliminates some requirements that were determined to be unnecessary to manage the consequences of an unexpected draining event, such as automatic initiation of an ECCS subsystem and control room ventilation. These changes do not affect the consequences of any accident previously evaluated since a draining event in Modes 4 and 5 is not a previously evaluated accident and the requirements are not needed to adequately respond to a draining event.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change replaces existing TS requirements related to OPDRVs with new requirements on RPV WIC that will protect Safety Limit 2.1.1.3. The proposed change will not alter the design function of the equipment involved. Under the proposed change, some systems that are currently required to be operable during OPDRVs would be required to be available within the limiting drain time or to be in service depending on the limiting drain time. Should those systems be unable to be placed into service, the consequences are no different than if those systems were unable to perform their function under the current TS requirements.

The event of concern under the current requirements and the proposed change is an unexpected draining event. The proposed change does not create new failure mechanisms, malfunctions, or accident initiators that would cause a draining event or a new or different kind of accident not previously evaluated or included in the design and licensing bases.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change replaces existing TS requirements related to OPDRVs with new requirements on RPV WIC. The current requirements do not have a stated safety basis and no margin of safety is established in the licensing basis. The safety basis for the new requirements is to protect Safety Limit 2.1.1.3. New requirements are added to determine the limiting time in which the RPV water inventory could drain to the top of the active fuel in the reactor vessel should an unexpected draining event occur. Plant configurations that could result in lowering the RPV water level to the TAF within one hour are now prohibited. New escalating compensatory measures based on the limiting drain time replace the current controls. The proposed TS establish a safety margin by providing defense-in-depth to ensure that the Safety Limit is protected and to protect the public health and safety. While some less restrictive requirements are proposed for plant configurations with long calculated drain times, the overall effect of the change is to improve plant safety and to add safety margin.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Jon P. Christinidis, DTE Energy, Expert Attorney—Regulatory, 688 WCB, One Energy Plaza, Detroit, MI 48226–1279.

Energy Northwest, Docket No. 50–397, Columbia Generating Station, Benton County, Washington

Date of amendment request: July 25, 2017. A publicly-available version is in ADAMS under Accession No. ML17206A543.

Description of amendment request: The amendment would delete the Note associated with Surveillance Requirement 3.5.1.2 to reflect the Residual Heat Removal system's design, and ensure that the system's operation is consistent with the limiting condition for operation requirements in Technical Specification 3.5.1, ''ECCS [Emergency Core Cooling System]—Operating.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

No physical changes to the facility will occur as a result of this proposed amendment. The proposed change will not alter the physical design. The current Technical Specification Note could make Columbia susceptible to potential water hammer in the Residual Heat Removal system if in the Shutdown Cooling Mode of Residual Heat Removal in Mode 3 when swapping from the Shutdown Cooling to Low Pressure Core Injection mode of Residual Heat Removal system. The proposed License Amendment Request will eliminate the risk for cavitation of the pump and voiding in the suction piping, thereby avoiding potential to damage the Residual Heat Removal system, including water hammer.

Therefore there is no significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously analyzed?

Response: No.

The proposed change does not alter the physical design, safety limits, or safety analysis assumptions associated with the operation of the plant. Accordingly, the change does not introduce any new accident initiators, nor does it reduce or adversely affect the capabilities of any plant structure, system, or component to perform their safety function. Deletion of the Technical Specification Note is appropriate because current Technical Specification could put the plant at risk for potential cavitation of the pump and voiding in the suction piping, resulting in potential to damage the Residual Heat Removal system, including water hammer.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change does not alter the physical design, safety limits, or safety analysis assumptions associated with the operation of the plant. Accordingly, the change does not introduce any new accident initiators, nor does it reduce or adversely affect the capabilities of any plant structure, system, or component to perform their safety function. Deletion of the Technical Specification Note is appropriate because current Technical Specification could put the plant at risk for potential cavitation of the pump and voiding in the suction piping, resulting in potential to damage the Residual Heat Removal system, including water hammer.

Therefore, the proposed change does not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: William A. Horin, Esq., Winston & Strawn, 1700 K Street NW., Washington, DC 20006–3817.

NRC Branch Chief: Robert J. Pascarelli.

Entergy Nuclear Operations, Inc., Docket No. 50–255, Palisades Nuclear Plant (PNP), Van Buren County, Michigan

Date of amendment request: March 30, 2017, as supplemented by letter dated October 17, 2017. Publicly-available versions are in ADAMS under Accession Nos. ML17089A380 and ML17290A342, respectively.

Description of amendment request: The license amendment request was originally noticed in the **Federal Register** on May 23, 2017 (82 FR 23623). The notice is being reissued in its entirety to include the revised scope, description of the amendment request, and proposed no significant hazards consideration determination. The proposed amendment would revise the PNP Cyber Security Plan Milestone 8 full implementation date from December 15, 2017, to March 31, 2019.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes to the CSP [Cyber Security Plan] implementation schedule is administrative in nature. This change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, system, and components relied upon to mitigate the consequences of postulated accidents, and has no impact on the probability or consequences of an accident previously evaluated.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes to the CSP implementation schedule is administrative in nature. This proposed change does not alter accident analysis assumptions, add any initiators, or affect the function of plant systems or the manner in which systems are operated, maintained, modified, tested, or inspected. The proposed change does not require any plant modifications which affect the performance capability of the structures, systems, and components relied upon to mitigate the consequences of postulated accidents and does not create the possibility of a new or different kind of accident from any accident previously evaluated.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

Plant safety margins are established through limiting conditions for operation, limiting safety system settings, and safety limits specified in the technical specifications. The proposed changes to the CSP implementation schedule is administrative in nature. In addition, the milestone date delay for full implementation of the CSP has no substantive impact because other measures have been taken which provide adequate protection during this period of time. Because there is no change to established safety margins as a result of this change, the proposed change does not involve a significant reduction in a margin of safety.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: William Glew, Associate General Counsel—Nuclear, Entergy Services, Inc., 440 Hamilton Ave., White Plains, NY 10601.

NRC Branch Chief: David J. Wrona.

Exelon Generation Company, LLC, Docket No. 50–333, James A. FitzPatrick Nuclear Power Plant, Oswego County, New York

Date of amendment request: September 14, 2017. A publicly-available version is in ADAMS under Accession No. ML17257A193.

Description of amendment request: The amendment would revise the James A. FitzPatrick Nuclear Power Plant

Technical Specifications (TSs) to address secondary containment personnel access door openings.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change addresses conditions during which the secondary containment SR [Surveillance Requirement] 3.6.4.1.3 is not met. The secondary containment is not an initiator of any accident previously evaluated. As a result, the probability of any accident previously evaluated is not increased. The consequences of an accident previously evaluated while utilizing the proposed changes are no different than the consequences of an accident while utilizing the existing four-hour Completion Time for an inoperable secondary containment. As a result, the consequences of an accident previously evaluated are not significantly increased.

Therefore, the proposed changes do not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not alter the protection system design, create new failure modes, or change any modes of operation. The proposed change does not involve a physical alteration of the plant; and no new or different kind of equipment will be installed. Consequently, there are no new initiators that could result in a new or different kind of accident.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change would provide an allowance for brief, inadvertent, simultaneous opening of redundant secondary containment personnel access doors during normal entry and exit conditions. The allowance for both an inner and outer secondary containment access door to be open simultaneously for entry and exit does not significantly impact the ability to maintain the required secondary containment vacuum as the doors are promptly closed after entry or exit, thereby restoring the secondary containment boundary. In addition, brief, inadvertent, simultaneous opening and closing of redundant secondary containment personnel access doors during entry and exit conditions does not significantly impact the ability of the Standby Gas Treatment (SGT) System to maintain the required secondary containment vacuum. Therefore, the safety function of the secondary containment is not affected.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: Donald P. Ferraro, Assistant General Counsel, Exelon Generation Company, LLC, 200 Exelon Way, Suite 305, Kennett Square, PA 19348.

NRC Branch Chief: James G. Danna.

FirstEnergy Nuclear Operating Company, et al., Docket Nos. 50–334 and 50–412, Beaver Valley Power Station, Unit Nos. 1 and 2, Beaver County, Pennsylvania

FirstEnergy Nuclear Operating Company, et al., Docket No. 50–346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

FirstEnergy Nuclear Operating Company, et al., Docket No. 50–440, Perry Nuclear Power Plant, Unit No. 1, Lake County, Ohio

Date of amendment request: August 11, 2017. A publicly-available version is in ADAMS under Accession No. ML17227A172.

Description of amendment request: The proposed amendments change the respective technical specifications (TSs) as follows:

The proposed changes revise Section 1.3, ''Completion Times,'' and Section 3.0, ''LCO Applicability'' of the TSs to clarify the use and application of the TS usage rules, as described below:

- Section 1.3 is revised to clarify ''discovery'' and to discuss exceptions to starting the Completion Time at condition entry.
- Limiting Condition for Operation (LCO) 3.0.4.b is revised to clarify that LCO 3.0.4.a, LCO 3.0.4.b, and LCO 3.0.4.c are independent options.
- Surveillance Requirement (SR) 3.0.3 is revised to allow application of SR 3.0.3 when an SR has not been previously performed and to clarify the application of SR 3.0.3.

The proposed changes to the TSs are consistent with Technical Specification Task Force (TSTF–529), Revision 4, ''Clarify Use and Application Rules.'' The NRC staff issued a safety evaluation for TSTF–529 (ADAMS Accession No. ML16060A440) provided to the Technical Specifications Task Force in a letter dated April 21, 2016 (ADAMS Package Accession No. ML16060A441). This review included a review of the NRC staff's evaluation, as well as the information provided in TSTF–529. The NRC letter dated April 21, 2016, included the model application, No Significant Hazards Consideration (NSHC) Determination, and the model safety evaluation for referencing in license amendment applications. The licensee affirmed the applicability of the model NSHC determination in its application dated August 11, 2017, which is presented below.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below, along with NRC edits in square brackets:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes to Section 1.3 and LCO 3.0.4 have no effect on the requirement for systems to be Operable and have no effect on the application of TS actions. The proposed change to SR 3.0.3 states that the allowance may only be used when there is a reasonable expectation the surveillance will be met when performed. Since the proposed change does not significantly affect system Operability, the proposed change will have no significant effect on the initiating events for accidents previously evaluated and will have no significant effect on the ability of the systems to mitigate accidents previously evaluated.

Therefore, it is concluded that this change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any previously evaluated?

Response: No.

The proposed change to the TS usage rules does not affect the design or function of any plant systems. The proposed change does not change the Operability requirements for plant systems or the actions taken when plant systems are not operable.

Therefore, it is concluded that this change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change clarifies the application of Section 1.3 and LCO 3.0.4 and does not result in changes in plant operation. SR 3.0.3 is revised to allow application of SR 3.0.3 when an SR has not been previously performed if there is reasonable expectation that the SR will be met when performed. This expands the use of SR 3.0.3 while ensuring the affected system is capable of performing

its safety function. As a result, plant safety is either improved or unaffected.

Therefore, it is concluded that this change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David W. Jenkins, FirstEnergy Nuclear Operating Company, FirstEnergy Corporation, 76 South Main Street, Mail Stop A–GO–15, Akron, OH 44308.

NRC Acting Branch Chief: David J. Wrona.

FirstEnergy Nuclear Operating Company, Docket No. 50–440, Perry Nuclear Power Plant, Unit No. 1, Lake County, Ohio

Date of amendment request: September 11, 2017. A publicly-available version is in ADAMS under Accession No. ML17254A495.

Description of amendment request: The proposed amendment would revise the technical specification (TS) requirements in TS 3.3.6.1, ''Primary Containment and Drywell Isolation Instrumentation,'' by adding an Actions note allowing intermittent opening, under administrative control, of penetration flow paths that are isolated. The proposed change is consistent with NRC-approved Technical Specifications Task Force (TSTF) traveler TSTF–306–A, Revision 2, ''Add Action to [Limiting Condition for Operation (LCO)] 3.3.6.1 to Give Option to Isolate the Penetration.''

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed change to adopt TSTF–306–A allows primary containment and drywell isolation valves to be unisolated under administrative controls when the associated isolation instrumentation is not operable. The isolation function is an accident mitigating function and is not an initiator of an accident previously evaluated. Administrative controls are required to be in effect when the valves are unisolated so that the penetration can be rapidly isolated when the need is indicated.

The addition of the note that the penetration flow paths may be unisolated under administrative control provides consistency and clarification with the intermittent opening allowances contained in LCO 3.6.1.3, ''Primary Containment Isolation Valves (PCIVs),'' and LCO 3.6.5.3, ''Drywell Isolation Valves,'' allowed elsewhere in the Technical Specifications (TS).

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed change does not involve any physical changes to plant equipment and does not change the method by which any safety-related system performs its function. The Perry Nuclear Power Plant TS currently allow containment and drywell isolation valves to be open under administrative control after being closed to comply with TS ACTIONS for inoperable valves.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The proposed change does not affect the operation of plant equipment or the function of any equipment assumed in the accident analysis. The allowance to unisolate a penetration flow path will not have a significant effect on the margin of safety because the penetration flow path can be isolated manually, if needed. This change simply provides consistency with what is already allowed elsewhere in the TSs. There are no changes being made to safety analysis assumptions or results. When the valves are unisolated, the design basis function of containment isolation is maintained by administrative controls.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: David W. Jenkins, Attorney, FirstEnergy Corporation, Mail Stop A–GO–15, 76 South Main Street, Akron, OH 44308.

NRC Branch Chief: David J. Wrona.

Florida Power & Light Company, et al., Docket Nos. 50–335 and 50–389, St. Lucie Plant Unit Nos. 1 and 2, St. Lucie County, Florida

Date of amendment request: September 14, 2017. A publicly-available version is in ADAMS under Accession No. ML17257A300.

Description of amendment request: The amendments would revise the Technical Specifications related to inoperable Auxiliary Feedwater pump steam supply.

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The Auxiliary Feedwater (AFW) system is not an initiator of any design basis accident or event, and therefore the proposed changes do not increase the probability of any accident previously evaluated. The proposed changes to address the condition of one inoperable AFW pump due to an inoperable steam supply or one inoperable AFW pump due to an inoperable steam supply concurrent with one inoperable motor-driven AFW pump do not change the response of the plant to any accidents. The proposed changes do not adversely affect accident initiators or precursors nor alter the design assumptions, conditions, and configuration of the facility or the manner in which the plant is operated and maintained. The proposed changes do not adversely affect the ability of structures, systems, and components (SSCs) to perform their intended safety function to mitigate the consequences of an initiating event within the assumed acceptance limits. The proposed changes do not affect the source term, containment isolation, or radiological release assumptions used in evaluating the radiological consequences of any accident previously evaluated. Further, the proposed changes do not increase the types and amounts of radioactive effluent that may be released offsite, nor significantly increase individual or cumulative occupational/public radiation exposures.

Therefore, facility operation in accordance with the proposed license amendments would not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes do not result in a change in the manner in which the AFW system provides plant protection. The AFW system will continue to supply water to the Steam Generators to remove decay heat and other residual heat by delivering at least the minimum required flow rate. There are no design changes associated with the proposed changes. The changes to the required actions and completion times do not change any existing accident scenarios, nor create any new or different accident scenarios. The changes do not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed) or a change in the methods governing normal plant operation. In addition, the changes do not

impose any new or different requirements or eliminate any existing requirements. The changes do not alter assumptions made in the safety analysis. The proposed changes are consistent with the safety analysis assumptions and current plant operating practice.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed changes do not alter the manner in which safety limits, limiting safety system settings or limiting conditions for operation are determined. The safety analysis acceptance criteria are not impacted by these changes. The proposed changes will not result in plant operation in a configuration outside the design basis.

Therefore, operation of the facility in accordance with the proposed amendment will not involve a significant reduction in the margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

Attorney for licensee: William S. Blair, Managing Attorney—Nuclear, Florida Power & Light Company, 700 Universe Boulevard, MS LAW/JB, Juno Beach, FL 33408–0420.

NRC Branch Chief: Undine Shoop.

Pacific Gas and Electric Company, Docket Nos. 50–275 and 50–323, Diablo Canyon Nuclear Power Plant, Units 1 and 2, San Luis Obispo County, California

Date of amendment request: September 28, 2017. A publicly-available version is in ADAMS under Accession No. ML17271A090.

Description of amendment request: The amendments would revise Technical Specifications (TSs) 3.1.4, ''Rod Group Alignment Limits''; 3.1.5, ''Shutdown Bank Insertion Limits''; 3.1.6, ''Control Rod Insertion Limits''; and 3.1.7, ''Rod Position Indication,'' to adopt Technical Specification Task Force (TSTF) Traveler TSTF–547, Revision 1, ''Clarification of Rod Position Requirements (ADAMS Accession No. ML15365A610). The NRC staff approved the TSTF and issued an associated model safety evaluation by letter dated March 4, 2016 (ADAMS Accession No. ML16012A126).

Basis for proposed no significant hazards consideration determination: As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

Control and shutdown rods are assumed to insert into the core to shut down the reactor in evaluated accidents. Rod insertion limits ensure that adequate negative reactivity is available to provide the assumed shutdown margin (SDM). Rod alignment and overlap limits maintain an appropriate power distribution and reactivity insertion profile.

Control and shutdown rods are initiators to several accidents previously evaluated, such as rod ejection. The proposed change does not change the limiting conditions for operation for the rods or make any technical changes to the Technical Specification (TS) Surveillance Requirements (SRs) governing the rods. Therefore, the proposed change has no effect on the probability of any accident previously evaluated.

Revising the TS Actions to provide a limited time to repair rod movement control has no effect on the SDM assumed in the accident analysis as the proposed Actions require verification that SDM is maintained. The effects on power distribution will not cause a significant increase in the consequences of any accident previously evaluated as all TS requirements on power distribution continue to be applicable.

Revising the TS Actions to provide an alternative to frequent use of the moveable incore detector system or the Power Distribution Monitoring System to verify the position of rods with inoperable rod position indicator does not change the requirement for the rods to be aligned and within the insertion limits.

Therefore, the assumptions used in any accidents previously evaluated are unchanged and there is no significant increase in the consequences.

The proposed change to resolve the differences in the TS ensure that the intended Actions are followed when equipment is inoperable. Actions taken with inoperable equipment are not assumptions in the accidents previously evaluated and have no significant effect on the consequences.

The proposed change to eliminate an unnecessary action has no effect on the consequences of accidents previously evaluated as the analysis of those accidents did not consider the use of the action.

The proposed change to increase consistency within the TS has no effect on the consequences of accidents previously evaluated as the proposed change clarifies the application of the existing requirements and does not change the intent.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different accident from any accident previously evaluated?

Response: No.

The proposed change does not involve a physical alteration of the plant (*i.e.,* no new or different type of equipment will be installed). The change does not alter assumptions made in the safety analyses. The proposed change does not alter the limiting conditions for operation for the rods or make any technical changes to the Surveillance Requirements governing the rods. The proposed change maintains or improves safety when equipment is inoperable and does not introduce new failure modes.

Therefore, the proposed change does not create the possibility of a new or different accident from any accident previously evaluated.

3. Does the proposed change involve a significant reduction in a margin of safety?

Response: No.

The proposed change to allow an alternative method of verifying rod position has no effect on the safety margin as actual rod position is not affected. The proposed change to provide time to repair rods that are operable but immovable does not result in a significant reduction in the margin of safety because all rods must be verified to be operable, and all other banks must be within the insertion limits. The remaining proposed changes to make the requirements internally consistent and to eliminate unnecessary actions do not affect the margin of safety as the changes do not affect the ability of the rods to perform their specified safety function.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment requests involve no significant hazards consideration.

Attorney for licensee: Jennifer Post, Esq., Pacific Gas and Electric Company, P.O. Box 7442, San Francisco, California 94120.

NRC Branch Chief: Robert J. Pascarelli.

III. Notice of Issuance of Amendments to Facility Operating Licenses and Combined Licenses

During the period since publication of the last biweekly notice, the Commission has issued the following amendments. The Commission has determined for each of these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant

hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** as indicated.

Unless otherwise indicated, the Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments. If the Commission has prepared an environmental assessment under the special circumstances provision in 10 CFR 51.22(b) and has made a determination based on that assessment, it is so indicated.

For further details with respect to the action see (1) the applications for amendment, (2) the amendment, and (3) the Commission's related letter, Safety Evaluation and/or Environmental Assessment as indicated. All of these items can be accessed as described in the ''Obtaining Information and Submitting Comments'' section of this document.

Entergy Operations, Inc., Docket No. 50–313, Arkansas Nuclear One, Unit 1 (ANO–1), Pope County, Arkansas

Date of amendment request: April 24, 2017.

Brief description of amendment: The amendment revised technical specification requirements regarding steam generator tube inspections and reporting as described in Technical Specifications Task Force (TSTF) Traveler TSTF–510, Revision 2, ''Revision to Steam Generator Program Inspection Frequencies and Tube Sample Selection,'' using the Consolidated Line Item Improvement Process for ANO–1.

Date of issuance: October 10, 2017.

Effective date: As of the date of issuance and shall be implemented within 90 days from the date of issuance.

Amendment No.: 258. A publicly-available version is in ADAMS under Accession No. ML17235A519; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–51: Amendment revised the Operating License and Technical Specifications.

*Date of initial notice in **Federal Register**:* July 5, 2017 (82 FR 31092).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 10, 2017.

No significant hazards consideration comments received: No.

Entergy Operations, Inc., Docket No. 50–368, Arkansas Nuclear One, Unit 2 (ANO–2), Pope County, Arkansas

Date of amendment request: April 24, 2017.

Brief description of amendment: The amendment revised technical specification requirements regarding steam generator tube inspections and reporting as described in Technical Specifications Task Force (TSTF) Traveler TSTF–510, Revision 2, ''Revision to Steam Generator Program Inspection Frequencies and Tube Sample Selection,'' using the Consolidated Line Item Improvement Process for ANO–2.

Date of issuance: October 10, 2017.

Effective date: As of the date of issuance and shall be implemented within 90 days from the date of issuance.

Amendment No.: 307. A publicly-available version is in ADAMS under Accession No. ML17251A211; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. NPF–6: Amendment revised the Operating License and Technical Specifications.

*Date of initial notice in **Federal Register**:* July 5, 2017 (82 FR 31093).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 10, 2017.

No significant hazards consideration comments received: No.

FirstEnergy Nuclear Operating Company and FirstEnergy Nuclear Generation, LLC, Docket Nos. 50–334 and 50–412, Beaver Valley Power Station, Units 1 and 2, Beaver County, Pennsylvania

Date of amendment request: September 28, 2016, as supplemented by letters dated May 20, 2017; September 7, 2017; and September 20, 2017.

Brief description of amendments: The amendments revised the Beaver Valley Power Station, Units 1 and 2, emergency action level (EAL) scheme to one based on Nuclear Energy Institute (NEI) document NEI 99–01, Revision 6, ''Development of Emergency Action Level for Non-Passive Reactors,'' November 2012.

Date of issuance: October 12, 2017.

Effective date: As of the date of issuance and shall be implemented within 180 days of issuance.

Amendment Nos.: 300 (Unit 1) and 189 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML17216A570; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–66 and NPF–73: Amendments revised the Renewed Facility Operating Licenses.

*Date of initial notice in **Federal Register**:* December 20, 2016 (81 FR 92868). The supplemental letters dated May 20, 2017; September 7, 2017; and September 20, 2017, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 12, 2017.

No significant hazards consideration comments received: No.

FirstEnergy Nuclear Operating Company, et al., Docket No. 50–346, Davis-Besse Nuclear Power Station, Unit No. 1, Ottawa County, Ohio

Date of application for amendment: January 11, 2017.

Brief description of amendment: The amendment changes Technical Specification 3.3.1, ''Reactor Protection System (RPS) Instrumentation'' for Davis-Besse Nuclear Power Station, Unit No. 1, by modifying the format and by providing an alternative set of required actions, with longer completion times, to be used when the ultrasonic flow meter is out of service.

Date of issuance: October 19, 2017.

Effective date: As of the date of issuance and shall be implemented within 60 days from the date of issuance.

Amendment No.: 296. A publicly-available version is in ADAMS under Accession No. ML17270A112; documents related to this amendment are listed in the Safely Evaluation enclosed with the amendment.

Renewed Facility Operating License No. NPF–3: The amendment revised the renewed facility operating license and technical specifications.

*Date of initial notice in **Federal Register**:* March 14, 2017 (82 FR 13665).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 19, 2017.

No significant hazards consideration comments received: No.

FirstEnergy Nuclear Operating Company, Docket No. 50–440, Perry Nuclear Power Plant (PNPP), Unit No. 1, Lake County, Ohio

Date of amendment request: April 26, 2017.

Brief description of amendment: The amendment revised the PNPP Environmental Protection Plan (Nonradiological) to clarify and enhance wording, to remove duplicative or outdated program information, and to relieve the burden of submitting unnecessary or duplicative information to the NRC.

Date of issuance: October 19, 2017.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment No.: 178. A publicly-available version is in ADAMS under Accession No. ML17257A098; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Facility Operating License No. NPF–58: Amendment revised the Facility Operating License.

Date of initial notice in ***Federal Register****:* July 5, 2017 (82 FR 31097).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 19, 2017.

No significant hazards consideration comments received: No.

Florida Power & Light Company, et al., Docket Nos. 50–335 and 50–389, St. Lucie Plant, Unit Nos. 1 and 2, St. Lucie County, Florida

Date of amendment request: May 2, 2017.

Brief description of amendments: The amendments revised the Renewed Facility Operating Licenses' ''Fire Protection'' license conditions. The changes incorporated new references into these license conditions that approved a revision to plant modifications previously approved in the March 31, 2016, NRC issuance of National Fire Protection Association Standard 805 license amendments (ADAMS Accession No. ML15344A346).

Date of issuance: October 23, 2017.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: 242 (Unit No. 1) and 193 (Unit No. 2). A publicly-available version is in ADAMS under Accession No. ML17248A379; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Renewed Facility Operating License Nos. DPR–67 and NPF–16: Amendments revised the Renewed Facility Operating Licenses.

Date of initial notice in ***Federal Register****:* July 5, 2017 (82 FR 31098).

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 23, 2017.

No significant hazards consideration comments received: No.

NextEra Energy Duane Arnold, LLC, Docket No. 50–331, Duane Arnold Energy Center (DAEC), Linn County, Iowa

Date of amendment request: March 31, 2017.

Brief description of amendment: The amendment revised the DAEC Plume Exposure Pathway Emergency Planning Zone (EPZ) in its Emergency Preparedness Plan. The DAEC Evacuation Time Estimates Study has also been revised to encompass the changes proposed to the DAEC Plume Exposure Pathway EPZ boundary.

Date of issuance: October 18, 2017.

Effective date: As of the date of issuance and shall be implemented within 180 days.

Amendment No.: 301. A publicly-available version is in ADAMS under Accession No. ML17212A646; documents related to this amendment are listed in the Safety Evaluation enclosed with the amendment.

Renewed Facility Operating License No. DPR–49: The amendment revised the Emergency Plan.

Date of initial notice in ***Federal Register****:* June 6, 2017 (82 FR 26132).

The Commission's related evaluation of the amendment is contained in a Safety Evaluation dated October 18, 2017.

No significant hazards consideration comments received: No.

Tennessee Valley Authority, Docket Nos. 50–390 and 50–391, Watts Bar Nuclear Plant, Units 1 and 2, Rhea County, Tennessee

Date of amendment request: October 20, 2016, as supplemented by letters dated May 5, 2017, and July 21, 2017.

Brief description of amendments: The amendments revised Technical Specification 3.7.12, ''Auxiliary Building Gas Treatment System (ABGTS),'' to provide an action when both trains of the ABGTS are inoperable due to the auxiliary building secondary containment enclosure boundary being inoperable.

Date of issuance: October 17, 2017.

Effective date: As of the date of issuance and shall be implemented within 60 days of issuance.

Amendment Nos.: 116 (Unit 1) and 16 (Unit 2). A publicly-available version is in ADAMS under Accession No. ML17236A057; documents related to these amendments are listed in the Safety Evaluation enclosed with the amendments.

Facility Operating License Nos. NPF–90 and NPF–96: Amendments revised the Facility Operating Licenses and Technical Specifications.

Date of initial notice in ***Federal Register****:* February 28, 2017 (82 FR 12137). The supplemental letters dated May 5, 2017, and July 21, 2017, provided additional information that clarified the application, did not expand the scope of the application as originally noticed, and did not change the NRC staff's original proposed no significant hazards consideration determination as published in the **Federal Register**.

The Commission's related evaluation of the amendments is contained in a Safety Evaluation dated October 17, 2017.

No significant hazards consideration comments received: No.

For the Nuclear Regulatory Commission.

Anne T. Boland,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2017–23749 Filed 11–6–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0215]

Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft guidance; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is revising its licensing guidance for licenses authorizing the use of Yttrium-90 (Y–90) Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®. The NRC is requesting public comment on the draft revision of the licensing guidance (Rev. 10). The document has been revised to significantly update the criteria for training and experience, medical event reporting, inventory requirement specifications, and waste disposal issues. The revised guidance document

also provides new information regarding cremation and autopsy. This guidance is intended for use by NRC applicants, NRC licensees, and the NRC staff.

DATES: Submit comments by January 8, 2018. Comments received after this date will be considered if it is practical to do so, but the NRC is only able to ensure consideration of comments received on or before this date.

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

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0215. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* May Ma, Office of Administration, Mail Stop: OWFN–2–A13, 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: Lisa Dimmick, Office of Nuclear Material Safety and Safeguards; U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–0694; email: *Lisa.Dimmick@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2017–0215 when contacting the NRC about the availability of information regarding this action. You may obtain publicly-available information related to this action by the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0215.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The draft Y–90 Microsphere Brachytherapy Sources and Devices Licensing Guidance, Revision 10, is available in ADAMS under Accession No. ML17107A375.
- *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.

The draft Y–90 Microsphere Brachytherapy Sources and Devices Licensing Guidance, Revision 10, is also available on the NRC's public Web site on the ''Medical Uses Licensee Toolkit'' page at *https://www.nrc.gov/materials/miau/med-use-toolkit.html.*

B. Submitting Comments

Please include Docket ID NRC–2017–0215 in your comment submission.

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

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

II. Background

The NRC is requesting public comment on the draft licensing guidance entitled ''Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance.'' This draft would be revision 10 to this licensing guidance. The licensing guidance provides medical use applicants with an acceptable means of satisfying the requirements for a license for the use of TheraSphere® and SIR-Spheres® and is not intended to be the only means of satisfying the requirements for a license. The licensing guidance provides the NRC with a set of standard criteria for evaluating a license application, although an applicant may submit alternative information and commitments for review by the NRC staff to make a licensing determination unless the information is specifically required by regulation. This guidance will also be available for voluntary use by Agreement States.

The licensing guidance for Y–90 microsphere brachytherapy was initially published in October 2002 and subsequently revised in 2004, 2007, 2008, 2011, 2012, and 2016. Following years of using the current licensing guidance, the NRC staff, stakeholders, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI) have identified numerous issues that need to be addressed. A working group comprised of Agreement State representatives and NRC staff was formed to address identified issues. The document has been revised to significantly update the criteria for training and experience, medical event reporting, inventory requirement specifications, and waste disposal issues. The revised guidance document also provides new information regarding cremation and autopsy.

As described in the draft licensing guidance, the NRC is recommending removal of the alternate, manufacturer provided clinical training pathway to complete the training and experience criteria listed in Section B of the training and experience section of the licensing guidance. During an ACMUI meeting on October 7, 2016 (ML16357A688), the ACMUI recommended that the NRC leave this alternate pathway in the Y–90 microsphere licensing guidance to allow access to Y–90 microsphere brachytherapy in areas where there may not already be approved AUs to supervise new physicians. However, after licensing Y–90 microspheres under 10 CFR 35.1000 for over 10 years, there should be substantial facilities and AUs available to offer training for Y–90 microspheres, similar to other therapeutic modalities, and therefore this pathway should be removed to bring Y–90 microsphere brachytherapy training and experience (T&E) in line with other T&E requirements in 10 CFR part 35.

The manufacturers stated, during the same ACMUI meeting, that training under the supervision of a manufacturer representative should remain as a T&E pathway because their representatives are highly knowledgeable about their devices. The NRC agrees with the manufacturers that the individual who provides the training in the operation of the device should be knowledgeable about the device, and this could include a manufacturer representative as well as the licensees' personnel. The proposed licensing guidance still requires the physician to receive training on the operation of the device. However, the

clinical experience a physician received during the 3 patient cases should include more than operation of the device. At a minimum, the clinical experience should also include evaluation of dose and activity of Y–90 microspheres to be administered to each treatment site, calculating and measuring the activity and safely preparing the Y–90 microspheres to be delivered, using administrative controls to prevent a medical event, and following up and reviewing each patient's case history. During the ACMUI meeting, the ACMUI recommended that this type of training be provided by someone with defined medical experience, but left it up to the NRC to decide what medical experience would be necessary. As this T&E is specific to patient care and patient follow-up, the proposed licensing guidance recommends this type of training be provided by an AU for each type of Y–90 microsphere for which the individual is seeking AU status, similar to how other modalities are regulated in 10 CFR part 35. Additionally, changing the criteria would not preclude the manufacturer representatives from providing training, as is normally done for other therapies.

III. Request for Comments

The NRC is requesting comments on the proposed licensing guidance, entitled, ''Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, Revision 10.'' While the NRC is requesting comments on the entirety of the proposed guidance, the NRC is specifically seeking comments on several sections.

(1) *Recommended Minimum Clinical Experience:* Due to the complexity of delivery of Y–90 microspheres, the licensing guidance historically and currently recommends that a prospective AU demonstrate he or she has clinical experience with the device. The current recommendation is that 3 patient cases for each type of microsphere should be completed for each prospective authorized user prior to approval. This recommendation is similar to requirements in other therapy modalities, such as section 35.390 of title 10 of the *Code of Federal Regulations* (10 CFR). The NRC is seeking specific comments on whether 3 patient cases provide adequate clinical experience for a physician to gain AU status for Y–90 microspheres.

(2) *Adding Authorization for Other Microsphere Type:* The NRC is seeking comments to determine additional training needed when an AU who is already authorized to use one type of microsphere requests authorization for use of another type of microsphere. For instance, are 3 additional cases for the other type of microsphere necessary for the AU to gain the knowledge to safely administer the new microsphere, or should the number of cases be left to the discretion of the supervising AU?

(3) *Written Attestation from Preceptor:* Historically, the NRC has not required a written attestation, signed by a preceptor AU, because there was not a sufficient number of AUs to supervise the training and sign the written attestation. However, given that the NRC and Agreement States have licensed Y–90 microsphere brachytherapy AUs for over 10 years, the NRC is seeking comments to determine if there is anything unique about Y–90 microsphere brachytherapy compared to other types of manual brachytherapy that would obviate the need for a written attestation.

(4) Clinical Experience under the Supervision of a Manufacturer Representative: The proposed licensing guidance removes the alternate pathway, which allows an individual to become an AU for Y–90 microsphere brachytherapy prior to completing any patient cases if the applicant commits that the first three patient cases completed by that AU will be hands-on and supervised in the physical presence of a manufacturer representative. This alternate pathway remained in the licensing guidance for several years because there were a limited number of AUs who were authorized for each type of Y–90 microsphere, which made it difficult for physicians who were seeking authorization to complete the necessary clinical experience described in Section B under the supervision of another AU already authorized for the use of Y–90 microspheres. The NRC is seeking comments on whether completing the recommended clinical experience under the supervision of AU(s) authorized for the type of microsphere for which the new physician is seeking authorization still presents an undue burden on physicians. Further, the NRC is seeking comments on whether any unique characteristics of Y–90 microsphere brachytherapy warrant continuation of this alternate training pathway. Additionally, the NRC is seeking comments on whether finding licensed facilities at which the physicians could complete this clinical experience would be difficult.

(5) Timeliness for Completion of In-Vivo Cases: The NRC is seeking comments on whether the proposed one in-vivo case prior to treating patients would be appropriate if 6 months has passed to ensure recentness of training or whether this proposal could potentially lower licensee's safety standards for the patients being treated.

(6) Medical Event Definition: The NRC is seeking comments on the definition of medical events (ME) for Y–90 microspheres as provided in the proposed guidance. A primary purpose of ME reporting is to identify the cause of the event in order to correct them and prevent their recurrence. In the last 2 years there have been several MEs reported where the administration of the Y–90 results in dose or activity to the lobe opposite the lobe documented in the written directive. The working group was informed that in some instances, the AU may determine in the interventional radiology suite that they may be unable to deliver the amount of Y–90 microspheres to the intended lobe, but still wish to perform the treatment knowing some dose or activity may go to the lobe opposite the lobe documented in the written directive. The NRC is seeking specific comments on whether the delivery of Y–90 microspheres can be controlled to a specific lobe or location as described in the written directive and, if not, whether flexibility in the written directive is necessary to avoid reporting of events that cannot be controlled using the current technology. If flexibility is necessary, the NRC is seeking comments on whether the use of dose or activity ranges in the written directive or an ability to change the written directive in the interventional radiology suite prior to administering the Y–90 microspheres would be adequate. This type of revision could be made verbally by the AU, as long as the revision is documented in writing and signed by the AU within 24 hours of providing the revision verbally, consistent with other uses in 10 CFR part 35.

Dated at Rockville, Maryland, this 1st day of November, 2017.

For the U.S. Nuclear Regulatory Commission.

Daniel S. Collins,

Director, Division of Material Safety, State, Tribal and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2017–24129 Filed 11–6–17; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81995; File No. SR–FINRA–2017–033]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Establish Fees for the New TRACE Security Activity Report and End-of-Day TRACE Transaction File

November 1, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 24, 2017, 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. FINRA has designated the proposed rule change as ''establishing or changing a due, fee or other charge'' under Section 19(b)(3)(A)(ii) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend Rule 7730 to establish fees for the new TRACE Security Activity Report and End-of-Day TRACE Transaction File.

The text of the proposed rule change is available on FINRA's Web site 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's TRACE data product offerings, set forth in Rule 7730 (Trade Reporting and Compliance Engine (TRACE)), include both real-time as well as historic data for most TRACE-eligible securities.[5] The SEC recently approved a new (i) TRACE Security Activity Report and (ii) End-of-Day TRACE Transaction File.[6] The new TRACE Security Activity Report is a monthly report that provides aggregated statistics by security for TRACE-Eligible Securities that are Corporate and Agency Bonds (''CA Bonds''). The report will contain basic descriptive security elements, aggregate par value volume information, number of transactions, number of unique market participant identifiers (''MPIDs''), and top 5 statistics for disseminated transactions in CA Bonds. The new End-of-Day TRACE Transaction File is a daily file available after the TRACE system closes that includes all transaction data disseminated as part of Real-Time TRACE transaction data on that day and is separately available for each data set for which Real-Time TRACE transaction data is available (*i.e.,* the Corporate Bond Data Set, Agency Data Set, SP Data Set, and Rule 144A Data Set).

FINRA is now proposing to amend Rule 7730 to establish fees for the TRACE Security Activity Report and the End-of-Day TRACE Transaction File. FINRA is proposing to establish a fee of $750 per month for receipt of the TRACE Security Activity Report, unless the subscriber is a qualifying tax-exempt organization, in which case FINRA would charge $250 per month. FINRA also is proposing to establish a fee of $750 per month per data set for receipt of the End-of-Day TRACE Transaction File, unless the subscriber is a qualifying tax-exempt organization, in which case FINRA would charge $250 per month per data set. However, subscribers to the Vendor Real-Time Data Feed will not be charged a fee to receive the End-of-Day TRACE Transaction File for the Vendor Real-Time data set(s) to which they have subscribed. FINRA believes that these fees are reasonable, and notes that subscribing to each product is optional for members and others.

FINRA has filed the proposed rule change for immediate effectiveness. The effective date of the proposed rule change will be the date of effectiveness of the TRACE Security Activity Report and End-of-Day TRACE Transaction File.[7]

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,[8] which requires, among other things, that FINRA rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls.

Pursuant to the proposal, FINRA will establish fees for (i) the TRACE Security Activity Report that will provide interested parties with a means for receiving aggregated statistics by security for CA Bonds, and (ii) the End-of-Day TRACE Transaction File that will provide interested parties with an alternative means of receiving the transaction information disseminated each trading day as part of the Real-Time TRACE transaction data product. The TRACE Security Activity Report will be made available to subscribers for a fee of $750 per month, or $250 per month for qualifying tax-exempt organizations. FINRA believes that the proposed fees are reasonable.

The TRACE Security Activity Report is an entirely new report and is not comparable to any current FINRA TRACE data product offering. FINRA cannot at this time estimate the number of persons that may subscribe to the product. However, as indicated by the comment letters received by the Commission on the proposal to adopt

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] Rule 6710 (Definitions) provides that a ''TRACE-Eligible Security'' is a debt security that is United States (''U.S.'') dollar-denominated and issued by a U.S. or foreign private issuer, and, if a ''restricted security'' as defined in Securities Act Rule 144(a)(3), sold pursuant to Securities Act Rule 144A; or is a debt security that is U.S. dollar-denominated and issued or guaranteed by an Agency as defined in paragraph (k) or a Government-Sponsored Enterprise as defined in paragraph (n); or a U.S. Treasury Security as defined in paragraph (p). ''TRACE-Eligible Security'' does not include a debt security that is issued by a foreign sovereign or a Money Market Instrument as defined in paragraph (o).

[6] *Id.* [*sic*]

[7] *See* Securities Exchange Act Release No. 81318 (August 4, 2017), 82 FR 37484 (August 10, 2017) (Order Approving File No. SR–FINRA–2017–021); *see also* Securities Exchange Act Release No. 81114 (July 11, 2017), 82 FR 32728 (July 17, 2017) (Order Approving File No. SR–FINRA–2017–015). FINRA will announce the effective date of each data product in a *Regulatory Notice.* The effective date will be no later than 365 days following Commission approval of each respective data product.

[8] 15 U.S.C. 78*o*–3(b)(5).

the TRACE Security Activity Report,[9] FINRA believes that there will be some interest in the report, including in connection with compliance efforts with respect to regulatory obligations under the Investment Company Act of 1940.[10] FINRA believes that the fee of $750 per month is reasonable given the costs to be incurred by FINRA in developing the report and providing ongoing administrative, functional and technical support to subscribers, while still being priced at an amount that should allow it to be accessible to interested parties. FINRA also notes that, for a qualifying tax-exempt organization, the fee for the TRACE Security Activity Report will be $250 per month. Where feasible, FINRA generally endeavors to provide TRACE data products to qualifying tax-exempt organizations at a reduced subscription fee to encourage access to TRACE data to facilitate bond market research.

The End-of-Day TRACE Transaction File will be made available to subscribers for a fee of $750 per month per data set, $250 per month per data set for qualifying tax-exempt organizations, or at no cost to subscribers to the Vendor Real-Time Data Feed for the Vendor Real-Time data set(s) to which they have subscribed. FINRA believes that the proposed fees are reasonable. FINRA currently charges $1,500 per month per data set for the Vendor Real-Time Data Feed. The End-of-Day TRACE Transaction File will provide access to all of the transactions that were disseminated via the Real-Time Data Feed throughout the trading day, but in a single file only available at the end of the trading day. This option not only provides a lower-priced alternative to the Vendor Real-Time Data Feed, it also requires less technological infrastructure from subscribers. Given the current fees established for this somewhat related product, FINRA believes that the proposed fee of $750 per month per data set is reasonable, which is half of the cost of the Vendor Real-Time Data Feed. FINRA also believes this fee is reasonable given the costs to be incurred by FINRA in developing the report and providing ongoing administrative, functional and technical support to subscribers. FINRA also notes that any current subscribers to Vendor Real-Time Data will not be charged a fee for receipt of the End-of-Day TRACE Transaction File for the Vendor Real-Time data set(s) to which they have subscribed. FINRA cannot at this time estimate the number of persons that may subscribe to the product; however, as stated in the Notice, some market participants have indicated that a simpler alternative that allows them to receive transaction information once a day in an end-of-day file would be useful.[11] As is the case with the TRACE Security Activity Report, FINRA will make the End-of-Day TRACE Transaction File available to qualifying tax-exempt organizations at a reduced subscription fee (of $250 per month per data set) to encourage access to TRACE data to facilitate bond market research.

FINRA believes that the proposed fees are reasonable, and notes that the fees will be applied equally to all similarly situated interested parties that choose to subscribe to either data product. Thus, FINRA believes that the proposed rule change is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal to establish fees in connection with the new TRACE Security Activity Report and End-of-Day TRACE Transaction File applies only to members that choose to subscribe to these data products, and the proposed fees for each data product will apply equally to all similarly situated subscribers. Subscribers to the Vendor Real-Time Data Feed will not be charged a fee to receive the End-of-Day TRACE Transaction File for the Vendor Real-Time data set(s) to which they have subscribed.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and paragraph (f)(2) of Rule 19b–4 thereunder.[13] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–FINRA–2017–033 on the subject line.

Paper Comments

- Send paper comments in triplicate to Robert W. Errett, Deputy Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2017–033. 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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal

[9] *See* letter to Brent J. Fields, Secretary, Commission, from Bennett Golub, Chief Risk Officer, and Alexis Rosenblum, Director, BlackRock, Inc., dated July 20, 2017; and letter to Robert W. Errett, Deputy Secretary, Commission, from Sean Davy, Managing Director, Capital Markets Division, Securities Industry and Financial Markets Association, dated July 20, 2017.

[10] 17 CFR 270.22e–4.

[11] *See* Securities Exchange Act Release No. 80805 (May 30, 2017), 82 FR 25862 (June 5, 2017) (Notice of Filing of File No. SR–FINRA–2017–015) (''Notice'').

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(2).

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–2017–033 and should be submitted on or before November 28, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24131 Filed 11–6–17; 8:45 am]

BILLING CODE 8011–01–P

[14] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32892; 812–14830]

Reinhart Partners, Inc., et al.

November 1, 2017.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act.

APPLICANTS: Reinhart Partners, Inc. (the ''Adviser''), Managed Portfolio Series (the ''Trust''), and Quasar Distributors, LLC (the ''Distributor'').

SUMMARY OF APPLICATION: Applicants request an order (''Order'') that permits: (a) Actively managed series of certain open-end management investment companies to issue shares (''Shares'') redeemable in large aggregations only (''Creation Units''); (b) secondary market transactions in Shares to occur at the next-determined net asset value plus or minus a market-determined premium or discount that may vary during the trading day; (c) certain series to pay redemption proceeds, under certain circumstances, more than seven days from the tender of Shares for redemption; (d) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the series to acquire Shares; and (f) certain series to create and redeem Shares in kind in a master-feeder structure. The Order would incorporate by reference terms and conditions of a previous order granting the same relief sought by applicants, as that order may be amended from time to time (''Reference Order'').[1]

FILING DATE: The application was filed on October 4, 2017 and amended on October 12, 2017.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on November 27, 2017, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: Reinhart Partners, Inc., 1500 West Market Street, Suite 100, Mequon, Wisconsin 53092; Managed Portfolio Series, 615 East Michigan Street, 4th Floor, Milwaukee, Wisconsin 53202; Quasar Distributors, LLC, 777 East Wisconsin Avenue, 6th Floor, Milwaukee, Wisconsin 53202.

FOR FURTHER INFORMATION CONTACT: Courtney S. Thornton, Senior Counsel, at (202) 551–6812, or Robert H. Shapiro, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

[1] Eaton Vance Management, *et al.,* Investment Company Act Rel. Nos. 31333 (Nov. 6, 2014) (notice) and 31361 (Dec. 2, 2014) (order).

Summary of the Application

1. The Trust is registered as an open-end management investment company under the Act and is a statutory trust organized under the laws of Delaware. Applicants seek relief with respect to Reinhart Intermediate Bond NextShares (the ''Initial Fund''). The portfolio positions of each Fund (as defined below) will consist of securities and other assets selected and managed by its Adviser or Subadviser (as defined below) to pursue the Fund's investment objective.

2. The Adviser, a Wisconsin corporation, will be the investment adviser to the Initial Fund. An Adviser (as defined below) will serve as investment adviser to each Fund. The Adviser is, and any other Adviser will be, registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). The Adviser may retain one or more subadvisers (each a ''Subadviser'') to manage the portfolios of the Funds. Any Subadviser will be registered, or not subject to registration, under the Advisers Act.

3. The Distributor is a Delaware limited liability company and a broker-dealer registered under the Securities Exchange Act of 1934 and will act as the principal underwriter of Shares of the Funds. Applicants request that the requested relief apply to any distributor of Shares, whether affiliated or unaffiliated with the Adviser (included in the term ''Distributor''). Any Distributor will comply with the terms and conditions of the Order.

Requested Exemptive Relief

4. Applicants seek the requested Order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act. The requested Order would permit applicants to offer exchange-traded managed funds. Because the relief requested is the same as the relief granted by the Commission under the Reference Order and because the Adviser has entered into, or anticipates entering into, a licensing agreement with Eaton Vance Management, or an affiliate thereof in order to offer exchange-traded managed funds,[2] the Order would incorporate by reference

[2] Eaton Vance Management has obtained patents with respect to certain aspects of the Funds' method of operation as exchange-traded managed funds.

the terms and conditions of the Reference Order.

5. Applicants request that the Order apply to the Initial Fund and to any other existing or future open-end management investment company or series thereof that: (a) Is advised by the Adviser or any entity controlling, controlled by, or under common control with the Adviser (any such entity included in the term ''Adviser''); and (b) operates as an exchange-traded managed fund as described in the Reference Order; and (c) complies with the terms and conditions of the Order and of the Reference Order, which is incorporated by reference herein (each such company or series and Initial Fund, a ''Fund'').[3]

6. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provisions of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of the registered investment company and the general purposes of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors.

7. Applicants submit that for the reasons stated in the Reference Order: (1) With respect to the relief requested pursuant to section 6(c) of the Act, the relief is appropriate, in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act; (2) with respect to the relief request pursuant to section 17(b) of the Act, the proposed transactions are reasonable and fair and do not involve overreaching on the part of any person concerned, are consistent with the policies of each registered investment company concerned and consistent with the general purposes of the Act; and (3) with respect to the relief requested pursuant to section 12(d)(1)(J) of the Act, the relief is consistent with the public interest and the protection of investors.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24138 Filed 11–6–17; 8:45 am]

BILLING CODE 8011–01–P

[3] All entities that currently intend to rely on the Order are named as applicants. Any other entity that relies on the Order in the future will comply with the terms and conditions of the Order and of the Reference Order, which is incorporated by reference herein.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81996; File No. SR–NYSEAMER–2017–27]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Annual Listing Fees for Common Stocks and Warrants

November 1, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 25, 2017, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend annual listing fees for common stocks and warrants. The proposed change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 141 of the NYSE American Company Guide to amend certain of its listing fee provisions. The amended fees will take effect in the 2018 calendar year. The following are the proposed fee increases:

- The annual fee for a common stock with 50 million shares or less outstanding would increase from $35,000 to $40,000.
- The annual fee for a common stock with more than 50 million and up to 75 million shares outstanding would increase from $45,000 to $50,000.
- The annual fee for a common stock with more than 75 million shares outstanding would increase from $50,000 to $60,000.
- The flat annual fee applicable to warrants would increase from $5,000 to $10,000.

As described below, the Exchange proposes to make the aforementioned fee increases to better reflect the Exchange's costs related to listing equity securities and the corresponding value of such listing to issuers.

The Exchange also proposes to remove a number of references in Section 141 to fees that are no longer applicable as they were superseded by new fee rates specified in the rule text.

2. *Statutory Basis*

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[3] in general, and furthers the objectives of Section 6(b)(4)[4] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(5) of the Act,[5] in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(4).

[5] 15 U.S.C. 78f(b)(5).

mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that it is reasonable to increase the annual listing fees for common stocks and warrants because these fees have not been increased since 2015. In that regard, the Exchange notes that, since the fees were last amended, the Exchange has improved and increased the services it provides to listed companies. These improvements include the continued development and enhancement of an interactive web-based platform designed to improve communication between the Exchange and listed companies, the availability to listed companies of the Exchange's new state-of-the-art conference facilities at 11 Wall Street, and continued development and content in an investor relations tool available to all listed companies which provides companies with information enabling them to better understand the trading and ownership of their securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is designed to ensure that the fees charged by the Exchange accurately reflect the services provided and benefits realized by listed companies. The market for listing services is extremely competitive. Each listing exchange has a different fee schedule that applies to issuers seeking to list securities on its exchange. Issuers have the option to list their securities on these alternative venues based on the fees charged and the value provided by each listing. Because issuers have a choice to list their securities on a different national securities exchange, the Exchange does not believe that the proposed fee changes impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[6] of the Act and subparagraph (f)(2) of Rule 19b–4[7] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[8] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2017–27 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2017–27. 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 Web site (*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 Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2017–27, and should be submitted on or before November 28, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24132 Filed 11–6–17; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(2).

[8] 15 U.S.C. 78s(b)(2)(B).

[9] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, November 9, 2017.

PLACE: Closed Commission Hearing Room 10800.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(7), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

Commissioner Stein, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matters of the closed meeting will be:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

CONTACT PERSON FOR MORE INFORMATION: For further information and to ascertain what, if any, matters have been added, deleted or postponed; please contact Brent J. Fields from the Office of the Secretary at (202) 551–5400.

Dated: November 2, 2017.

Brent J. Fields,

Secretary.

[FR Doc. 2017–24260 Filed 11–3–17; 11:15 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–81994; File No. SR–ICEEU–2017–013]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change, Security-Based Swap Submission or Advance Notice Relating to the ICE Clear Europe Procyclicality Framework

November 1, 2017.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on October 23, 2017, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II, and III below, which Items have been prepared primarily by ICE Clear Europe. 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 principal purpose of the changes is to adopt a new policy framework for addressing the procyclicality of its risk management policies by establishing such a framework that addresses the risk appetite, model design, monitoring and assessment and management of procyclicality in the risk models used by ICE Clear Europe to manage default risk.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe 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

(a) Purpose

The purpose of the Procyclicality Framework is to establish an overall framework for the risk appetite, model design, monitoring and assessment and management of procyclicality in the risk models used by ICE Clear Europe to manage default risk. The European Market Infrastructure Regulation [3] (''EMIR'') and related implementing standards require that a central counterparty (''CCP'') ensure that its margin framework provides, among other matters, stable and prudent margin requirements that limit procyclicality to the extent that the soundness and financial security of the central counterparty is not negatively affected.[4] Those standards also require that central counterparties implement at least one of several specified options for mitigating procyclicality with respect to margin requirements.[5]

Although ICE Clear Europe's current margin policies incorporate the anti-procyclicality (''APC'') measures required by EMIR (and ICE Clear Europe does not propose to change such measures at this time), it is proposing to adopt the Procyclicality Framework in order to provide a more defined framework for considering the impact of procyclicality on margining, membership, collateral haircuts, stress testing and concentration risk policies. The framework is designed to set out (1) the aspects of ICE Clear Europe risk policies relevant to procyclicality considerations, (2) how the clearing house will assess procyclicality (both as a qualitative and a quantitative matter) and (3) how the clearing house will factor considerations of procyclicality into its response to emerging risks.

Although ''procyclicality'' is not expressly defined in EMIR, ICE Clear Europe considers procyclicality for purposes of the proposed framework to be the extent to which changes in market conditions can have an effect on a clearing member's ability to manage its liquidity to meet ICE Clear Europe's changing margin requirements. For example, a typical initial margin model would require increased margin in stressed margin conditions, and such increases may potentially occur rapidly and/or over-react to the change in conditions. Such margin increases, in turn, may stress a clearing member's ability to obtain liquidity to meet the increased requirements.

The framework identifies sources of procyclicality, in particular in margin models, stress testing, and collateral haircut policies, and references existing mitigation strategies and stress testing arrangements used by the clearing house. Stress testing scenarios that are based on models similar to margin models but targeting a higher confidence quantile may also be procyclical due to changing market conditions, which may lead to increased stress shock results and therefore in default fund requirements. The framework also addresses how ICE Clear Europe intends to address procyclicality on an ongoing basis. Under the framework, ICE Clear Europe will assess procyclicality by monitoring the 95th percentile expected shortfall of the 5-day percentage change in initial margin (or other relevant risk mitigant) over a rolling 250-day window. ICE Clear Europe established this period, in consultation with Clearing Members, as an appropriate period to reflect short-term spikes in margin. ICE Clear Europe will also monitor the largest percentage changes to facilitate observation of both the maximum and a tail estimate to remove extreme outliers. A red-amber-green (''R–A–G'') escalation framework will be used with respect to implementing APC measures based on certain defined thresholds for expected 95th percentile expected shortfall metric, which are detailed in an appendix to the framework. The escalation framework specifies appropriate responses where the expected shortfall level is at an amber or green level. ICE Clear Europe will assess procyclicality both on a regular basis in monitoring model performance and making margin rate adjustments as part of risk model design.

The framework requires that the model design process take into consideration the procyclicality

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories, as well as various implementing regulations and technical standards.

[4] Article 28 of Commission Delegated Regulation (EU) No 153/2013 of 19 December 2012 supplementing Regulation (EU) No 648/2012 of the European Parliament and of the Council with regard to regulatory technical standards on requirements for central counterparties.

[5] The CPMI–IOSCO Principles for Financial Market Infrastructures (''PFMIs'') similarly provide that a clearing house should limit procyclicality for margin requirements and haircuts. See Principles 5 (Collateral) and 6 (Margin).

characteristics of the model. This should include analysis of the performance of APC measures during periods of increasing volatility (in light of defined threshold conditions specified in the framework), in a range of market conditions, including stress periods.

In addition to the quantitative metrics, there are a number of qualitative inputs that are given consideration under the framework. For example, ICE Clear Europe will take into consideration the periodicity of margin updates and will attempt to mitigate the effect of such updates by communicating any such updates to the cleared markets up to a week in advance. The framework also includes procedures for considering the impact of prospective margin changes on the portfolios of Clearing Members and communicating with Clearing Members that may be significantly affected by such changes. The framework also takes into account the activities of other CCPs in the relevant market (including whether they are implementing APC measures), expectations of market participants, the potential for moral hazard created by an expectation of gradual margin changes (which may not be possible in extreme situations), and the ability of the clearing house to override normal APC measures in extreme circumstances. The framework recognizes that different APC measures and thresholds may be appropriate in different markets based on their historical performance. ICE Clear Europe also takes into account the different liquidity resources and practices of different types of Clearing Members, including banks, broker-dealers and other traders, and the need for margin add-ons to mitigate particular liquidity and/or concentration risks. The framework also sets out APC considerations for new products and material changes in existing products.

Appendices to the framework set out more specific analysis of procyclicality for F&O and CDS products. These analyses are calculated using several different measures of procyclicality, on both whole period and stressed period bases, and both taking into account price change effects and without price change effects, among other factors. The appendices also detail an ICE Clear Europe approach to back testing initial margin calculations, both with and without anti-procyclicality measures under its existing margin policies.

Pursuant to the framework, ICE Clear Europe will disclose its APC methodology on its Web site. The framework further provides for ongoing governance, including the role of the chief risk officer, and review by the relevant product risk committees and board risk committee, as appropriate.

(b) Statutory Basis

ICE Clear Europe believes that the proposed APC framework is consistent with the requirements of Section 17A of the Act [6] and the regulations thereunder applicable to it, including the standards under Rule 17Ad–22.[7] Section 17A(b)(3)(F) of the Act [8] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest. The proposed amendments are designed to enhance and formalize the overall assessment and management of procyclicality in the clearing house's margin and haircut models, among other matters, consistent with regulatory requirements under EMIR. The model is thus intended to strengthen the risk models and procedures already used by the clearing house, particularly the margin model, and limit on an ongoing basis the risks of procyclicality for Clearing Members and the clearing house itself. The framework will also provide greater clarity and transparency for Clearing Members and others as to the clearing house's approach to managing procyclicality. As a result, ICE Clear Europe believes that the proposed changes will promote the prompt and accurate clearance and settlement of cleared transactions, and in general protect investors and the public interest, within the meaning of Section 17A(b)(3)(F).[9] In addition, the changes are consistent with the requirements of Rule 17Ad–22(e)(2),[10] which requires that a clearing agency have governance arrangements that are clear and transparent, prioritize the safety and efficiency of the clearing agency and support the public interest requirements of Section 17A of the Act applicable to clearing agencies and the objectives of owners and participants, among other matters. The amendments also generally strengthen the clearing house's risk management procedures, consistent with the requirements of Rule 17Ad–22(e)(3) and (6).[11]

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed amendments would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes are designed to provide additional protections against the effects of procyclicality by setting forth a methodology to identify and mitigate such risks, consistent with the requirements of EMIR. As such, the changes are intended to reduce the potential liquidity burden for Clearing Members of increases in margin requirements during stressed scenarios. As a result, ICE Clear Europe does not believe the changes will adversely affect the cost to clearing members or other market participants of clearing services. The changes will otherwise not affect the terms or conditions of any cleared contract or the standards or requirements for participation in or use of the Clearing House. The changes should not, in the Clearing House's view, adversely affect competition among Clearing Members, or the ability of market participants to access clearing services generally. As a result, ICE Clear Europe believes that any impact on competition is appropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed changes to the rules have not been solicited or received. ICE Clear Europe will notify the Commission of any written comments received by ICE Clear Europe.

III. Date of Effectiveness of the Proposed Rule Change

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

[6] 15 U.S.C. 78q–1.

[7] 17 CFR 240.17Ad–22.

[8] 15 U.S.C. 78q–1(b)(3)(F).

[9] 15 U.S.C. 78q–1(b)(3)(F).

[10] 17 CFR 240.17Ad–22(e)(2).

[11] 17 CFR 240.17Ad–22(e)(3) and (6).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ICEEU–2017–013 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2017–013 This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change, security-based swap submission or advance notice that are filed with the Commission, and all written communications relating to the proposed rule change, security-based swap submission or advance notice between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's Web site at *https://www.theice.com/notices/Notices.shtml?regulatoryFilings.*

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–ICEEU–2017–013 and should be submitted on or before November 28, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24130 Filed 11–6–17; 8:45 am]

BILLING CODE 8011–01–P

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32894; File No. 812–14776]

Princeton Fund Advisors, LLC. et al.

November 2, 2017.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application for an order under section 12(d)(1)(J) of the Investment Company Act of 1940 (the ''Act'') for an exemption from sections 12(d)(1)(A) and (B) of the Act and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (2) of the Act. The requested order would permit open-end management investment companies registered under the Act to acquire shares of open-end management investment companies registered under the Act that are outside of the same group of investment companies as the acquiring companies.

APPLICANTS: Northern Lights Fund Trust, a Delaware statutory trust registered under the Act as an open-end management investment company with multiple series (the ''Trust''); Princeton Fund Advisors, LLC, a Deleware limited liability company (the ''Adviser''), registered as an investment adviser under the Investment Advisers Act of 1940; and Foreside Distribution Services, L.P., a Delaware limited liability company, and Northern Lights Distributors, LLC, a Nebraska limited liability company (together the ''Distributors''), each registered as a broker-dealer under the Securities Exchange Act of 1934 (''Exchange Act'').

FILING DATES: The application was filed on May 16, 2017 and amended on August 16, 2017.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on November 28, 2017 and should be accompanied by proof of service on the applicants, in the form of an affidavit, or, for lawyers, a certificate of service. Pursuant to Rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: Thompson Hine LLP, 41 South High Street, Suite 1700, Columbus, OH 43215.

FOR FURTHER INFORMATION CONTACT: Rochelle Kauffman Plesset, Senior Counsel, at (202) 551–6840 or David Marcinkus, Branch Chief, at (202) 551–6882 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm,* or by calling (202) 551–8090.

Summary of the Application

1. Applicants request an order to permit (a) registered open-end management investment companies (the ''Investing Funds'') that are not part of the same ''group of investment companies,'' within the meaning of section 12(d)(1)(G)(ii) of the Act, as the Trust, to acquire shares in series of the Trust[1] advised by the Adviser in excess of the limits in sections 12(d)(1)(A) of the Act and (b) the Funds, their principal underwriters and any broker

[1] Applicants request that the order apply to (1) each existing series of the Trust that currently is part of the same ''group of investment companes'' as the Trust and is advised by the Adviser, (2) to any future series of the Trust, and any other existing or future registered open-end management investment companies and any series thereof that are, or may in the future be, advised by the Advisor and that are part of the same group of investment companies (each, a ''Fund'' and collectively the ''Funds''), and (3) any principal underwriter and distributor for a Fund. Certain of the Funds may have obtained exemptions from the Commission necessary to permit their shares to be listed and traded on a national securities exchange at negotiated prices and, accordingly, to operate as an exchange-traded fund (''ETF''). For purposes of the request for relief, the term ''group of investment companies'' means any two or more registered investment companies that hold themselves out to investors as related companies for purposes of investment and investor services.

or dealer registered under the Exchange Act to sell shares of the Funds to the Investing Funds in excess of the limits in section 12(d)(1)(B) of the Act. Applicants also request an order of exemption under sections 6(c) and 17(b) of the Act from the prohibition on certain affiliated transactions in section 17(a) of the Act to the extent necessary to permit the Funds to sell their shares to, and redeem their shares from, the Investing Funds.[2] Applicants state that such transactions will be consistent with the policies of each Fund and each Investing Fund and with the general purposes of the Act and will be based on the net asset values of the Funds.

2. Applicants agree that any order granting the requested relief will be subject to the terms and conditions stated in the application.[3] Such terms and conditions are designed to, among other things, help prevent any potential (i) undue influence over a Fund that is not in the same ''group of investment companies'' as the Investing Fund through control or voting power, or in connection with certain services, transactions, and underwritings, (ii) excessive layering of fees, and (iii) overly complex fund structures, which are the concerns underlying the limits in sections 12(d)(1)(A) and (B) of the Act.

3. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities, or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Section 17(b) of the Act authorizes the Commission to grant an order permitting a transaction otherwise prohibited by section 17(a) if it finds that (a) the terms of the proposed transaction are fair and reasonable and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policies of each registered investment company involved; and (c) the proposed transaction is consistent with the general purposes of the Act. Section 6(c) of the Act permits the Commission to exempt any persons or transactions from any provision of the Act if such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24225 Filed 11–6–17; 8:45 am]

BILLING CODE 8011–01–P

[2] An Investing Fund generally would purchase and sell shares of a Fund that operates as an ETF through secondary market transactions rather than through principal transactions with the Fund. The requested relief is intended to cover tranasactions directly between Funds and Investing Funds. Applicants are not seeking relief from Section 17(a) for, and the requested relief will not apply to, transactions where an ETF could be deemed an affiliated person, or an affiliated person of an affiliated person, of an Investing Fund because an investment adviser to the ETF or an entity controlling, controlled by or under common control with the investment adviser to the ETF is also an investment adviser to the Investing Fund.

[3] Applicants state that each Investing Fund that intends to invest in a Fund in excess of the limits of section 12(d)(1)(A) would be required to sign an agreement that the Investing Fund would adhere to the terms and conditions of the order.

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 32893; File No. 812–14809]

Brandes Investment Trust, et al.

November 2, 2017.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

SUMMARY: Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and (a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act.

APPLICANTS: Brandes Investment Trust (the ''Trust''), Brandes Investment Partners, L.P. (the ''Adviser'') and ALPS Distributors, Inc. (the ''Distributor'').

SUMMARY OF APPLICATION: Applicants request an order (''Order'') that permits: (a) Actively managed series of certain open-end management investment companies to issue shares (''Shares'') redeemable in large aggregations only (''Creation Units''); (b) secondary market transactions in Shares to occur at the next-determined net asset value plus or minus a market-determined premium or discount that may vary during the trading day; (c) certain series to pay redemption proceeds, under certain circumstances, more than seven days from the tender of Shares for redemption; (d) certain affiliated persons of the series to deposit securities into, and receive securities from, the series in connection with the purchase and redemption of Creation Units; (e) certain registered management investment companies and unit investment trusts outside of the same group of investment companies as the series to acquire Shares; and (f) certain series to create and redeem Shares in kind in a master-feeder structure. The Order would incorporate by reference terms and conditions of a previous order granting the same relief sought by applicants, as that order may be amended from time to time (''Reference Order'').[1]

DATES: The application was filed on August 11, 2017.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicants with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on November 27, 2017, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090. Applicants: Thomas Quinlan, Esq., Brandes Investment Partners L.P., 11988 El Camino Real, Suite 600, San Diego, California 92130.

FOR FURTHER INFORMATION CONTACT: Laura J. Riegel, Senior Counsel, at (202) 551–3038, or Robert H. Shapiro, Branch Chief, at (202) 551–6821 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

[1] Eaton Vance Management, *et al.,* Investment Company Act Rel. Nos. 31333 (Nov. 6, 2014) (notice) and 31361 (Dec. 2, 2014) (order).

Applicants

1. The Trust is registered as an open-end management investment company under the Act and is a statutory trust organized under the laws of Delaware. Applicants seek relief with respect to one Fund (as defined below, and that Fund, the ''Initial Fund''). The portfolio positions of each Fund will consist of securities and other assets selected and managed by its Adviser or Subadviser (as defined below) to pursue the Fund's investment objective.

2. The Adviser, a Delaware limited partnership, will be the investment adviser to the Initial Fund. An Adviser (as defined below) will serve as investment adviser to each Fund. The Adviser is, and any other Adviser will be, registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). The Adviser may retain one or more subadvisers (each a ''Subadviser'') to manage the portfolios of the Funds. Any Subadviser will be registered, or not subject to registration, under the Advisers Act.

3. The Distributor is a Colorado corporation and a broker-dealer registered under the Securities Exchange Act of 1934 and will act as the principal underwriter of Shares of the Funds. Applicants request that the requested relief apply to any distributor of Shares, whether affiliated or unaffiliated with the Adviser (included in the term ''Distributor''). Any Distributor will comply with the terms and conditions of the Order.

Applicants' Requested Exemptive Relief

4. Applicants seek the requested Order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and (B) of the Act. The requested Order would permit applicants to offer exchange-traded managed funds. Because the relief requested is the same as the relief granted by the Commission under the Reference Order and because the Adviser has entered into, or anticipates entering into, a licensing agreement with Eaton Vance Management, or an affiliate thereof in order to offer exchange-traded managed funds,[2] the Order would incorporate by reference the terms and conditions of the Reference Order.

5. Applicants request that the Order apply to the Initial Fund and to any other existing or future open-end management investment company or series thereof that: (a) Is advised by the Adviser or any entity controlling, controlled by, or under common control with the Adviser (any such entity included in the term ''Adviser''); and (b) operates as an exchange-traded managed fund as described in the Reference Order; and (c) complies with the terms and conditions of the Order and of the Reference Order, which is incorporated by reference herein (each such company or series and Initial Fund, a ''Fund'').[3]

6. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any class of persons, securities or transactions, from any provisions of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the proposed transaction is consistent with the policies of the registered investment company and the general purposes of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors.

7. Applicants submit that for the reasons stated in the Reference Order: (1) With respect to the relief requested pursuant to section 6(c) of the Act, the relief is appropriate, in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act; (2) with respect to the relief request pursuant to section 17(b) of the Act, the proposed transactions are reasonable and fair and do not involve overreaching on the part of any person concerned, are consistent with the policies of each registered investment company concerned and consistent with the general purposes of the Act; and (3) with respect to the relief requested pursuant to section 12(d)(1)(J) of the Act, the relief is consistent with the public interest and the protection of investors.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–24224 Filed 11–6–17; 8:45 am]

BILLING CODE 8011–01–P

[2] Eaton Vance Management has obtained patents with respect to certain aspects of the Funds' method of operation as exchange-traded managed funds.

[3] All entities that currently intend to rely on the Order are named as applicants. Any other entity that relies on the Order in the future will comply with the terms and conditions of the Order and of the Reference Order, which is incorporated by reference herein.

DEPARTMENT OF STATE

[Public Notice: 10177]

60-Day Notice of Proposed Information Collection: Supplemental SIV Chief of Mission Application

ACTION: Notice of request for public comment.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collection described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on this collection from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collection to OMB.

DATES: The Department will accept comments from the public up to *January 8, 2018*.

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

- *Web:* Persons with access to the Internet may comment on this notice by going to *www.Regulations.gov*. You can search for the document by entering ''Docket Number: DOS–2017–0041'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: PRA_BurdenComments@state.gov*.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to S. Taylor at *PRA_BurdenComments@state.gov*.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Supplemental SIV Chief of Mission Application.
- *OMB Control Number:* 1405–0134.
- *Type of Request:* Revision of a Currently Approved Collection.
- *Originating Office:* Bureau of Consular Affairs, Visa Office (CA/VO/L/R).
- *Form Number:* DS–157.
- *Respondents:* Afghan Special Immigrant Visa Applicants.
- *Estimated Number of Respondents:* 8,700.
- *Estimated Number of Responses:* 8,700.
- *Average Time per Response:* 1 hour.
- *Total Estimated Burden Time:* 8,700 hours.
- *Frequency:* Once per respondent.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collection

Department of State uses Form DS–157 (Supplemental SIV Chief of Mission Application) in order to facilitate the Chief of Mission approval process required for special immigrant visa (SIV) applicants under section 602(b) of the Afghan Allies Protection Act of 2009 (Pub. L. 111–8). The information requested on the form is limited to that which the Chief of Mission uses to evaluate eligibility of SIV applicants. The DS–157 is only being used by Afghan SIV applicants for Chief of Mission approval.

Methodology

Applicants are required to complete the DS–157, along with other required documentation, and to submit their package to the appropriate SIV email address.

Edward Ramotowski,

Deputy Assistant Secretary, Bureau of Consular Affairs, Department of State.

[FR Doc. 2017–24207 Filed 11–6–17; 8:45 am]

BILLING CODE 4710–06–P

DEPARTMENT OF STATE

[Public Notice 10194]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition Determinations: ''Paper Promises: Early American Photography'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Paper Promises: Early American Photography,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owner or custodian. I also determine that the exhibition or display of the exhibit objects at The J. Paul Getty Museum at the Getty Center, Los Angeles, California, from on or about February 27, 2018, until on or about May 27, 2018, and at possible additional exhibitions or venues yet to be determined, is in the national interest.

FOR FURTHER INFORMATION CONTACT: Elliot Chiu in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257–1 of December 11, 2015). I have ordered that Public Notice of these determinations be published in the **Federal Register**.

Alyson Grunder,

Deputy Assistant Secretary for Policy, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2017–24160 Filed 11–6–17; 8:45 am]

BILLING CODE 4710–05–P

TENNESSEE VALLEY AUTHORITY

Sunshine Act Meetings

Meeting No. 17–04

The TVA Board of Directors will hold a public meeting on November 9, 2017, at Pickwick Landing State Park Inn, 116 State Park Lane, Counce, Tennessee 38326. The public may comment on any agenda item or subject at a *public listening session* which begins at 9:30 a.m. (CT). Following the end of the public listening session, the meeting will be called to order to consider the agenda items listed below. On-site registration will be available until 15 minutes before the public listening session begins at 9:30 a.m. (CT). Preregistered speakers will address the Board first. TVA management will answer questions from the news media following the Board meeting.

STATUS: Open.

Agenda

Chair's Welcome

Old Business

Approval of minutes of the August 23, 2017, Board Meeting

New Business

1. Report from President and CEO
2. Report of the Finance, Rates, and Portfolio Committee
   A. Financial Performance Update
   B. Long Term Service Agreement for Lagoon Creek
   C. Large and Medium Transformers
3. Report of the People and Performance Committee
   A. Fiscal Year 2017 Performance and Compensation
   B. CEO Compensation for Fiscal Year 2018
4. Report of the Audit, Risk, and Regulation Committee
5. Report of the Nuclear Oversight Committee
6. Report of the External Relations Committee
   A. Direct-served power arrangements

FOR MORE INFORMATION: Please call TVA Media Relations at (865) 632–6000, Knoxville, Tennessee. People who plan to attend the meeting and have special needs should call (865) 632–6000. Anyone who wishes to comment on any of the agenda in writing may send their comments to: TVA Board of Directors, Board Agenda Comments, 400 West Summit Hill Drive, Knoxville, Tennessee 37902.

Dated: November 2, 2017.

Sherry A. Quirk,

General Counsel.

[FR Doc. 2017–24298 Filed 11–3–17; 11:15 am]

BILLING CODE 8120–08–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2017–82]

Petition for Exemption; Summary of Petition Received; Auburn University

AGENCY: Federal Aviation Administration (FAA), 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. The FAA is republishing this notice to include pertinent information not contained in the previous summary posted to the *Federal Docket* on September 27, 2017, to clarify that the petitioner specifically requests to utilize an FAA-approved Precision Flight Controls model DCX MAX Advanced Aviation Training Device (AATD) for fifty (50) percent of the training requirements described in Part 141 Appendix G, for the Flight Instructor Instrument certification. The FAA letter of authorization for this trainer currently allows for (5) percent of the training requirements.

DATES: Comments on this petition must identify the petition docket number and must be received on or before November 17, 2017.

ADDRESSES: Send comments identified by docket number FAA–2017–0860 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 (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Clarence Garden (202) 267–7489, 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.

Lirio Liu,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2017–0860.

Petitioner: Auburn University.

Section(s) of 14 CFR Affected: 141, Appendix G 4. (4).

Description of Relief Sought: Auburn University seeks exemption from 14 CFR part 141, Appendix G to Part 141, Flight Instructor Instrument (Airplane) Certification Course, 4. (4). Auburn University seeks an exemption to allow an increase in the Flight Simulation Training Device (FSTD) allowance to fifty (50) percent of the 15.0 hours required from five (5) percent currently allowed. More specifically, Auburn University requests to utilize an FAA-approved Precision Flight Controls model DCX MAX Advanced Aviation Training Device (AATD) for fifty (50) percent of the training requirements described in Part 141 Appendix G, for the Flight Instructor Instrument certification. The FAA letter of authorization for this trainer currently allows for (5) percent of the training requirements.

[FR Doc. 2017–24165 Filed 11–6–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Twenty Fifth RTCA SC–223 IPS and AeroMACS Plenary

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

ACTION: Twenty Fifth RTCA SC–223 IPS and AeroMACS Plenary.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Twenty Fifth RTCA SC–223 IPS and AeroMACS Plenary.

DATES: The meeting will be held December 4–8, 2017 9:00 a.m.—5:00 p.m.

ADDRESSES: The meeting will be held at: RTCA Headquarters, 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Rebecca Morrison at *rmorrison@rtca.org* or 202–330–0654, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington DC, 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Twenty Fifth RTCA SC–223 IPS and AeroMACS Plenary. The agenda will include the following:

Monday, December 4, 2017 9:00 a.m.–5:00 p.m.

1. Welcome, Introductions, Administrative Remarks
2. Review of previous meeting notes and action items
3. Review of Current State of Industry Standards
   - A. ICAO WG–I
   - B. AEEC IPS Sub Committee
   - C. EUROCAE WG status
4. Current State of Industry Activities
   - A. SESAR Programs
   - B. ESA IRIS Precursor
   - C. Any Other Activities
5. IPS Technical Discussions
   - A. Review of IPS high level profile (working papers)
   - B. Review of IPS RFC detail Profiles
   - C. Prioritization of additional IETF RFCs for Profiling
6. Any Other Topics of Interest
7. Plans for Next Meetings

Tuesday December 5, 2017 9:00 a.m.–5:00 p.m.

8. Continue with Plenary Agenda

Wednesday, December 6, 2017 9:00 a.m.–5:00 p.m.

9. Continue with Plenary Agenda

Thursday, December 7, 2017 9:00 a.m.–5:00 p.m.

10. Continue with Plenary Agenda

Friday, December 8, 2017 9:00 a.m.–12:00 p.m.

11. Continue with Plenary Agenda
12. Review of Action Items and Meeting Summary
13. Adjourn

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC on November 2, 2017.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division,

Federal Aviation Administration.

[FR Doc. 2017–24158 Filed 11–6–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Twenty First RTCA SC–227 Standards of Navigation Performance Plenary

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

ACTION: Twenty First RTCA SC–227 Standards of Navigation Performance Plenary.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of Twenty First RTCA SC–227 Standards of Navigation Performance Plenary.

DATES: The meeting will be held December 4–8, 2017, 9:00 a.m.–5:00 p.m.

ADDRESSES: The meeting will be held at: RTCA Headquarters, 1150 18th Street NW., Suite 910, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Rebecca Morrison at *rmorrison@rtca.org* or 202–330–0654, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the Twenty First RTCA SC–227 Standards of Navigation Performance Plenary. The agenda will include the following:

Monday December 4, 2017, 9:00 a.m.–5:00 p.m.

1. Welcome and Administrative Remarks
2. Introduction
3. Review of Minutes from Meeting 20.
4. Agenda Overview
5. Schedule
6. New Business
7. Review and disposition comments received from Final Review and Comment period
8. Review updated TOR

Tuesday December 5, 2017, 9:00 a.m.–5:00 p.m.

9. Continue Plenary Agenda

Wednesday December 8, 2017, 9:00 a.m.–5:00 p.m.

10. Continue Plenary Agenda

Thursday December 7, 2017, 9:00 a.m.–5:00 p.m.

11. Continue Plenary Agenda

Friday December 8, 2017, 9:00 a.m.–5:00 p.m.

12. Continue Plenary Agenda
13. Adjourn when Agenda is complete

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC on November 2, 2017.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17, NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2017–24219 Filed 11–6–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–2016–0136]

Pipeline Safety: Meetings of the Gas Pipeline Advisory Committee and the Liquid Pipeline Advisory Committee

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of advisory committee meetings.

SUMMARY: This notice announces both a public meeting of the Technical Pipeline Safety Standards Committee, also known as the Gas Pipeline Advisory Committee (GPAC), to discuss topics and provisions of the proposed rule titled ''Safety of Gas Transmission and Gathering Pipelines,'' and a joint meeting of the GPAC and the Technical Hazardous Liquid Pipeline Safety Standards Committee, also known as the Liquid Pipeline Advisory Committee (LPAC). The purpose of the joint meeting of the GPAC and LPAC is to discuss a variety of policy issues and topics relative to pipeline safety.

DATES: The GPAC and LPAC will meet in a joint session on December 13, 2017, from 8:30 a.m. to 5:00 p.m., and the GPAC only will meet on December 14, 2017, from 8:30 a.m. to 5:00 p.m. and on December 15, 2017, from 8:30 a.m. to 12:00 p.m. ET. Members of the public who wish to attend in person are asked to register no later than December 3, 2017. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify PHMSA by December 3, 2017. For additional information see the **ADDRESSES** section.

ADDRESSES: The meeting will be held at the Hilton Arlington, 950 North Stafford Street, Arlington, Virginia 22203. The agenda and any additional information for the meetings will be published on the following pipeline advisory committee meeting and registration page: *https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=127.*

The meetings will not be webcast; however, presentations will be available on the meeting Web site and posted on the E-Gov Web site, *https://www.regulations.gov/,* under docket number PHMSA–2016–0136 within 30 days following the meeting.

Public Participation

These meetings will be open to the public. Members of the public who attend in person will also be provided

an opportunity to make a statement during the meetings.

Written comments: Persons who wish to submit written comments on the meetings may submit them to the docket in the following ways:

E-Gov Web site: https://www.regulations.gov. This site allows the public to enter comments on any **Federal Register** notice issued by any agency.

Fax: 1–202–493–2251.

Mail: Docket Management Facility; U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., West Building, Room W12–140, Washington, DC 20590–0001.

Hand Delivery: Room W12–140 on the ground level of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except on Federal holidays.

Instructions: Identify the docket number PHMSA–2016–0136 at the beginning of your comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). Therefore, consider reviewing DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000; (65 FR 19477), or view the Privacy Notice at *https://www.regulations.gov* before submitting comments.

Docket: For docket access or to read background documents or comments, go to *https://www.regulations.gov* at any time or to Room W12–140 on the ground level of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

If you wish to receive confirmation of receipt of your written comments, please include a self-addressed, stamped postcard with the following statement: ''Comments on PHMSA–2016-0136.'' The docket clerk will date stamp the postcard prior to returning it to you via the U.S. mail.

Privacy Act Statement

In accordance with 5 U.S.C. 553(c), the DOT solicits comments from the public to better inform its rulemaking process. The DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Services for Individuals with Disabilities: The public meeting will be physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Cheryl Whetsel at *cheryl.whetsel@dot.gov.*

FOR FURTHER INFORMATION CONTACT: For information about the meeting, contact Cheryl Whetsel by phone at 202–366–4431 or by email at *cheryl.whetsel@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Meeting Details and Agenda

The GPAC and LPAC will meet in a joint session to discuss a variety of topics to keep committee members up-to-date on the pipeline safety program and policy issues.

The GPAC will be considering the proposed rule titled ''Safety of Gas Transmission and Gathering Pipelines,'' which was published in the **Federal Register** on April 8, 2016; (81 FR 20722), and the associated regulatory analysis. Based on discussions at the previous GPAC meetings, the topics that will be discussed at this meeting are material documentation and the integrity verification process. If time permits, strengthened assessment requirements would also be discussed.

Prior to these meetings, PHMSA will finalize the agendas and will publish them on the PHMSA meeting page at *https://primis.phmsa.dot.gov/meetings/MtgHome.mtg?mtg=127.*

II. Committee Background

The GPAC and the LPAC are statutorily mandated advisory committees that advise PHMSA on proposed gas pipeline and hazardous liquid pipeline safety standards, respectively, and their associated risk assessments. The committees are established in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, as amended) and 49 U.S.C. 60115. The committees consist of 15 members with membership evenly divided among Federal and State governments, the regulated industry, and the general public. The committees advise PHMSA on the technical feasibility, reasonableness, cost-effectiveness, and practicability of each proposed pipeline safety standard.

Issued in Washington, DC on November 2, 2017, under authority delegated in 49 CFR 1.97.

John A. Gale,

Director, Office of Standards and Rulemaking.

[FR Doc. 2017–24206 Filed 11–6–17; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Performance Review Board Members

AGENCY: Corporate Senior Executive Management Office, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Under provisions of law agencies are required to publish a notice in the **Federal Register** of the appointment of Performance Review Board (PRB) members. This notice announces the appointment of individuals to serve on the PRB of the Department of Veterans Affairs.

DATES: This notice is applicable October 31, 2017.

ADDRESSES: Corporate Senior Executive Management Office, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420.

FOR FURTHER INFORMATION CONTACT: Contact Tia N. Butler, Executive Director, Corporate Senior Executive Management Office (052), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 461–7865.

SUPPLEMENTARY INFORMATION: The membership of the Department of Veterans Affairs Performance Review Board is as follows:

Wright Simpson, Vivieca (Chair)
Breyfogle, Cynthia
Hyduke, Barbara
Rivera, Fernando
Frueh, Michael
Rawls, Cheryl
Hipolit, Richard
Johnson, Harvey
Sullivan, Matthew
Hanson, Anita
Chandler, Richard
Skelly, Jonathan (Alternate)
MacDonald, Edna (Alternate)
Hogan, Michael (Alternate)
Powers, Glenn (Alternate)

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. David J. Schulkin, Secretary of Veterans

Affairs, Department of Veterans Affairs, approved this document on October 31, 2017, for publication.

Authority: 5 U.S.C. 4314(c)(4)

Dated:October 31, 2017.

Jeffrey Martin,

Office Program Manager, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2017–24139 Filed 11–6–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974; Matching Program

AGENCY: Department of Veterans Affairs.

ACTION: Notice of Modified Matching Program.

SUMMARY: The Department of Veterans Affairs (VA) has a current 12 month computer matching agreement (CMA) re-establishment agreement with the Federal Bureau of Prisons (BOP) regarding Veterans who are in Federal prison and are also in receipt of compensation and pension benefits. The purpose of this CMA is to renew the agreement between VA, Veterans Benefits Administration (VBA) and the United States Department of Justice (DOJ), BOP. BOP will disclose information about individuals who are in federal prison. VBA will use this information as a match for recipients of Compensation and Pension benefits for adjustments of awards.

DATES: Comments on this new system of records must be received no later than 30 days after date of publication in the **Federal Register**. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by VA, the new system will become effective 30 days after date of publication in the **Federal Register**. This matching program will be valid for 18 months from the effective date of this notice.

ADDRESSES: Written comments may be submitted through *www.Regulations.gov*; by mail or hand-delivery to Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Ave. NW., Room 1064, Washington, DC 20420; or by fax to (202) 273–9026 (not a toll-free number). Comments should indicate that they are submitted in response to CMA re-establishment agreement with the Federal BOP. Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, comments may be viewed online at *www.Regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Eric Robinson (VBA), 202–443–6016 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: This agreement continues an arrangement for a periodic computer-matching program between VA (VBA as the matching recipient agency) and DOJ (BOP as the matching source agency). This agreement sets forth the responsibilities of VBA and BOP with respect to information disclosed pursuant to this agreement and takes into account both agencies' responsibilities under the Privacy Act of 1974, 5 U.S.C. 552a, as amended by the Computer Matching and Privacy Protection Act of 1988, as amended, and the regulations promulgated thereunder, including computer matching portions of a revision of OMB Circular No. A–130, 65 FR 77677 dated December 12, 2000.

Participating Agencies: VA (VBA as the matching recipient agency) and DOJ (BOP as the matching source agency).

Authority for Conducting the Matching Program: The legal authority to conduct this match is 38 U.S.C. 1505, 5106, and 5313. Section 5106 requires any Federal department or agency to provide VA such information as VA requests for the purposes of determining eligibility for, or the amount of VA benefits, or verifying other information with respect thereto. Section 1505 provides that no VA pension benefits shall be paid to or for any person eligible for such benefits, during the period of that person's incarceration as the result of conviction of a felony or misdemeanor, beginning on the 61st day of incarceration. Section 5313 provides that VA compensation or dependency and indemnity compensation above a specified amount shall not be paid to any person eligible for such benefit, during the period of that person's incarceration as the result of conviction of a felony, beginning on the 61st day of incarceration.

Purpose(s): The purpose of this matching program between VBA and BOP is to identify those Veterans and VA beneficiaries who are in receipt of certain VA benefit payments and who are confined (see Article II.G.) for a period exceeding 60 days due to a conviction for a felony or a misdemeanor. VBA has the obligation to reduce or suspend compensation, pension, and dependency and indemnity compensation benefit payments to Veterans and VA beneficiaries on the 61st day following conviction and incarceration in a Federal, State, or Local institution for a felony or a misdemeanor. VBA will use the BOP records provided in the match to update the master records of Veterans and VA beneficiaries receiving benefits and to adjust their VA benefits, accordingly, if needed.

Categories of Individuals: Veterans who have applied for compensation for service-connected disability under 38 U.S.C. Chapter 11; Veterans who have applied for nonservice-connected disability under 38 U.S.C. Chapter 15; Veterans entitled to burial benefits under 38 U.S.C. Chapter 23; Surviving spouses and children who have claimed pensions based on nonservice-connected death of a Veteran under 38 U.S.C. Chapter 15; Surviving spouses and children who have claimed death compensation based on service-connected death of a Veteran under 38 U.S.C. Chapter 11; Surviving spouses and children who have claimed dependency and indemnity compensation for service connected death of a Veteran under 38 U.S.C. Chapter 13; Parents who have applied for death compensation based on service connected death of a Veteran under 38 U.S.C. Chapter 11; Parents who have applied for dependency and indemnity compensation for service-connected death of a Veteran under 38 U.S.C. Chapter 13; Individuals who applied for educational assistance benefits administered by VA under title 38 of the U.S. Code; Individuals who applied for educational assistance benefits maintained by the Department of Defense under title 10 of the U.S. Code that are administered by VA; Veterans who apply for training and employers who apply for approval of their programs under the provisions of the Emergency Veterans' Job Training Act of 1983, Public Law 98–77; Any VA employee who generates or finalizes adjudicative actions using the Benefits Delivery Network (BDN) or the Veterans Service Network (VETSNET) computer processing systems; Veterans who apply for training and employers who apply for approval of their programs under the provisions of the Service Members Occupational Conversion and Training Act of 1992, Public Law 102–484; Representatives of individuals covered by the system.

CATEGORIES OF RECORDS:

The record, or information contained in the record, may include identifying information (*e.g.,* name, address, social security number); military service and active duty separation information (*e.g.,* name, service number, date of birth, rank, sex, total amount of active service, branch of service, character of service, pay grade, assigned separation reason,

service period, whether Veteran was discharged with a disability, reenlisted, received a Purple Heart or other military decoration); payment information (*e.g.,* Veteran payee name, address, dollar amount of readjustment service pay, amount of disability or pension payments, number of non-pay days, any amount of indebtedness (accounts receivable) arising from title 38 U.S.C. benefits and which are owed to the VA); medical information (*e.g.,* medical and dental treatment in the Armed Forces including type of service-connected disability, medical facilities, or medical or dental treatment by VA health care personnel or received from private hospitals and health care personnel relating to a claim for VA disability benefits or medical or dental treatment); personal information (*e.g.,* marital status, name and address of dependents, occupation, amount of education of a Veteran or a dependent, dependent's relationship to Veteran); education benefit information (*e.g.,* information arising from utilization of training benefits such as a Veteran trainee's induction, reentrance or dismissal from a program or progress and attendance in an education or training program): Applications for compensation, pension, education, and vocational rehabilitation benefits and training which may contain identifying information, military service and active duty separation information, payment information, medical and dental information, personal and education benefit information relating to a Veteran or beneficiary's incarceration in a penal institution (*e.g.,* name of incarcerated Veteran or beneficiary, claims folder number, name and address of penal institution, date of commitment, type of offense, scheduled release date, Veteran's date of birth, beneficiary relationship to Veteran and whether Veteran or beneficiary is in a work release or half-way house program, on parole or has been released from incarceration); the VA employee's BDN or VETSNET identification numbers, the number and kind of actions generated and/or finalized by each such employee, the compilation of cases returned for each employee.

SYSTEM(S) OF RECORDS:

Compensation, Pension, Education, and Vocational Rehabilitation and Employment Records—VA (58 VA 21/22/28)'', published at 74 FR 29275 (June 19, 2009), last amended at 77 FR 42593 on July 19, 2012. Justice/BOP–005,'' published on June 7, 1984 (48 FR 2371 1), republished on May 9, 2002 (67 FR 31371), January 25, 2007 (72 FR 3410) and April 26, 2012 (77 FR 24982) and last modified on April 18, 2016 (81 FR 22639), routine use (i).

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on June 12, 2017 for publication.

Dated: November 2, 2017.

Kathleen M. Manwell,

Program Analyst, VA Privacy Service, Office of Privacy Information and Identity Protection, Office of Quality, Privacy and Risk, Office of Information and Technology, Department of Veterans Affairs.

[FR Doc. 2017–24168 Filed 11–6–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Joint Biomedical Laboratory Research and Development and Clinical Science Research and Development Services Scientific Merit Review Board Amended Notice of Meetings

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463; Title 5 U.S.C. App. 2 (Federal Advisory Committee Act) that the subcommittees of the Joint Biomedical Laboratory Research and Development and Clinical Science Research and Development Services Scientific Merit Review Board (JBL/CS SMRB) will meet from 8 a.m. to 5 p.m. on the dates indicated below (unless otherwise listed):

Subcommittee	Date	Location
Surgery	November 15, 2017	20 F Conference Center.
Pulmonary Medicine	November 15, 2017	20 F Conference Center.
Infectious Diseases—B	November 16, 2017	20 F Conference Center.
Oncology—A/D	November 16, 2017	20 F Conference Center.
Hematology	November 17, 2017	20 F Conference Center.
Oncology—C	November 17, 2017	20 F Conference Center.
Cellular & Molecular Medicine	November 20, 2017	VA Central Office.*
Oncology—B	November 20, 2017	20 F Conference Center.
Infectious Diseases—A	November 21, 2017	VA Central Office.*
Epidemiology	November 28, 2017	VA Central Office.*
Mental Health & Behavioral Sciences—A	November 28, 2017	20 F Conference Center.
Nephrology	November 28, 2017	20 F Conference Center.
Oncology—E	November 28, 2017	20 F Conference Center.
Immunology & Dermatology—A	November 29, 2017	20 F Conference Center.
Mental Health & Behavioral Sciences—B	November 29–30, 2017	20 F Conference Center.
Cardiovascular Studies—A	November 30, 2017	20 F Conference Center.
Endocrinology—A	November 30, 2017	20 F Conference Center.
Neurobiology—C	November 30, 2017	20 F Conference Center.
Neurobiology—A	December 1, 2017	20 F Conference Center.
Neurobiology—E	December 1, 2017	20 F Conference Center.
Endocrinology—B	December 4, 2017	20 F Conference Center.
Neurobiology—B	December 5, 2017	20 F Conference Center.
Special Panel for Sheep Review	December 5, 2017	VA Central Office.*
Neurobiology—F	December 6, 2017	VA Central Office.*
Cardiovascular Studies—B	December 7, 2017	20 F Conference Center.
Gastroenterology	December 7, 2017	20 F Conference Center.
Neurobiology—D	December 8, 2017	20 F Conference Center.
Gulf War Research	December 8, 2017	VA Central Office.*
Special Emphasis Panel on Million Veteran Prog Proj	January 11–12, 2018	20 F Conference Center.
Eligibility	January 19, 2018	20 F Conference Center.

Subcommittee	Date	Location
JBL/CS SMRB	January 25, 2018	VA Central Office.*

* Teleconference.

The addresses of the meeting sites are:

20 F Conference Center, 20 F Street NW., Washington, DC

VA Central Office, 1100 First Street NE., Suite 600, Washington, DC

The purpose of the subcommittees is to provide advice on the scientific quality, budget, safety and mission relevance of investigator-initiated research proposals submitted for VA merit review evaluation. Proposals submitted for review include various medical specialties within the general areas of biomedical, behavioral and clinical science research.

These subcommittee meetings will be closed to the public for the review, discussion, and evaluation of initial and renewal research proposals, which involve reference to staff and consultant critiques of research proposals. Discussions will deal with scientific merit of each proposal and qualifications of personnel conducting the studies, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. Additionally, premature disclosure of research information could significantly obstruct implementation of proposed agency action regarding the research proposals. As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing the subcommittee meetings is in accordance with Title 5 U.S.C. 552b(c)(6) and (9)(B).

Those who would like to obtain a copy of the minutes from the closed subcommittee meetings and rosters of the subcommittee members should contact Holly Krull, Ph.D., Manager, Merit Review Program (10P9B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, at (202) 632–8522 or email at *holly.krull@va.gov.*

Dated: November 2, 2017.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2017–24169 Filed 11–6–17; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 82 Tuesday,

No. 214 November 7, 2017

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 484

Medicare and Medicaid Programs; CY 2018 Home Health Prospective Payment System Rate Update and CY 2019 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 484

[CMS–1672–F]

RIN 0938–AT01

Medicare and Medicaid Programs; CY 2018 Home Health Prospective Payment System Rate Update and CY 2019 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the home health prospective payment system (HH PPS) payment rates, including the national, standardized 60-day episode payment rates, the national per-visit rates, and the non-routine medical supply (NRS) conversion factor, effective for home health episodes of care ending on or after January 1, 2018. This rule also: Updates the HH PPS case-mix weights using the most current, complete data available at the time of rulemaking; implements the third year of a 3-year phase-in of a reduction to the national, standardized 60-day episode payment to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between calendar year (CY) 2012 and CY 2014; and discusses our efforts to monitor the potential impacts of the rebasing adjustments that were implemented in CY 2014 through CY 2017. In addition, this rule finalizes changes to the Home Health Value-Based Purchasing (HHVBP) Model and to the Home Health Quality Reporting Program (HH QRP). We are not finalizing the implementation of the Home Health Groupings Model (HHGM) in this final rule.

DATES: These regulations are effective on January 1, 2018.

FOR FURTHER INFORMATION CONTACT:

For general information about the Home Health Prospective Payment System (HH PPS), please send your inquiry via email to: *HomehealthPolicy@cms.hhs.gov.*

For information about the Home Health Value-Based Purchasing (HHVBP) Model, please send your inquiry via email to: *HHVBPquestions@cms.hhs.gov.*

Contact Joan Proctor, (410) 786–0949 for information about the Home Health Quality Reporting Program (HH QRP).

SUPPLEMENTARY INFORMATION: Wage index addenda will be available only through the internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/coding_billing.html.*

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Acronyms

In addition, because of the many terms to which we refer by abbreviation in this final rule, we are listing these abbreviations and their corresponding terms in alphabetical order below:

ACH LOS Acute Care Hospital Length of Stay
ADL Activities of Daily Living
AM–PAC Activity Measure for Post-Acute Care
APR DRG All-Patient Refined Diagnosis-Related Group
APU Annual Payment Update
ASPE Assistant Secretary for Planning and Evaluation
BBA Balanced Budget Act of 1997, Public Law 105–33
BBRA Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (Pub. L. 106–113)
BIMS Brief Interview for Mental Status
BLS Bureau of Labor Statistics
CAD Coronary Artery Disease
CAH Critical Access Hospital
CAM Confusion Assessment Method
CARE Continuity Assessment Record and Evaluation
CASPER Certification and Survey Provider Enhanced Reports
CBSA Core-Based Statistical Area
CCN CMS Certification Number
CHF Congestive Heart Failure
CMI Case-Mix Index
CMP Civil Money Penalty
CMS Centers for Medicare & Medicaid Services
CoPs Conditions of Participation
COPD Chronic Obstructive Pulmonary Disease
CVD Cardiovascular Disease
CY Calendar Year
DM Diabetes Mellitus
DRA Deficit Reduction Act of 2005, Public Law 109–171, enacted February 8, 2006
DRG Diagnosis-Related Group
DTI Deep Tissue Injury
EOC End of Care
FDL Fixed Dollar Loss
FI Fiscal Intermediaries
FR Federal Register
FY Fiscal Year
HAVEN Home Assessment Validation and Entry System
HCC Hierarchical Condition Categories
HCIS Health Care Information System
HH Home Health
HHA Home Health Agency

HHCAHPS Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey
HH PPS Home Health Prospective Payment System
HHGM Home Health Groupings Model
HHQRP Home Health Quality Reporting Program
HHRG Home Health Resource Group
HHVBP Home Health Value-Based Purchasing
HIPPS Health Insurance Prospective Payment System
HVBP Hospital Value-Based Purchasing
IADL Instrumental Activities of Daily Living
ICD–9–CM International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–CM International Classification of Diseases, Tenth Revision, Clinical Modification
IH Inpatient Hospitalization
IMPACT Act Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185)
IPPS [Acute Care Hospital] Inpatient Prospective Payment System
IPR Interim Performance Report
IRF Inpatient Rehabilitation Facility
IRF–PAI IRF Patient Assessment Instrument
IV Intravenous
LCDS LTCH CARE Data Set
LEF Linear Exchange Function
LTCH Long-Term Care Hospital
LUPA Low-Utilization Payment Adjustment
MACRA Medicare Access and CHIP Reauthorization Act of 2015
MAP Measure Applications Partnership
MDS Minimum Data Set
MFP Multifactor productivity
MMA Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, enacted December 8, 2003
MSA Metropolitan Statistical Area
MSS Medical Social Services
NQF National Quality Forum
NQS National Quality Strategy
NRS Non-Routine Supplies
OASIS Outcome and Assessment Information Set
OBRA Omnibus Budget Reconciliation Act of 1987, Public Law 100–2–3, enacted December 22, 1987
OCESAA Omnibus Consolidated and Emergency Supplemental Appropriations Act, Public Law 105–277, enacted October 21, 1998
OES Occupational Employment Statistics
OIG Office of Inspector General
OLS Ordinary Least Squares
OT Occupational Therapy
OMB Office of Management and Budget
PAC Post-Acute Care
PAC–PRD Post-Acute Care Payment Reform Demonstration
PAMA Protecting Access to Medicare Act of 2014
PEP Partial Episode Payment Adjustment
PHQ–2 Patient Health Questionnaire-2
PPOC Primary Point of Contact
PPS Prospective Payment System
PRA Paperwork Reduction Act
PRRB Provider Reimbursement Review Board
PT Physical Therapy
PY Performance Year
QAP Quality Assurance Plan
QIES Quality Improvement Evaluation System
QRP Quality Reporting Program
RAP Request for Anticipated Payment
RF Renal Failure
RFA Regulatory Flexibility Act, Public Law 96—354
RHHIs Regional Home Health Intermediaries
RIA Regulatory Impact Analysis
ROC Resumption of Care
SAF Standard Analytic File
SLP Speech-Language Pathology
SN Skilled Nursing
SNF Skilled Nursing Facility
SOC Start of Care
SSI Surgical Site Infection
TEP Technical Expert Panel
TPS Total Performance Score
UMRA Unfunded Mandates Reform Act of 1995
VAD Vascular Access Device
VBP Value-Based Purchasing

I. Executive Summary

A. Purpose

This final rule updates the payment rates for home health agencies (HHAs) for calendar year (CY) 2018, as required under section 1895(b) of the Social Security Act (the Act). This final rule also updates the case-mix weights under section 1895(b)(4)(A)(i) and (b)(4)(B) of the Act for CY 2018 and implements a 0.97 percent reduction to the national, standardized 60-day episode payment amount to account for case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014, under the authority of section 1895(b)(3)(B)(iv) of the Act. Additionally, this rule finalizes changes to the Home Health Value Based Purchasing (HHVBP) Model under the authority of section 1115A of the Act, and Home Health Quality Reporting Program (HH QRP) requirements under the authority of section 1895(b)(3)(B)(v) of the Act. We are not finalizing the implementation of the Home Health Groupings Model (HHGM) in this final rule. We received a number of comments from the public that we would like to take into further consideration.

B. Summary of the Major Provisions

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized our proposal to recalibrate the case-mix weights every year with the most current and complete data available at the time of rulemaking. In section III.B. of this final rule, we are recalibrating the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget-neutral manner. Also in section III.B. of this final rule, as finalized in the CY 2016 HH PPS final rule (80 FR 68624), we are implementing a reduction to the national, standardized 60-day episode payment rate for CY 2018 of 0.97 percent to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014. In section III.C. of this final rule, we update the payment rates under the HH PPS by 1 percent for CY 2018 in accordance with section 411(d) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015) which amended section 1895(b)(3)(B) of the Act. Additionally, section III.C. of this final rule, updates the CY 2018 home health wage index using FY 2014 hospital cost report data. In section III.D. of this final rule, we note that the fixed-dollar loss ratio remains 0.55 for CY 2018 to pay up to, but no more than, 2.5 percent of total payments as outlier payments, as required by section 1895(b)(5)(A) of the Act.

In section IV of this final rule, we are finalizing changes to the Home Health Value-Based Purchasing (HHVBP) Model implemented January 1, 2016. We are amending the definition of ''applicable measure'' to mean a measure for which a competing HHA has provided a minimum of 40 completed surveys for Home Health Care Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) measures, beginning with Performance Year (PY) 1, for purposes of receiving a performance score for any of the HHCAHPS measures, and for PY 3 and subsequent years, we are finalizing the removal of the Outcome and Assessment Information Set (OASIS)-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures.

In section V. of this final rule, we are finalizing updates to the Home Health Quality Reporting Program, including: The replacement of one quality measure and the adoption of two new quality measures, data submission requirements, exception and extension requirements, and reconsideration and appeals procedures. We have also finalized the removal of 235 data elements from 33 current OASIS items, effective with all HHA assessments on or after January 1, 2019. We are not finalizing the standardized patient assessment data elements that we proposed to adopt for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments.

C. Summary of Costs and Benefits

TABLE 1—SUMMARY OF COSTS AND TRANSFERS

Provision description	Costs	Transfers
CY 2018 HH PPS Payment Rate Update.	.....	The overall economic impact of the HH PPS payment rate update is an estimated −$80 million (−0.4 percent) in payments to HHAs.
CY 2018 HHVBP Model	.....	The overall economic impact of the HHVBP Model provision for CY 2018 through 2022 is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry (none of which is attributable to the changes finalized in this final rule). As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to the HHAs competing in the model.
CY 2019 HH QRP	The overall economic impact of the HH QRP changes is a savings to HHAs of an estimated $146.0 million, beginning January 1, 2019.	

II. Background

A. Statutory Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, enacted August 5, 1997), significantly changed the way Medicare pays for Medicare home health services. Section 4603 of the BBA mandated the development of the HH PPS. Until the implementation of the HH PPS on October 1, 2000, HHAs received payment under a retrospective reimbursement system.

Section 4603(a) of the BBA mandated the development of a HH PPS for all Medicare-covered home health services provided under a plan of care (POC) that were paid on a reasonable cost basis by adding section 1895 of the Act, entitled ''Prospective Payment For Home Health Services.'' Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. Section 1895(b)(2) of the Act requires that, in defining a prospective payment amount, the Secretary shall consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services.

Section 1895(b)(3)(A) of the Act requires the following: (1) The computation of a standard prospective payment amount include all costs for HH services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; and (2) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs.

Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the home health applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of an appropriate case-mix change adjustment factor for significant variation in costs among different units of services.

Similarly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level. Under section 1895(b)(4)(C) of the Act, the wage-adjustment factors used by the Secretary may be the factors used under section 1886(d)(3)(E) of the Act.

Section 1895(b)(5) of the Act gives the Secretary the option to make additions or adjustments to the payment amount otherwise paid in the case of outliers due to unusual variations in the type or amount of medically necessary care. Section 3131(b)(2) of the Affordable Care Act revised section 1895(b)(5) of the Act so that total outlier payments in a given year would not exceed 2.5 percent of total payments projected or estimated. The provision also made permanent a 10 percent agency-level outlier payment cap.

In accordance with the statute, as amended by the BBA, we published a final rule in the July 3, 2000 **Federal Register** (65 FR 41128) to implement the HH PPS legislation. The July 2000 final rule established requirements for the new HH PPS for home health services as required by section 4603 of the BBA, as subsequently amended by section 5101 of the Omnibus Consolidated and Emergency Supplemental Appropriations Act for Fiscal Year 1999 (OCESAA), (Pub. L. 105–277, enacted October 21, 1998); and by sections 302, 305, and 306 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, (BBRA) (Pub. L. 106–113, enacted November 29, 1999). The requirements include the implementation of a HH PPS for home health services, consolidated billing requirements, and a number of other related changes. The HH PPS described in that rule replaced the retrospective reasonable cost-based system that was used by Medicare for the payment of home health services under Part A and Part B. For a complete and full description of the HH PPS as required by the BBA, see the July 2000 HH PPS final rule (65 FR 41128 through 41214).

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. If an HHA does not submit quality data, the home health market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006 **Federal Register** (71 FR 65884, 65935), we published a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-

for-reporting requirement was implemented on January 1, 2007.

The Affordable Care Act made additional changes to the HH PPS. One of the changes in section 3131 of the Affordable Care Act is the amendment to section 421(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003) as amended by section 5201(b) of the DRA. Section 421(a) of the MMA, as amended by section 3131 of the Affordable Care Act, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on for 2 more years. Section 421(a) of the MMA, as amended by section 210 of the MACRA, requires that the Secretary increase, by 3 percent, the payment amount otherwise made under section 1895 of the Act, for home health services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act) with respect to episodes and visits ending on or after April 1, 2010, and before January 1, 2018. Section 411(d) of MACRA amended section 1895(b)(3)(B) of the Act such that for home health payments for CY 2018, the market basket percentage increase shall be 1 percent.

B. Current System for Payment of Home Health Services

Generally, Medicare currently makes payment under the HH PPS on the basis of a national, standardized 60-day episode payment rate that is adjusted for the applicable case-mix and wage index. The national, standardized 60-day episode rate includes the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is not part of the national, standardized 60-day episode rate, but is computed by multiplying the relative weight for a particular NRS severity level by the NRS conversion factor. Payment for durable medical equipment covered under the HH benefit is made outside the HH PPS payment system. To adjust for case-mix, the HH PPS uses a 153-category case-mix classification system to assign patients to a home health resource group (HHRG). The clinical severity level, functional severity level, and service utilization are computed from responses to selected data elements in the OASIS assessment instrument and are used to place the patient in a particular HHRG. Each HHRG has an associated case-mix weight which is used in calculating the payment for an episode. Therapy service use is measured by the number of therapy visits provided during the episode and can be categorized into nine visit level categories (or thresholds): 0 to 5; 6; 7 to 9; 10; 11 to 13; 14 to 15; 16 to 17; 18 to 19; and 20 or more visits.

For episodes with four or fewer visits, Medicare pays national per-visit rates based on the discipline(s) providing the services. An episode consisting of four or fewer visits within a 60-day period receives what is referred to as a low-utilization payment adjustment (LUPA). Medicare also adjusts the national standardized 60-day episode payment rate for certain intervening events that are subject to a partial episode payment adjustment (PEP adjustment). For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

C. Updates to the Home Health Prospective Payment System

As required by section 1895(b)(3)(B) of the Act, we have historically updated the HH PPS rates annually in the **Federal Register**. The August 29, 2007 final rule with comment period set forth an update to the 60-day national episode rates and the national per-visit rates under the HH PPS for CY 2008. The CY 2008 HH PPS final rule included an analysis performed on CY 2005 home health claims data, which indicated a 12.78 percent increase in the observed case-mix since 2000. Case-mix represents the variations in conditions of the patient population served by the HHAs. Subsequently, a more detailed analysis was performed on the 2005 case-mix data to evaluate if any portion of the 12.78 percent increase was associated with a change in the actual clinical condition of home health patients. We identified 8.03 percent of the total case-mix change as real, and therefore, decreased the 12.78 percent of total case-mix change by 8.03 percent to get a final nominal case-mix increase measure of 11.75 percent (0.1278 * (1 − 0.0803) = 0.1175).

To account for the changes in case-mix that were not related to an underlying change in patient health status, we implemented a reduction, over 4 years, to the national, standardized 60-day episode payment rates. That reduction was to be 2.75 percent per year for 3 years beginning in CY 2008 and 2.71 percent for the fourth year in CY 2011. In the CY 2011 HH PPS final rule (76 FR 68532), we updated our analyses of case-mix change and finalized a reduction of 3.79 percent, instead of 2.71 percent, for CY 2011 and deferred finalizing a payment reduction for CY 2012 until further study of the case-mix change data and methodology was completed.

In the CY 2012 HH PPS final rule (76 FR 68526), we updated the 60-day national episode rates and the national per-visit rates. In addition, as discussed in the CY 2012 HH PPS final rule (76 FR 68528), our analysis indicated that there was a 22.59 percent increase in overall case-mix from 2000 to 2009 and that only 15.76 percent of that overall observed case-mix percentage increase was due to real case-mix change. As a result of our analysis, we identified a 19.03 percent nominal increase in case-mix. At that time, to fully account for the 19.03 percent nominal case-mix growth identified from 2000 to 2009, we finalized a 3.79 percent payment reduction in CY 2012 and a 1.32 percent payment reduction for CY 2013.

In the CY 2013 HH PPS final rule (77 FR 67078), we implemented the 1.32 percent reduction to the payment rates for CY 2013 finalized the previous year, to account for nominal case-mix growth from 2000 through 2010. When taking into account the total measure of case-mix change (23.90 percent) and the 15.97 percent of total case-mix change estimated as real from 2000 to 2010, we obtained a final nominal case-mix change measure of 20.08 percent from 2000 to 2010 (0.2390 * (1 − 0.1597) = 0.2008). To fully account for the remainder of the 20.08 percent increase in nominal case-mix beyond that which was accounted for in previous payment reductions, we estimated that the percentage reduction to the national, standardized 60-day episode rates for nominal case-mix change would be 2.18 percent. Although we considered proposing a 2.18 percent reduction to account for the remaining increase in measured nominal case-mix, we finalized the 1.32 percent payment reduction to the national, standardized 60-day episode rates in the CY 2012 HH PPS final rule (76 FR 68532).

Section 3131(a) of the Affordable Care Act requires that, beginning in CY 2014, we apply an adjustment to the national, standardized 60-day episode rate and other amounts that reflect factors such as changes in the number of visits in an episode, the mix of services in an episode, the level of intensity of services in an episode, the average cost of providing care per episode, and other relevant factors. Additionally, we must phase in any adjustment over a 4-year

period in equal increments, not to exceed 3.5 percent of the amount (or amounts) as of the date of enactment of the Affordable Care Act, and fully implement the rebasing adjustments by CY 2017. The statute specifies that the maximum rebasing adjustment is to be no more than 3.5 percent per year of the CY 2010 rates. Therefore, in the CY 2014 HH PPS final rule (78 FR 72256) for each year, CY 2014 through CY 2017, we finalized a fixed-dollar reduction to the national, standardized 60-day episode payment rate of $80.95 per year, increases to the national per-visit payment rates per year, and a decrease to the NRS conversion factor of 2.82 percent per year. We also finalized three separate LUPA add-on factors for skilled nursing, physical therapy, and speech-language pathology and removed 170 diagnosis codes from assignment to diagnosis groups in the HH PPS Grouper. In the CY 2015 HH PPS final rule (79 FR 66032), we implemented the second year of the 4-year phase-in of the rebasing adjustments to the HH PPS payment rates and made changes to the HH PPS case-mix weights. In addition, we simplified the face-to-face encounter regulatory requirements and the therapy reassessment timeframes.

In the CY 2016 HH PPS final rule (80 FR 68624), we implemented the third year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as outlined previously). In the CY 2016 HH PPS final rule, we also recalibrated the HH PPS case-mix weights, using the most current cost and utilization data available, in a budget-neutral manner and finalized reductions to the national, standardized 60-day episode payment rate in CY 2016, CY 2017, and CY 2018 of 0.97 percent in each year to account for estimated case-mix growth unrelated to increases in patient acuity (that is, nominal case-mix growth) between CY 2012 and CY 2014. Finally, section 421(a) of the MMA, as amended by section 210 of the MACRA, extended the payment increase of 3 percent for HH services provided in rural areas (as defined in section 1886(d)(2)(D) of the Act) to episodes or visits ending before January 1, 2018.

In the CY 2017 HH PPS final rule (81 FR 76702), we implemented the last year of the 4-year phase-in of the rebasing adjustments to the national, standardized 60-day episode payment amount, the national per-visit rates and the NRS conversion factor (as outlined previously). We also finalized changes to the methodology used to calculate outlier payments under the authority of section 1895(b)(5) of the Act. Lastly, in accordance with section 1834(s) of the Act, as added by section 504(a) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113, enacted December 18, 2015), we implemented changes in payment for furnishing Negative Pressure Wound Therapy (NPWT) using a disposable device for patients under a home health plan of care for which payment would otherwise be made under section 1895(b) of the Act.

D. Report to Congress: Home Health Study on Access to Care for Vulnerable Patient Populations and Subsequent Research and Analyses

Section 3131(d) of the Affordable Care Act required CMS to conduct a study on home health agency costs involved with providing ongoing access to care to low-income Medicare beneficiaries or beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness and submit a report to Congress. As discussed in the CY 2016 HH PPS proposed rule (80 FR 39840) and the CY 2017 HH PPS proposed rule (81 FR 43744), the findings from the Report to Congress on the ''Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations,'' found that payment accuracy could be improved under the current payment system, particularly for patients with certain clinical characteristics requiring more nursing care than therapy.[1]

The research for the Report to Congress, released in December 2014, consisted of extensive analysis of both survey and administrative data. The CMS-developed surveys were given to physicians who referred vulnerable patient populations to Medicare home health and to Medicare-certified HHAs.[2] The response rates were 72 percent and 59 percent for the HHA and physician surveys, respectively. The results of the survey revealed that over 80 percent of respondent HHAs and over 90 percent of respondent physicians reported that access to home health care for Medicare fee-for-service beneficiaries in their local area was excellent or good. When survey respondents reported access issues, specifically their inability to place or admit Medicare fee-for-service patients into home health, the most common reason reported (64 percent of respondent HHAs surveyed) was that the patients did not qualify for the Medicare home health benefit. HHAs and physicians also cited family or caregiver issues as an important contributing factor in the inability to admit or place patients. Only 17.2 percent of HHAs and 16.7 percent of physicians reported insufficient payment as an important contributing factor in the inability to admit or place patients. The results of the CMS-conducted surveys suggested that CMS' ability to improve access for certain vulnerable patient populations through payment policy may be limited. However, we are able to revise the case-mix system to minimize differences in payment that could potentially be serving as a barrier to receiving care. In the near future, we intend to better align payment with resource use so that it reduces HHAs' financial incentives to select certain patients over others.

We also performed an analysis of Medicare administrative data (CY 2010 Medicare claims and cost report data) and calculated margins for episodes of care. This was done because margin differences associated with patient clinical and social characteristics can indicate whether financial incentives exist in the current HH PPS to provide home health care for certain types of patients over others. Lower margins, if systematically associated with care for vulnerable patient populations, may indicate financial disincentives for HHAs to admit these patients, potentially creating access to care issues. The findings from the data analysis found that certain patient characteristics appear to be strongly associated with margin levels, and thus may create financial incentives to select certain patients over others. Margins were estimated to be lower for patients who required parenteral nutrition, who had traumatic wounds or ulcers, or required substantial assistance in bathing. For example, in CY 2010, episodes for patients with parenteral nutrition were, on average, associated with a $178.53 lower margin than episodes for patients without parenteral nutrition. Given that these variables are already included in the HH PPS case-mix system, the results indicated that modifications to the way the current case-mix system accounts for resource use differences may be needed to mitigate any financial incentives to select certain patients over others. Margins were also lower for beneficiaries who were admitted after acute or post-acute stays or who had certain poorly-controlled clinical

[1] The Report to Congress can be found in its entirety at *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/HomeHealthPPS/Downloads/HH-Report-to-Congress.pdf.*

[2] For the purposes of the surveys, ''vulnerable patient populations'' were defined as beneficiaries who were either eligible for the Part D low-income subsidy (LIS) 27 or residing in a health professional shortage area (HPSA).

conditions, such as poorly controlled pulmonary disorders, indicating that accounting for additional patient characteristic variables in the HH PPS case-mix system may also reduce financial incentives to select certain types of patients over others. More information on the results from the home health study required by section 3131(d) of the Affordable Care Act can be found in the Report to Congress on the ''Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations'' available at https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html.

Section 3131(d)(5) of the Affordable Care Act authorized the Secretary to determine whether it would be appropriate to conduct a Medicare demonstration project based on the result of the home health study. If the Secretary determined it was appropriate to conduct the demonstration project under this subsection, the Secretary was to conduct the project for a 4-year period beginning not later than January 1, 2015. We did not determine that it was appropriate to conduct a demonstration project based on the findings from the home health study. Rather, the findings from the home health study suggested that follow-on work should be conducted to better align payments with costs under the authority of section 1895 of the Act.

In addition to the findings from the Report to Congress on the ''Medicare Home Health Study: An Investigation on Access to Care and Payment for Vulnerable Patient Populations,'' concerns have also been raised about the use of therapy thresholds in the current payment system. Under the current payment system, HHAs receive higher payments for providing more therapy visits once certain thresholds are reached. As a result, the average number of therapy visits per 60-day episode of care have increased since the implementation of the HH PPS, while the number of skilled nursing and home health aide visits have decreased over the same time period (82 FR 35280 (Figure 3)). A study examining an option of using predicted, rather than actual, therapy visits in the home health found that in 2013, 58 percent of home health episodes included some therapy services, and these episodes accounted for 72 percent of all Medicare home health payments.[3] Figure 1, from that study, demonstrates that the percentage of episodes, and the average episode payment by the number of therapy visits for episodes with at least one therapy visit in 2013 increased sharply in therapy provision just over payment thresholds at 6, 7, and 16. According to the study, the presence of sharp increases in the percentage of episodes just above payment thresholds suggests a response to financial incentives in the home health payment system. Similarly, between 2008 and 2013, MedPAC reported a 26 percent increase in the number of episodes with at least 6 therapy visits, compared with a 1 percent increase in the number of episodes with 5 or fewer therapy visits.[4] CMS analysis demonstrates that the average share of therapy visits across all 60-day episodes of care increased from 9 percent of all visits in 1997, prior to the implementation of the HH PPS (see 64 FR 58151), to 39 percent of all visits in 2015 (82 FR 35277 through 35278 (Table 2)).

[3] Fout B, Plotzke M, Christian T. (2016). Using Predicted Therapy Visits in the Medicare Home Health Prospective Payment System. Home Health Care Management & Practice, 29(2), 81–90. *http://journals.sagepub.com/doi/abs/10.1177/1084822316678384.*

[4] Medicare Payment Advisory Commission (MedPAC). ''Home Health Care Services.'' *Report to Congress: Medicare Payment Policy.* Washington, DC, March 2015. P. 223. Accessed on March 28, 2017 at: *http://www.medpac.gov/docs/default-source/reports/mar2015_entirereport_revised.pdf?sfvrsn=0.*

FIGURE 1: Percent of Episodes and Average Payment by Number of Therapy Visits

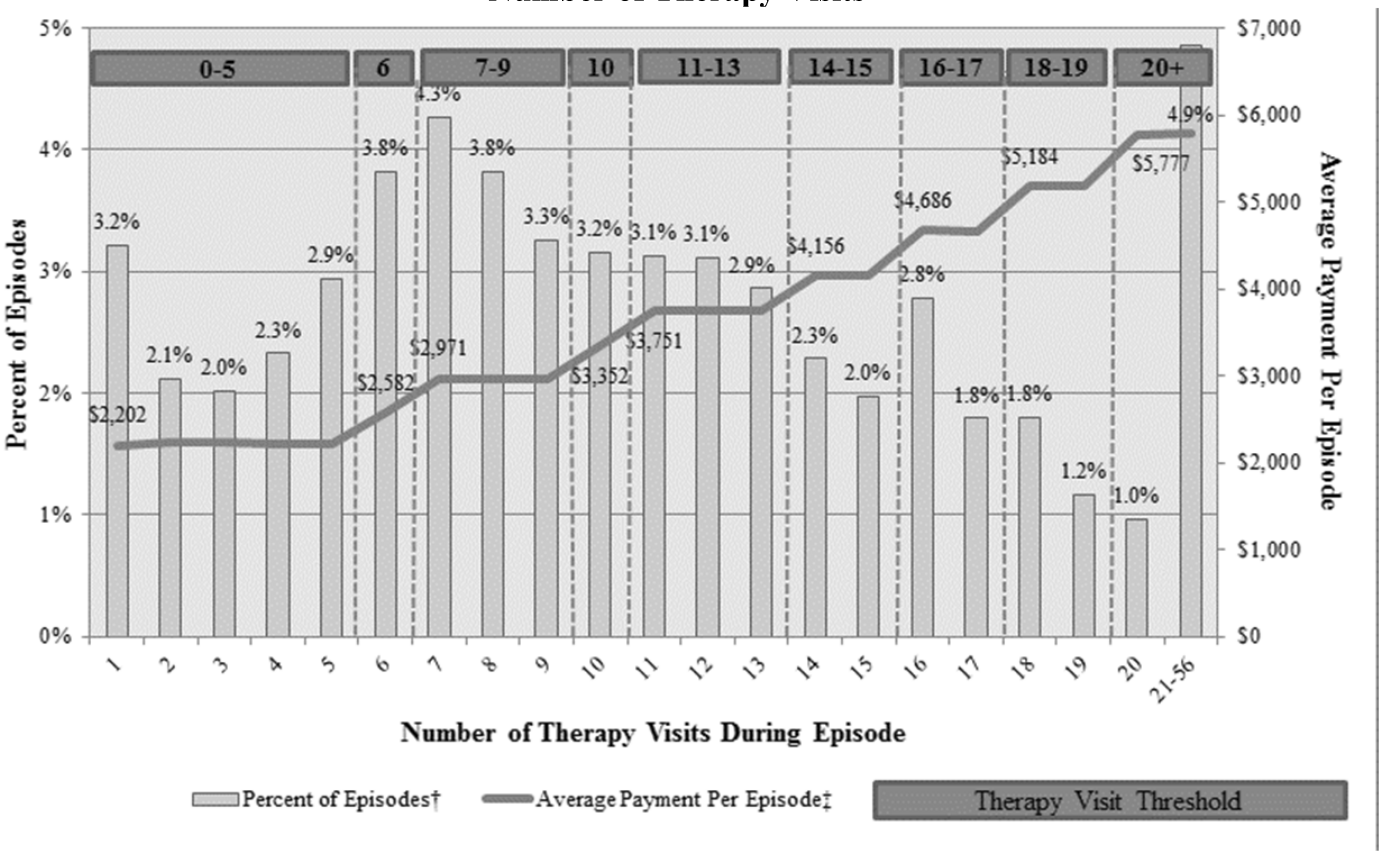

Figure 1 suggests that HHAs may be responding to financial incentives in the home health payment system when making care plan decisions. Additionally, an investigation into the therapy practices of the four largest publically-traded home health companies, conducted by the Senate Committee on Finance in 2010, found that three out of the four companies investigated ''encouraged therapists to target the most profitable number of therapy visits, even when patient need alone may not have justified such patterns''.[5] The Senate Committee on Finance investigation also highlighted the abrupt and dramatic responses the home health industry has taken to maximize reimbursement under the therapy threshold models (both the original 10-visit threshold model and under the revised thresholds implemented in the CY 2008 HH PPS final rule (72 FR 49762)). The report noted that, under the HH PPS, HHAs have broad discretion over the number of therapy visits to provide patients, and therefore, have control of the single-largest variable in determining reimbursement and overall margins. The report recommended that CMS closely examine a future payment approach that focuses on patient well-being and health characteristics, rather than the numerical utilization measures.

MedPAC also continues to recommend the removal of the therapy thresholds used for determining payment from the HH PPS, as it believes that such thresholds run counter to the goals of a prospective payment system, create financial incentives that detract from a focus on patient characteristics and care needs when agencies are setting plans of care for their patients, and incentivize unnecessary therapy utilization. For the average HHA, according to MedPAC, the increase in payment for therapy visits rises faster than costs, resulting in financial incentives for HHAs to overprovide therapy services.[6] HHAs that provide more therapy episodes tend to be more profitable and this higher profitability and rapid growth in the number of therapy episodes suggest that financial incentives are causing agencies to favor therapy services when possible.[7] Eliminating therapy as a payment factor will base home health payment solely on patient characteristics, which is a more patient-focused approach to payment, as recommended by both MedPAC and previously by the Senate Committee on Finance.

After considering the findings from the Report to Congress and recommendations from MedPAC and the Senate Committee on Finance, CMS, along with our contractor, conducted additional research on ways to improve the payment accuracy under the current payment system. Exploring all options and different models ultimately led us to further develop the Home Health Groupings Model (HHGM). As discussed in the CY 2018 HH PPS proposed rule (82 FR 35294), we shared

[5] Committee on Finance, United States Senate. Staff Report on Home Health and the Medicare Therapy Threshold. Washington, DC, 2011. Accessed on March 28, 2017 at *https://www.finance.senate.gov/imo/media/doc/Home_Health_Report_Final4.pdf.*

[6] Medicare Payment Advisory Commission (MedPAC). ''Home Health Services.'' Report to Congress: Medicare Payment Policy. Washington, DC, March 2011. P. 182–183. Accessed on March 28, 2017 at *http://www.medpac.gov/docs/default-source/reports/Mar11_Ch08.pdf?sfvrsn=0.*

[7] Medicare Payment Advisory Commission (MedPAC). ''Home Health Care Services.'' Report to Congress: Medicare Payment Policy. Washington, DC, March 2017. P. 243–244. Accessed on March 28, 2017 at *http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch9.pdf?sfvrsn=0.*

the analysis and development of the HHGM with both internal and external stakeholders via technical expert panels, clinical workgroups, special open door forums, in the CY 2016 HH PPS proposed rule (80 FR 39840) and the CY 2017 HH PPS proposed rule (81 FR 43744), in a detailed technical report posted on the CMS Web site in December 2016 (followed by additional technical and clinical expert panels) and a National Provider Call in January 2017. The HHGM uses 30-day periods, rather than 60-day episodes, and relies more heavily on clinical characteristics and other patient information (for example, principal diagnosis, functional level, comorbid conditions, admission source, and timing) to place patients into meaningful payment categories, rather than the current therapy-driven system, which are the major differences between the current system and the HHGM.

III. Provisions of the Proposed Rule: Payment Under the Home Health Prospective Payment System (HH PPS) and Responses to Comments

In the July 28, 2017 **Federal Register** (82 FR 35270 through 35393), we published the proposed rule titled ''Medicare and Medicaid Programs; CY 2018 Home Health Prospective Payment System Rate Update and Proposed CY 2019 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements''. We received approximately 1,346 timely comments from the public, including comments from home health agencies, national and state provider associations, patient and other advocacy organizations, nurses, and physical therapists. In the following sections, we summarize the proposed provisions and the public comments, and provide the responses to comments.

A. Monitoring for Potential Impacts—Affordable Care Act Rebasing Adjustments

In the CY 2018 HH PPS proposed rule (82 FR 35277), we provided a summary of analysis on fiscal year (FY) 2015 HHA cost report data and how such data, if used, would impact our estimate of the percentage difference between Medicare payments and HHA costs used to calculate the Affordable Care Act rebasing adjustments. In addition, we presented information on Medicare home health utilization statistics and trends that included HHA claims data through CY 2016. We will continue monitoring the impacts due to the rebasing adjustments and other policy changes and will provide the industry with periodic updates on our analysis in rulemaking and announcements on the HHA Center Web page at *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html.*

The following is a summary of the comments received on the analysis of HHA cost report and utilization data and our responses.

Comment: A commenter noted that it may come as no surprise that payments exceed costs by 21 percent, given that Medicare payment for home health is statutorily required to be based on a prospective payment system and the industry is now 90 percent for-profit, with incentives to admit only the most profitable cases. The commenter went on to state that home health payments from Medicare Advantage (MA) plans are inadequate and that HHAs subsidize low payments from MA plans with payments for fee-for-service patients. The commenter further noted that the number of patients coming into home health care from the community (rather than following an acute or post-acute care stay) has risen in response to deliberate Medicare and public health effort to keep patients out of the hospital. Similar comments from MedPAC stated that CMS's review of utilization is consistent with the Commission's findings on access to care, and the analysis of the cost and utilization data in the proposed rule underscores the Commission's long-standing concern that the Patient Protection and Affordable Care Act (PPACA) rebasing provision would not adequately reduce payments.

Response: We thank the commenters for their feedback on the HHA cost and utilization data presented in the proposed rule. We will continue monitoring the impacts due to the rebasing adjustments and other policy changes and will provide the industry with periodic updates on our analysis in rulemaking or announcements on the HHA Center Web page at: *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.html.*

Comment: A commenter questioned whether CMS did any trimming to the cost report data used to populate Table 2 in the CY 2018 HH PPS proposed rule and whether NRS costs were excluded from this calculation.

Response: As we noted in the CY 2018 HH PPS proposed rule (82 FR 35277), to determine the 2015 average cost per visit per discipline, we applied the same trimming methodology outlined in the CY 2014 HH PPS proposed rule (78 FR 40284) and weighted the costs per visit from the 2015 cost reports by size, facility type, and urban/rural location so the costs per visit were nationally representative according to 2015 claims data. The 2015 average number of visits was taken from 2015 claims data (82 FR 35277). Because CMS currently pays for NRS using a separate conversion factor, NRS costs were not included in Table 2 as the national, standardized 60-day episode payment amount only reflects the cost of care related to skilled nursing, physical therapy, occupational therapy, speech-language pathology, home health aide, and medical social services. The payment for NRS is calculated through the NRS conversion factor, multiplied by the weights for the six severity levels.

B. CY 2018 HH PPS Case-Mix Weights

In the CY 2015 HH PPS final rule (79 FR 66072), we finalized a policy to annually recalibrate the HH PPS case-mix weights—adjusting the weights relative to one another—using the most current, complete data available. To recalibrate the HH PPS case-mix weights for CY 2018, we will use the same methodology finalized in the CY 2008 HH PPS final rule (72 FR 49762), the CY 2012 HH PPS final rule (76 FR 68526), and the CY 2015 HH PPS final rule (79 FR 66032). Annual recalibration of the HH PPS case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns.

To generate the CY 2018 HH PPS case-mix weights, we used CY 2016 home health claims data (as of August 17, 2017) with linked OASIS data. These data are the most current and complete data available at this time. We noted in the proposed rule that we would use CY 2016 home health claims data (as of June 30, 2017 or later) with linked OASIS data to generate the CY 2018 HH PPS case-mix weights for this final rule. The process we used to calculate the HH PPS case-mix weights is outlined in this section.

Step 1: Re-estimate the four-equation model to determine the clinical and functional points for an episode using wage-weighted minutes of care as our dependent variable for resource use. The wage-weighted minutes of care are determined using the CY 2015 Bureau of Labor Statistics national hourly wage plus fringe rates for the six home health disciplines and the minutes per visit from the claim. The points for each of the variables for each leg of the model, updated with CY 2016 home health claims data, are shown in Table 2. The points for the clinical variables are added together to determine an episode's clinical score. The points for the functional variables are added

together to determine an episode's functional score.

TABLE 2—CASE-MIX ADJUSTMENT VARIABLES AND SCORES

	Episode number within sequence of adjacent episodes	1 or 2	1 or 2	3+	3+
	Therapy visits	0–13	14+	0–13	14+
	EQUATION:	1	2	3	4
	CLINICAL DIMENSION				
1	Primary or Other Diagnosis = Blindness/Low Vision				
2	Primary or Other Diagnosis = Blood disorders		1		
3	Primary or Other Diagnosis = Cancer, selected benign neoplasms		4		4
4	Primary Diagnosis = Diabetes		3		
5	Other Diagnosis = Diabetes	1			
6	Primary or Other Diagnosis = Dysphagia *AND* Primary or Other Diagnosis = Neuro 3—Stroke.	2	16	1	10
7	Primary or Other Diagnosis = Dysphagia *AND* M1030 (Therapy at home) = 3 (Enteral).	1	5		9
8	Primary or Other Diagnosis = Gastrointestinal disorders				2
9	Primary or Other Diagnosis = Gastrointestinal disorders *AND* M1630 (ostomy)= 1 or 2.		7		
10	Primary or Other Diagnosis = Gastrointestinal disorders *AND* Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis, *OR* Neuro 2—Peripheral neurological disorders, *OR* Neuro 3—Stroke, *OR* Neuro 4—Multiple Sclerosis.				
11	Primary or Other Diagnosis = Heart Disease *OR* Hypertension	1	3		2
12	Primary Diagnosis = Neuro 1—Brain disorders and paralysis	3	9	6	9
13	Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis *AND* M1840 (Toilet transfer) = 2 or more.		4		4
14	Primary or Other Diagnosis = Neuro 1—Brain disorders and paralysis *OR* Neuro 2—Peripheral neurological disorders *AND* M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3.	2	4	2	4
15	Primary or Other Diagnosis = Neuro 3—Stroke	3	9	2	4
16	Primary or Other Diagnosis = Neuro 3—Stroke *AND* M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3.		2		
17	Primary or Other Diagnosis = Neuro 3—Stroke *AND* M1860 (Ambulation) = 4 or more.				
18	Primary or Other Diagnosis = Neuro 4—Multiple Sclerosis *AND AT LEAST ONE OF THE FOLLOWING:* M1830 (Bathing) = 2 or more *OR* M1840 (Toilet transfer) = 2 or more *OR* M1850 (Transferring) = 2 or more *OR* M1860 (Ambulation) = 4 or more.	3	7	5	11
19	Primary or Other Diagnosis = Ortho 1—Leg Disorders or Gait Disorders *AND* M1324 (most problematic pressure ulcer stage) = 1, 2, 3 or 4.	7	1	7	
20	Primary or Other Diagnosis = Ortho 1—Leg *OR* Ortho 2—Other orthopedic disorders *AND* M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral).	3		3	7
21	Primary or Other Diagnosis = Psych 1—Affective and other psychoses, depression.				
22	Primary or Other Diagnosis = Psych 2—Degenerative and other organic psychiatric disorders.				
23	Primary or Other Diagnosis = Pulmonary disorders		2		1
24	Primary or Other Diagnosis = Pulmonary disorders *AND* M1860 (Ambulation) = 1 or more.				
25	Primary Diagnosis = Skin 1—Traumatic wounds, burns, and post-operative complications.	3	17	6	17
26	Other Diagnosis = Skin 1—Traumatic wounds, burns, post-operative complications.	6	14	7	14
27	Primary or Other Diagnosis = Skin 1—Traumatic wounds, burns, and post-operative complications *OR* Skin 2—Ulcers and other skin conditions *AND* M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral).	2			
28	Primary or Other Diagnosis = Skin 2—Ulcers and other skin conditions	2	16	8	18
29	Primary or Other Diagnosis = Tracheostomy	2	17		17
30	Primary or Other Diagnosis = Urostomy/Cystostomy		17		12
31	M1030 (Therapy at home) = 1 (IV/Infusion) or 2 (Parenteral)		15	5	15
32	M1030 (Therapy at home) = 3 (Enteral)		16		6
33	M1200 (Vision) = 1 or more				
34	M1242 (Pain)= 3 or 4	3		2	
35	M1311 = Two or more pressure ulcers at stage 3 or 4	4	6	4	6
36	M1324 (Most problematic pressure ulcer stage) = 1 or 2	4	19	7	17
37	M1324 (Most problematic pressure ulcer stage)= 3 or 4	9	31	10	25
38	M1334 (Stasis ulcer status) = 2	4	13	8	13
39	M1334 (Stasis ulcer status) = 3	7	17	9	17
40	M1342 (Surgical wound status) = 2	2	7	6	13
41	M1342 (Surgical wound status) = 3		6	5	10
42	M1400 (Dyspnea) = 2, 3, or 4	1	1		
43	M1620 (Bowel Incontinence) = 2 to 5		3		2
44	M1630 (Ostomy) = 1 or 2	4	11	2	8
45	M2030 (Injectable Drug Use) = 0, 1, 2, or 3				
	FUNCTIONAL DIMENSION				
46	M1810 or M1820 (Dressing upper or lower body) = 1, 2, or 3	1			
47	M1830 (Bathing) = 2 or more	6	5	6	2
48	M1840 (Toilet transferring) = 2 or more		1		

TABLE 2—CASE-MIX ADJUSTMENT VARIABLES AND SCORES—Continued

49	M1850 (Transferring) = 2 or more	3	1	2	.
50	M1860 (Ambulation) = 1, 2 or 3	7		4	
51	M1860 (Ambulation) = 4 or more	8	9	7	7

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 (as of August 17, 2017) for which we had a linked OASIS assessment. LUPA episodes, outlier episodes, and episodes with PEP adjustments were excluded.

Note(s): Points are additive; however, points may not be given for the same line item in the table more than once. Please see Medicare Home Health Diagnosis Coding guidance at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/coding_billing.html* for definitions of primary and secondary diagnoses.

In updating the four-equation model for CY 2018, using 2016 home health claims data (the last update to the four-equation model for CY 2017 used CY 2015 home health claims data), there were few changes to the point values for the variables in the four-equation model. These relatively minor changes reflect the change in the relationship between the grouper variables and resource use between CY 2015 and CY 2016. The CY 2018 four-equation model resulted in 120 point-giving variables being used in the model (as compared to the 124 variables for the CY 2017 recalibration). There were 8 variables that were added to the model and 12 variables that were dropped from the model due to the absence of additional resources associated with the variable. Of the variables that were in both the four-equation model for CY 2017 and the four-equation model for CY 2018, the points for 14 variables increased in the CY 2018 four-equation model and the points for 48 variables decreased in the CY 2018 4-equation model. There were 50 variables with the same point values.

Step 2: Redefining the clinical and functional thresholds so they are reflective of the new points associated with the CY 2018 four-equation model. After estimating the points for each of the variables and summing the clinical and functional points for each episode, we look at the distribution of the clinical score and functional score, breaking the episodes into different steps. The categorizations for the steps are as follows:

- Step 1: First and second episodes, 0–13 therapy visits.
- Step 2.1: First and second episodes, 14–19 therapy visits.
- Step 2.2: Third episodes and beyond, 14–19 therapy visits.
- Step 3: Third episodes and beyond, 0–13 therapy visits.
- Step 4: Episodes with 20+ therapy visits

Then, we divide the distribution of the clinical score for episodes within a step such that a third of episodes are classified as low clinical score, a third of episodes are classified as medium clinical score, and a third of episodes are classified as high clinical score. The same approach is then done looking at the functional score. It was not always possible to evenly divide the episodes within each step into thirds due to many episodes being clustered around one particular score.[8] Also, we looked at the average resource use associated with each clinical and functional score and used that as a guide for setting our thresholds. We grouped scores with similar average resource use within the same level (even if it meant that more or less than a third of episodes were placed within a level). The new thresholds, based off the CY 2018 four-equation model points are shown in Table 3.

TABLE 3—CY 2018 CLINICAL AND FUNCTIONAL THRESHOLDS

		1st and 2nd episodes		3rd+ episodes		All episodes
		0 to 13 therapy visits	14 to 19 therapy visits	0 to 13 therapy visits	14 to 19 therapy visits	20+ therapy visits
Grouping Step		1	2	3	4	5
Equations used to calculate points (see Table 1)		1	2	3	4	(2&4)
Dimension	Severity Level					
Clinical	C1	0 to 1	0 to 1	0 to 1	0 to 1	0 to 3
	C2	2 to 3	2 to 7	2	2 to 9	4 to 16
	C3	4+	8+	3+	10+	17+
Functional	F1	0 to 13	0 to 7	0 to 6	0 to 2	0 to 2
	F2	14	8 to 15	7 to 10	3 to 7	3 to 6
	F3	15+	16+	11+	8+	7+

Step 3: Once the clinical and functional thresholds are determined and each episode is assigned a clinical and functional level, the payment regression is estimated with an episode's wage-weighted minutes of care as the dependent variable. Independent variables in the model are indicators for the step of the episode as well as the clinical and functional levels within each step of the episode. Like the four-equation model, the payment regression model is also estimated with robust standard errors that are clustered at the beneficiary level. Table 4 shows the regression coefficients for the variables in the payment regression model updated with CY 2016 home health claims data. The R-squared value for the payment regression model is

[8] For Step 1, 45.3 percent of episodes were in the medium functional level (All with score 14).

For Step 2.1, 87.3 percent of episodes were in the low functional level (Most with scores 5 to 7).

For Step 2.2, 81.9 percent of episodes were in the low functional level (Most with score 2).

For Step 3, 46.3 percent of episodes were in the medium functional level (Most with score 10).

For Step 4, 48.7 percent of episodes were in the medium functional level (Most with score 5 or 6).

0.5095 (an increase from 0.4919 for the CY 2017 recalibration).

TABLE 4—PAYMENT REGRESSION MODEL

	Payment regression from 4-equation model for CY 2018
Step 1, Clinical Score Medium	$24.58
Step 1, Clinical Score High	54.24
Step 1, Functional Score Medium	72.76
Step 1, Functional Score High	107.48
Step 2.1, Clinical Score Medium	48.81
Step 2.1, Clinical Score High	135.99
Step 2.1, Functional Score Medium	31.51
Step 2.1, Functional Score High	57.73
Step 2.2, Clinical Score Medium	39.37
Step 2.2, Clinical Score High	194.18
Step 2.2, Functional Score Medium	21.53
Step 2.2, Functional Score High	56.25
Step 3, Clinical Score Medium	17.07
Step 3, Clinical Score High	95.93
Step 3, Functional Score Medium	59.15
Step 3, Functional Score High	90.40
Step 4, Clinical Score Medium	80.09
Step 4, Clinical Score High	263.75
Step 4, Functional Score Medium	27.97
Step 4, Functional Score High	62.20
Step 2.1, 1st and 2nd Episodes, 14 to 19 Therapy Visits	512.27
Step 2.2, 3rd+ Episodes, 14 to 19 Therapy Visits	523.60
Step 3, 3rd+ Episodes, 0–13 Therapy Visits	−72.22
Step 4, All Episodes, 20+ Therapy Visits	907.99
Intercept	389.35

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 (as of August 17, 2017) for which we had a linked OASIS assessment.

Step 4: We use the coefficients from the payment regression model to predict each episode's wage-weighted minutes of care (resource use). We then divide these predicted values by the mean of the dependent variable (that is, the average wage-weighted minutes of care across all episodes used in the payment regression). This division constructs the weight for each episode, which is simply the ratio of the episode's predicted wage-weighted minutes of care divided by the average wage-weighted minutes of care in the sample. Each episode is then aggregated into one of the 153 home health resource groups (HHRGs) and the ''raw'' weight for each HHRG was calculated as the average of the episode weights within the HHRG.

Step 5: The raw weights associated with 0 to 5 therapy visits are then increased by 3.75 percent, the weights associated with 14 to 15 therapy visits are decreased by 2.5 percent, and the weights associated with 20+ therapy visits are decreased by 5 percent. These adjustments to the case-mix weights were finalized in the CY 2012 HH PPS final rule (76 FR 68557) and were done to address MedPAC's concerns that the HH PPS overvalues therapy episodes and undervalues non-therapy episodes and to better align the case-mix weights with episode costs estimated from cost report data.[9]

Step 6: After the adjustments in Step 5 are applied to the raw weights, the weights are further adjusted to create an increase in the payment weights for the therapy visit steps between the therapy thresholds. Weights with the same clinical severity level, functional severity level, and early/later episode status were grouped together. Then within those groups, the weights for each therapy step between thresholds are gradually increased. We do this by interpolating between the main thresholds on the model (from 0 to 5 to 14 to 15 therapy visits, and from 14 to 15 to 20+ therapy visits). We use a linear model to implement the interpolation so the payment weight increase for each step between the thresholds (such as the increase between 0 and 5 therapy visits and 6 therapy visits and the increase between 6 therapy visits and 7 to 9 therapy visits) are constant. This interpolation is identical to the process finalized in the CY 2012 HH PPS final rule (76 FR 68555).

Step 7: The interpolated weights are then adjusted so that the average case-mix for the weights is equal to 1.0000.[10] This last step creates the final CY 2018 case-mix weights shown in Table 5.

[9] Medicare Payment Advisory Commission (MedPAC), *Report to the Congress: Medicare Payment Policy.* March 2011, p. 176.

[10] When computing the average, we compute a weighted average, assigning a value of one to each normal episode and a value equal to the episode length divided by 60 for PEPs.

TABLE 5—CY 2018 CASE-MIX PAYMENT WEIGHTS

Pay group	Description	Clinical and functional levels (1 = Low; 2 = Medium; 3 = High)	CY 2018 weight
10111	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F1S1	0.5595
10112	1st and 2nd Episodes, 6 Therapy Visits	C1F1S2	0.6911
10113	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F1S3	0.8227
10114	1st and 2nd Episodes, 10 Therapy Visits	C1F1S4	0.9543
10115	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0859
10121	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F2S1	0.6640
10122	1st and 2nd Episodes, 6 Therapy Visits	C1F2S2	0.7832
10123	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F2S3	0.9025
10124	1st and 2nd Episodes, 10 Therapy Visits	C1F2S4	1.0217
10125	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1409
10131	1st and 2nd Episodes, 0 to 5 Therapy Visits	C1F3S1	0.7139
10132	1st and 2nd Episodes, 6 Therapy Visits	C1F3S2	0.8302
10133	1st and 2nd Episodes, 7 to 9 Therapy Visits	C1F3S3	0.9466
10134	1st and 2nd Episodes, 10 Therapy Visits	C1F3S4	1.0629
10135	1st and 2nd Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1792
10211	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F1S1	0.5948
10212	1st and 2nd Episodes, 6 Therapy Visits	C2F1S2	0.7325
10213	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8703
10214	1st and 2nd Episodes, 10 Therapy Visits	C2F1S4	1.0080
10215	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1457
10221	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F2S1	0.6994
10222	1st and 2nd Episodes, 6 Therapy Visits	C2F2S2	0.8247
10223	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F2S3	0.9500
10224	1st and 2nd Episodes, 10 Therapy Visits	C2F2S4	1.0753
10225	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F2S5	1.2007
10231	1st and 2nd Episodes, 0 to 5 Therapy Visits	C2F3S1	0.7493
10232	1st and 2nd Episodes, 6 Therapy Visits	C2F3S2	0.8717
10233	1st and 2nd Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9941
10234	1st and 2nd Episodes, 10 Therapy Visits	C2F3S4	1.1166
10235	1st and 2nd Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2390
10311	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F1S1	0.6374
10312	1st and 2nd Episodes, 6 Therapy Visits	C3F1S2	0.7902
10313	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9429
10314	1st and 2nd Episodes, 10 Therapy Visits	C3F1S4	1.0957
10315	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F1S5	1.2484
10321	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F2S1	0.7420
10322	1st and 2nd Episodes, 6 Therapy Visits	C3F2S2	0.8823
10323	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0227
10324	1st and 2nd Episodes, 10 Therapy Visits	C3F2S4	1.1630
10325	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3034
10331	1st and 2nd Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7919
10332	1st and 2nd Episodes, 6 Therapy Visits	C3F3S2	0.9293
10333	1st and 2nd Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0668
10334	1st and 2nd Episodes, 10 Therapy Visits	C3F3S4	1.2042
10335	1st and 2nd Episodes, 11 to 13 Therapy Visits	C3F3S5	1.3417
21111	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2176
21112	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3807
21113	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5439
21121	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2601
21122	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4213
21123	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5826
21131	1st and 2nd Episodes, 14 to 15 Therapy Visits	C1F3S1	1.2955
21132	1st and 2nd Episodes, 16 to 17 Therapy Visits	C1F3S2	1.4600
21133	1st and 2nd Episodes, 18 to 19 Therapy Visits	C1F3S3	1.6244
21211	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2835
21212	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4598
21213	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6361
21221	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3260
21222	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F2S2	1.5004
21223	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6748
21231	1st and 2nd Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3614
21232	1st and 2nd Episodes, 16 to 17 Therapy Visits	C2F3S2	1.5390
21233	1st and 2nd Episodes, 18 to 19 Therapy Visits	C2F3S3	1.7166
21311	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4012
21312	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6188
21313	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F1S3	1.8364
21321	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F2S1	1.4437
21322	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F2S2	1.6594

TABLE 5—CY 2018 CASE-MIX PAYMENT WEIGHTS—Continued

Pay group	Description	Clinical and functional levels (1 = Low; 2 = Medium; 3 = High)	CY 2018 weight
21323	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F2S3	1.8751
21331	1st and 2nd Episodes, 14 to 15 Therapy Visits	C3F3S1	1.4791
21332	1st and 2nd Episodes, 16 to 17 Therapy Visits	C3F3S2	1.6981
21333	1st and 2nd Episodes, 18 to 19 Therapy Visits	C3F3S3	1.9170
22111	3rd+ Episodes, 14 to 15 Therapy Visits	C1F1S1	1.2328
22112	3rd+ Episodes, 16 to 17 Therapy Visits	C1F1S2	1.3909
22113	3rd+ Episodes, 18 to 19 Therapy Visits	C1F1S3	1.5489
22121	3rd+ Episodes, 14 to 15 Therapy Visits	C1F2S1	1.2619
22122	3rd+ Episodes, 16 to 17 Therapy Visits	C1F2S2	1.4225
22123	3rd+ Episodes, 18 to 19 Therapy Visits	C1F2S3	1.5832
22131	3rd+ Episodes, 14 to 15 Therapy Visits	C1F3S1	1.3088
22132	3rd+ Episodes, 16 to 17 Therapy Visits	C1F3S2	1.4688
22133	3rd+ Episodes, 18 to 19 Therapy Visits	C1F3S3	1.6288
22211	3rd++ Episodes, 14 to 15 Therapy Visits	C2F1S1	1.2860
22212	3rd+ Episodes, 16 to 17 Therapy Visits	C2F1S2	1.4615
22213	3rd+ Episodes, 18 to 19 Therapy Visits	C2F1S3	1.6369
22221	3rd+ Episodes, 14 to 15 Therapy Visits	C2F2S1	1.3151
22222	3rd+ Episodes, 16 to 17 Therapy Visits	C2F2S2	1.4931
22223	3rd+ Episodes, 18 to 19 Therapy Visits	C2F2S3	1.6712
22231	3rd+ Episodes, 14 to 15 Therapy Visits	C2F3S1	1.3620
22232	3rd+ Episodes, 16 to 17 Therapy Visits	C2F3S2	1.5394
22233	3rd+ Episodes, 18 to 19 Therapy Visits	C2F3S3	1.7168
22311	3rd+ Episodes, 14 to 15 Therapy Visits	C3F1S1	1.4951
22312	3rd+ Episodes, 16 to 17 Therapy Visits	C3F1S2	1.6814
22313	3rd+ Episodes, 18 to 19 Therapy Visits	C3F1S3	1.8677
22321	3rd+ Episodes, 14 to 15 Therapy Visits	C3F2S1	1.5241
22322	3rd+ Episodes, 16 to 17 Therapy Visits	C3F2S2	1.7130
22323	3rd+ Episodes, 18 to 19 Therapy Visits	C3F2S3	1.9019
22331	3rd+ Episodes, 14 to 15 Therapy Visits	C3F3S1	1.5710
22332	3rd+ Episodes, 16 to 17 Therapy Visits	C3F3S2	1.7593
22333	3rd+ Episodes, 18 to 19 Therapy Visits	C3F3S3	1.9476
30111	3rd+ Episodes, 0 to 5 Therapy Visits	C1F1S1	0.4557
30112	3rd+ Episodes, 6 Therapy Visits	C1F1S2	0.6111
30113	3rd+ Episodes, 7 to 9 Therapy Visits	C1F1S3	0.7666
30114	3rd+ Episodes, 10 Therapy Visits	C1F1S4	0.9220
30115	3rd+ Episodes, 11 to 13 Therapy Visits	C1F1S5	1.0774
30121	3rd+ Episodes, 0 to 5 Therapy Visits	C1F2S1	0.5407
30122	3rd+ Episodes, 6 Therapy Visits	C1F2S2	0.6850
30123	3rd+ Episodes, 7 to 9 Therapy Visits	C1F2S3	0.8292
30124	3rd+ Episodes, 10 Therapy Visits	C1F2S4	0.9734
30125	3rd+ Episodes, 11 to 13 Therapy Visits	C1F2S5	1.1177
30131	3rd+ Episodes, 0 to 5 Therapy Visits	C1F3S1	0.5856
30132	3rd+ Episodes, 6 Therapy Visits	C1F3S2	0.7303
30133	3rd+ Episodes, 7 to 9 Therapy Visits	C1F3S3	0.8749
30134	3rd+ Episodes, 10 Therapy Visits	C1F3S4	1.0195
30135	3rd+ Episodes, 11 to 13 Therapy Visits	C1F3S5	1.1642
30211	3rd+ Episodes, 0 to 5 Therapy Visits	C2F1S1	0.4802
30212	3rd+ Episodes, 6 Therapy Visits	C2F1S2	0.6414
30213	3rd+ Episodes, 7 to 9 Therapy Visits	C2F1S3	0.8025
30214	3rd+ Episodes, 10 Therapy Visits	C2F1S4	0.9637
30215	3rd+ Episodes, 11 to 13 Therapy Visits	C2F1S5	1.1249
30221	3rd+ Episodes, 0 to 5 Therapy Visits	C2F2S1	0.5652
30222	3rd+ Episodes, 6 Therapy Visits	C2F2S2	0.7152
30223	3rd+ Episodes, 7 to 9 Therapy Visits	C2F2S3	0.8652
30224	3rd+ Episodes, 10 Therapy Visits	C2F2S4	1.0151
30225	3rd+ Episodes, 11 to 13 Therapy Visits	C2F2S5	1.1651
30231	3rd+ Episodes, 0 to 5 Therapy Visits	C2F3S1	0.6101
30232	3rd+ Episodes, 6 Therapy Visits	C2F3S2	0.7605
30233	3rd+ Episodes, 7 to 9 Therapy Visits	C2F3S3	0.9109
30234	3rd+ Episodes, 10 Therapy Visits	C2F3S4	1.0612
30235	3rd+ Episodes, 11 to 13 Therapy Visits	C2F3S5	1.2116
30311	3rd+ Episodes, 0 to 5 Therapy Visits	C3F1S1	0.5936
30312	3rd+ Episodes, 6 Therapy Visits	C3F1S2	0.7739
30313	3rd+ Episodes, 7 to 9 Therapy Visits	C3F1S3	0.9542
30314	3rd+ Episodes, 10 Therapy Visits	C3F1S4	1.1345
30315	3rd+ Episodes, 11 to 13 Therapy Visits	C3F1S5	1.3148
30321	3rd+ Episodes, 0 to 5 Therapy Visits	C3F2S1	0.6786
30322	3rd+ Episodes, 6 Therapy Visits	C3F2S2	0.8477

TABLE 5—CY 2018 CASE-MIX PAYMENT WEIGHTS—Continued

Pay group	Description	Clinical and functional levels (1 = Low; 2 = Medium; 3 = High)	CY 2018 weight
30323	3rd+ Episodes, 7 to 9 Therapy Visits	C3F2S3	1.0168
30324	3rd+ Episodes, 10 Therapy Visits	C3F2S4	1.1859
30325	3rd+ Episodes, 11 to 13 Therapy Visits	C3F2S5	1.3550
30331	3rd+ Episodes, 0 to 5 Therapy Visits	C3F3S1	0.7235
30332	3rd+ Episodes, 6 Therapy Visits	C3F3S2	0.8930
30333	3rd+ Episodes, 7 to 9 Therapy Visits	C3F3S3	1.0625
30334	3rd+ Episodes, 10 Therapy Visits	C3F3S4	1.2320
30335	3rd+ Episodes, 11 to 13 Therapy Visits	C3F3S5	1.4015
40111	All Episodes, 20+ Therapy Visits	C1F1S1	1.7070
40121	All Episodes, 20+ Therapy Visits	C1F2S1	1.7438
40131	All Episodes, 20+ Therapy Visits	C1F3S1	1.7888
40211	All Episodes, 20+ Therapy Visits	C2F1S1	1.8124
40221	All Episodes, 20+ Therapy Visits	C2F2S1	1.8492
40231	All Episodes, 20+ Therapy Visits	C2F3S1	1.8942
40311	All Episodes, 20+ Therapy Visits	C3F1S1	2.0540
40321	All Episodes, 20+ Therapy Visits	C3F2S1	2.0908
40331	All Episodes, 20+ Therapy Visits	C3F3S1	2.1359

To ensure the changes to the HH PPS case-mix weights are implemented in a budget neutral manner, we then apply a case-mix budget neutrality factor to the CY 2018 national, standardized 60-day episode payment rate (see section III.C.3. of this final rule). The case-mix budget neutrality factor is calculated as the ratio of total payments when the CY 2018 HH PPS case-mix weights (developed using CY 2016 home health claims data) are applied to CY 2016 utilization (claims) data to total payments when CY 2017 HH PPS case-mix weights (developed using CY 2015 home health claims data) are applied to CY 2016 utilization data. This produces a case-mix budget neutrality factor for CY 2018 of 1.0160.

The following is a summary of the comments and our responses to comments on the CY 2018 case-mix weights:

Comment: A few commenters stated that CMS did not provide sufficient transparency of the details and methods used to recalibrate the HH PPS case-mix weights in the proposed rule. In addition, commenters stated that CMS provided little justification for recalibrating the case-mix weights just 1 year following the recalibration of case-mix weights in CY 2017, 2 years since the recalibration in 2016, and 5 years since the recalibration for the CY 2012 HH PPS final rule. The commenters noted that they opposed the recalibration of the case weights for CY 2018, but supported the budget neutrality adjustment to account for the recalibrated case-mix weights if CMS finalizes the recalibration.

Response: As stated in the CY 2018 HH PPS proposed rule (82 FR 35282), the methodology used to recalibrate the weights is identical to the methodology used in the CY 2012 recalibration except for the minor exceptions as noted in the CY 2015 HH PPS proposed and final rules (79 FR 38366 and 79 FR 66032, respectively). In the CY 2015 HH PPS final rule, we finalized annual recalibration and the methodology to be used for each year's recalibration (79 FR 66072). For more detail, we also encourage commenters to refer to the CY 2012 HH PPS proposed and final rules (76 FR 40988 and 76 FR 68526, respectively) and the November 1, 2011 ''Revision of the Case-Mix Weights for the HH PPS Report'' on our home page at: *https://www.cms.gov/center/provider-Type/home-Health-Agency-HHA-Center.html* for additional information about the recalibration methodology.

We note that in comparing the final CY 2018 HH PPS case-mix weights (see Table 5) to the final CY 2015 HH PPS case-mix weights (79 FR 66062), the case-mix weights change very little, with most case-mix weights either increasing or decreasing by 1 to 2 percent with no case-mix weights increasing by more than 3 percent or decreasing by more than 3 percent. The aggregate decreases in the case-mix weights are offset by the case-mix budget neutrality factor, which is applied to the national, standardized 60-day episode payment rate. In other words, although the case-mix weights themselves may increase or decrease from year-to-year, we correspondingly offset any estimated increases or decreases in total payments under the HH PPS, as a result of the case-mix recalibration, by applying a budget neutrality factor to the national, standardized 60-day episode payment rate. For CY 2018, the case-mix budget neutrality factor will be 1.0160 as described previously. The recalibration of the case-mix weights is not intended to increase or decrease overall HH PPS payments, but rather is used to update the relative differences in resource use amongst the 153 groups in the HH PPS case-mix system and maintain the level of aggregate payments before application of any other adjustments. We will continue to monitor the performance of any finalized case-mix model, and will make changes to it as necessary.

Final Decision: We are finalizing the recalibrated scores for the case-mix adjustment variables, clinical and functional thresholds, payment regression model, and case-mix weights in Tables 2 through 5. For this final rule, the CY 2018 scores for the case-mix variables, the clinical and functional thresholds, and the case-mix weights were developed using complete CY 2016 claims data as of August 17, 2017. We note that we finalized the recalibration methodology and the proposal to annually recalibrate the HH PPS case-mix weights in the CY 2015 HH PPS final rule (79 FR 66072). No additional proposals were made with regard to the recalibration methodology in the CY 2018 HH PPS proposed rule.

C. CY 2018 Home Health Payment Rate Update

1. CY 2018 Home Health Market Basket Update

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2018 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. The home health market basket was rebased and revised in CY 2013. A detailed description of how we derive the HHA market basket is available in the CY 2013 HH PPS final rule (77 FR 67080 through 67090).

Section 1895(b)(3)(B)(vi) of the Act, requires that, in CY 2015 (and in subsequent calendar years, except CY 2018 (under section 411(c) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015)), the market basket percentage under the HHA prospective payment system as described in section 1895(b)(3)(B) of the Act be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period) (the ''MFP adjustment''). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. Please see *http://www.bls.gov/mfp* to obtain the BLS historical published MFP data.

Prior to the enactment of the MACRA, which amended section 1895(b)(3)(B) of the Act, the home health update percentage for CY 2018 would have been based on the estimated home health market basket update of 2.5 percent (based on IHS Global Inc.'s third-quarter 2017 forecast with historical data through second-quarter 2017). Due to the requirements specified at section 1895(b)(3)(B)(vi) of the Act prior to the enactment of MACRA, the estimated CY 2018 home health market basket update of 2.5 percent would have been reduced by a MFP adjustment as mandated by the Affordable Care Act (currently estimated to be 0.6 percentage point for CY 2018). In effect, the home health payment update percentage for CY 2018 would have been 1.9 percent. However, section 411(c) of the MACRA amended section 1895(b)(3)(B) of the Act, such that, for home health payments for CY 2018, the market basket percentage increase is required to be 1 percent.

Section 1895(b)(3)(B) of the Act requires that the home health update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2018, the home health payment update will be −1 percent (1 percent minus 2 percentage points).

2. CY 2018 Home Health Wage Index

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of HH services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to HH payments. We proposed to continue this practice for CY 2018, as we continue to believe that, in the absence of HH-specific wage data, using inpatient hospital wage data is appropriate and reasonable for the HH PPS. Specifically, we proposed to continue to use the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2018, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2013, and before October 1, 2014 (FY 2014 cost report data). We apply the appropriate wage index value to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined by section 1861(m) of the Act as the beneficiary's place of residence).

To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2018 HH PPS wage index, we proposed to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals. For rural areas that do not have inpatient hospitals, we proposed to use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. Currently, the only rural area without a hospital from which hospital wage data could be derived is Puerto Rico. However, for rural Puerto Rico, we do not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we proposed to continue to use the most recent wage index previously available for that area. For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the state as a reasonable proxy for the wage index for that CBSA. For CY 2018, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980).

On February 28, 2013, OMB issued Bulletin No. 13–01, announcing revisions to the delineations of MSAs, Micropolitan Statistical Areas, and CBSAs, and guidance on uses of the delineation of these areas. In the CY 2015 HH PPS final rule (79 FR 66085 through 66087), we adopted the OMB's new area delineations using a 1-year transition. The most recent bulletin (No. 15–01) concerning the revised delineations was published by the OMB on July 15, 2015.

The CY 2018 wage index is available on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.html*.

3. CY 2018 Annual Payment Update

a. Background

The Medicare HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000 final rule (65 FR 41128), the base unit of payment under the Medicare HH PPS is a national, standardized 60-day episode payment rate. As set forth in § 484.220, we adjust the national, standardized 60-day episode payment rate by a case-mix relative weight and a wage index value based on the site of service for the beneficiary.

To provide appropriate adjustments to the proportion of the payment amount under the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. The labor-related share of the case-mix adjusted 60-day episode rate will continue to be 78.535 percent and the non-labor-related share will continue to be 21.465 percent as set out in the CY 2013 HH PPS final rule (77 FR 67068). The CY 2018 HH PPS rates use the same case-mix methodology as set forth in the CY 2008 HH PPS final rule with comment period (72 FR 49762) and will be adjusted as described in section III.B.

of this final rule. The following are the steps we take to compute the case-mix and wage-adjusted 60-day episode rate:

(1) Multiply the national 60-day episode rate by the patient's applicable case-mix weight.

(2) Divide the case-mix adjusted amount into a labor (78.535 percent) and a non-labor portion (21.465 percent).

(3) Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.

(4) Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 60-day episode rate, subject to any additional applicable adjustments.

In accordance with section 1895(b)(3)(B) of the Act, we proposed the annual update of the HH PPS rates. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with § 484.225(i), for a HHA that does not submit HH quality data, as specified by the Secretary, the unadjusted national prospective 60-day episode rate is equal to the rate for the previous calendar year increased by the applicable HH market basket index amount minus 2 percentage points. Any reduction of the percentage change will apply only to the calendar year involved and will not be considered in computing the prospective payment amount for a subsequent calendar year.

Medicare pays the national, standardized 60-day case-mix and wage-adjusted episode payment on a split percentage payment approach. The split percentage payment approach includes an initial percentage payment and a final percentage payment as set forth in § 484.205(b)(1) and (b)(2). We may base the initial percentage payment on the submission of a request for anticipated payment (RAP) and the final percentage payment on the submission of the claim for the episode, as discussed in § 409.43. The claim for the episode that the HHA submits for the final percentage payment determines the total payment amount for the episode and whether we make an applicable adjustment to the 60-day case-mix and wage-adjusted episode payment. The end date of the 60-day episode as reported on the claim determines which calendar year rates Medicare will use to pay the claim.

We may also adjust the 60-day case-mix and wage-adjusted episode payment based on the information submitted on the claim to reflect the following:

- A low-utilization payment adjustment (LUPA) is provided on a per-visit basis as set forth in §§ 484.205(c) and 484.230.
- A partial episode payment (PEP) adjustment as set forth in §§ 484.205(d) and 484.235.
- An outlier payment as set forth in §§ 484.205(e) and 484.240.

b. CY 2018 National, Standardized 60-Day Episode Payment Rate

Section 1895(b)(3)(A)(i) of the Act requires that the 60-day episode base rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different home health agencies in a budget neutral manner. To determine the CY 2018 national, standardized 60-day episode payment rate, we apply a wage index budget neutrality factor; a case-mix budget neutrality factor described in section III.B. of this final rule; a reduction of 0.97 percent to account for nominal case-mix growth from 2012 to 2014, as finalized in the CY 2016 HH PPS final rule (80 FR 68646); and the home health payment update percentage discussed in section III.C.1 of this final rule.

To calculate the wage index budget neutrality factor, we simulated total payments for non-LUPA episodes using the CY 2018 wage index and compared it to our simulation of total payments for non-LUPA episodes using the CY 2017 wage index. By dividing the total payments for non-LUPA episodes using the CY 2018 wage index by the total payments for non-LUPA episodes using the CY 2017 wage index, we obtain a wage index budget neutrality factor of 1.0004. We will apply the wage index budget neutrality factor of 1.0004 to the calculation of the CY 2018 national, standardized 60-day episode rate.

As discussed in section III.B. of the proposed rule, to ensure the changes to the case-mix weights are implemented in a budget neutral manner, we proposed to apply a case-mix weight budget neutrality factor to the CY 2018 national, standardized 60-day episode payment rate. The case-mix weight budget neutrality factor is calculated as the ratio of total payments when CY 2018 case-mix weights are applied to CY 2016 utilization (claims) data to total payments when CY 2017 case-mix weights are applied to CY 2016 utilization data. The case-mix budget neutrality factor for CY 2018 is 1.0160 as described in section III.B of this final rule.

Next, we apply a reduction of 0.97 percent to the national, standardized 60-day payment rate for CY 2018 to account for nominal case-mix growth between CY 2012 and CY 2014. Lastly, we will update the payment rates by the CY 2018 home health payment update percentage of 1 percent as mandated by section 1895(b)(3)(B)(iii) of the Act. The CY 2018 national, standardized 60-day episode payment rate is calculated in Table 6.

TABLE 6—CY 2018 60-DAY NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT

CY 2017 national, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	Nominal case-mix growth adjustment (1–0.0097)	CY 2018 HH payment update	CY 2018 national, standardized 60-day episode payment
$2,989.97	× 1.0004	× 1.0160	× 0.9903	× 1.01	$3,039.64

The CY 2018 national, standardized 60-day episode payment rate for an HHA that does not submit the required quality data is updated by the CY 2018 home health payment update of 1 percent minus 2 percentage points and is shown in Table 7.

TABLE 7—CY 2017 NATIONAL, STANDARDIZED 60-DAY EPISODE PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2017 national, standardized 60-day episode payment	Wage index budget neutrality factor	Case-mix weights budget neutrality factor	Nominal case-mix growth adjustment (1–0.0097)	CY 2018 HH payment update	CY 2018 national, standardized 60-day episode payment
$2,989.97	× 1.0004	× 1.0160	× 0.9903	× 0.99	$2,979.45

c. CY 2018 National Per-Visit Rates

The national per-visit rates are used to pay LUPAs (episodes with four or fewer visits) and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or HH discipline. The six HH disciplines are as follows:

- Home health aide (HH aide).
- Medical Social Services (MSS).
- Occupational therapy (OT).
- Physical therapy (PT).
- Skilled nursing (SN).
- Speech-language pathology (SLP).

To calculate the CY 2018 national per-visit rates, we started with the CY 2017 national per-visit rates. Then we applied a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments. We calculated the wage index budget neutrality factor by simulating total payments for LUPA episodes using the CY 2018 wage index and comparing it to simulated total payments for LUPA episodes using the CY 2017 wage index. By dividing the total payments for LUPA episodes using the CY 2018 wage index by the total payments for LUPA episodes using the CY 2017 wage index, we obtained a wage index budget neutrality factor of 1.0010. We apply the wage index budget neutrality factor of 1.0010 in order to calculate the CY 2018 national per-visit rates.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, there is no case-mix weights budget neutrality factor needed to ensure budget neutrality for LUPA payments. Lastly, the per-visit rates for each discipline are updated by the CY 2018 home health payment update percentage of 1 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for episodes that occur as the only episode or initial episode in a sequence of adjacent episodes. The CY 2018 national per-visit rates are shown in Tables 8 and 9.

TABLE 8—CY 2018 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2017 per-visit payment	Wage index budget neutrality factor	CY 2018 HH payment update	CY 2018 per-visit payment
Home Health Aide	$64.23	× 1.0010	× 1.01	$64.94
Medical Social Services	227.36	× 1.0010	× 1.01	229.86
Occupational Therapy	156.11	× 1.0010	× 1.01	157.83
Physical Therapy	155.05	× 1.0010	× 1.01	156.76
Skilled Nursing	141.84	× 1.0010	× 1.01	143.40
Speech-Language Pathology	168.52	× 1.0010	× 1.01	170.38

The CY 2018 per-visit payment rates for HHAs that do not submit the required quality data are updated by the CY 2018 HH payment update percentage of 1 percent minus 2 percentage points and are shown in Table 9.

TABLE 9—CY 2018 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2017 per-visit rates	Wage index budget neutrality factor	CY 2018 HH payment update minus 2 percentage points	CY 2018 per-visit rates
Home Health Aide	$64.23	× 1.0010	× 0.99	$63.65
Medical Social Services	227.36	× 1.0010	× 0.99	225.31
Occupational Therapy	156.11	× 1.0010	× 0.99	154.70
Physical Therapy	155.05	× 1.0010	× 0.99	153.65
Skilled Nursing	141.84	× 1.0010	× 0.99	140.56
Speech-Language Pathology	168.52	× 1.0010	× 0.99	167.00

d. Low-Utilization Payment Adjustment (LUPA) Add-On Factors

LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences. In the CY 2014 HH PPS final rule (78 FR 72305), we changed the methodology for calculating the LUPA add-on amount by finalizing the use of three LUPA add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. We multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by the appropriate factor to determine the LUPA add-on payment amount. For example, in the case of HHAs that do submit the required quality data, for LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes, if the first skilled visit is SN, the payment for that visit will be $264.59 (1.8451 multiplied by $143.40), subject to area wage adjustment.

e. CY 2018 Non-Routine Medical Supply (NRS) Payment Rates

All medical supplies (routine and nonroutine) must be provided by the HHA while the patient is under a home health plan of care. Examples of supplies that can be considered non-routine include dressings for wound care, I.V. supplies, ostomy supplies, catheters, and catheter supplies. Payments for NRS are computed by multiplying the relative weight for a particular severity level by the NRS conversion factor. To determine the CY 2018 NRS conversion factor, we updated the CY 2017 NRS conversion factor ($52.50) by the CY 2018 home health payment update percentage of 1 percent. We did not apply a standardization factor as the NRS payment amount calculated from the conversion factor is not wage or case-mix adjusted when the final claim payment amount is computed. The NRS conversion factor for CY 2018 is shown in Table 10.

TABLE 10—CY 2018 NRS CONVERSION FACTOR FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

CY 2017 NRS conversion factor	CY 2018 HH payment update	CY 2018 NRS conversion factor
$52.50	× 1.01	$53.03

Using the CY 2018 NRS conversion factor, the payment amounts for the six severity levels are shown in Table 11.

TABLE 11—CY 2018 NRS PAYMENT AMOUNTS FOR HHAS THAT DO SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2018 NRS payment amounts
1	0	0.2698	$14.31
2	1 to 14	0.9742	51.66
3	15 to 27	2.6712	141.65
4	28 to 48	3.9686	210.45
5	49 to 98	6.1198	324.53
6	99+	10.5254	558.16

For HHAs that do not submit the required quality data, we updated the CY 2017 NRS conversion factor ($52.50) by the CY 2018 home health payment update percentage of 1 percent minus 2 percentage points. The CY 2018 NRS conversion factor for HHAs that do not submit quality data is shown in Table 12.

TABLE 12—CY 2018 NRS CONVERSION FACTOR FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

CY 2017 NRS conversion factor	CY 2018 HH payment update percentage minus 2 percentage points	CY 2018 NRS conversion factor
$52.50	× 0.99	$51.98

The payment amounts for the various severity levels based on the updated conversion factor for HHAs that do not submit quality data are calculated in Table 13.

TABLE 13—CY 2018 NRS PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

Severity level	Points (scoring)	Relative weight	CY 2018 NRS payment amounts
1	0	0.2698	$14.02
2	1 to 14	0.9742	50.64
3	15 to 27	2.6712	138.85
4	28 to 48	3.9686	206.29
5	49 to 98	6.1198	318.11
6	99+	10.5254	547.11

f. Rural Add-On

Section 421(a) of the MMA required, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes or visits ending on or after April 1, 2004, and before April 1, 2005, that the Secretary increase the payment amount that otherwise would have been made under section 1895 of the Act for the services by 5 percent.

Section 5201 of the DRA amended section 421(a) of the MMA. The amended section 421(a) of the MMA required, for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), on or after January 1, 2006, and before January 1, 2007, that the Secretary increase the payment amount otherwise made under section 1895 of the Act for those services by 5 percent.

Section 3131(c) of the Affordable Care Act amended section 421(a) of the MMA to provide an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending on or after April 1, 2010, and before January 1, 2016.

Section 210 of the MACRA amended section 421(a) of the MMA to extend the rural add-on by providing an increase of 3 percent of the payment amount otherwise made under section 1895 of the Act for HH services provided in a rural area (as defined in section 1886(d)(2)(D) of the Act), for episodes and visits ending before January 1, 2018. Therefore, for episodes and visits that end on or after January 1, 2018, a rural add-on payment will not apply.

The following is a summary of the public comments received on the ''CY 2018 Home Health Payment Rate Update'' proposals and our responses:

Comment: Several commenters stated that they wanted CMS to rescind the nominal case-mix reduction for CY 2018. Some commenters stated that implementation of the nominal case-mix reductions in 2016, 2017, and 2018 violated the limits on payment reductions set out by the Congress, and urged CMS to adhere to the statutory limits on home health rate cuts. Commenters expressed concerns with the data and methodology used to develop the proposed case-mix cuts and stated that the annual recalibration may have eliminated any practice of assigning an inaccurate code to increase reimbursement and questioned the interaction between the rebasing adjustments, nominal case-mix growth reductions, and case-mix recalibration. A few commenters stated that the baseline used in calculating the amount of case-mix growth was inappropriate. Some commenters noted that actual program spending on home health was consistently less than Congressional Budget Office (CBO) estimates, and questioned CMS' authority to implement case mix weight adjustments when home health spending was less than these estimates. Commenters stated that there was no increase in aggregate expenditures that warranted the application of this statutory authority, and CMS should withdraw its proposal. Some commenters stated that CMS should implement program integrity measures to control aberrant coding by some providers instead of imposing across-the-board case mix creep adjustments on all providers.

Response: We finalized the nominal case-mix reduction for CY 2018 in the CY 2016 HH PPS final rule. We did not propose changes to the finalized reduction for CY 2018, nor did we propose any changes in the methodology used to calculate nominal case-mix growth in the CY 2018 HH PPS proposed rule. The majority of the comments received regarding the payment reductions for nominal case-mix growth were very similar to the comments submitted during the comment period for the CY 2016 HH PPS proposed rule. Therefore, we encourage commenters to review our responses to the comments we received on the payment reductions for nominal case-mix growth in the CY 2016 HH PPS final rule (80 FR 68639 through 68646), which include responses on the interaction between the rebasing and recalibration of the case-mix weights on the measurement of nominal case-mix growth between 2012 and 2014, our rationale for the methodology used to determine ''real'' versus ''nominal'' case-mix growth in CYs 2012–2014, the role of CBO estimates in our determination of nominal case-mix reductions, and our ability to target nominal case-mix reductions to certain providers rather the industry as a whole. We will continue to monitor real and nominal case-mix growth and may propose additional reductions for nominal case-mix growth, as needed, in the future.

Comment: MedPAC stated that they have long believed that it was necessary for CMS to make adjustments to account for nominal case-mix change to prevent additional overpayments. MedPAC stated that the CMS' reduction to account for nominal case-mix growth is consistent with the agency's past findings on trends in case-mix change in the payment system and thus is warranted to ensure the accuracy of payments under the home health PPS. MedPAC stated that a reduction of 0.97 percent should not significantly affect access to care.

Response: We thank MedPAC for their comments.

Comment: Several commenters stated their belief that the CY 2018 payment update of 1 percent is inadequate.

Response: We appreciate the commenters' concerns. However, the 1 percent payment update for CY 2018 is mandated by section 1895(b)(3)(B)(iii) of the Act, as amended by section 411(c) of the MACRA.

Comment: Several commenters urged CMS to continue providing rural add-on payments in order that beneficiaries in rural communities continue to have access to home health services.

Response: The sunset of rural add-on payments for CY 2018 is statutory and we do not have the authority to re-authorize rural add-on payments for episodes and visits ending on or after January 1, 2018.[11] However, we plan to continue to monitor the costs associated with providing home health care in rural versus urban areas. We note that in Chapter 9 of its 2013 Report to Congress (available at *http://medpac.gov/docs/default-source/reports/mar13_ch09.pdf?sfvrsn=0*), MedPAC stated that the use of the ''broadly targeted add-on, providing the same payment for all rural areas regardless of access, results in rural areas with the highest utilization drawing a disproportionate share of the add-on payments.'' MedPAC stated that ''70 percent of the episodes that received the add-on payments in 2011 were in rural counties with utilization significantly higher than the national average'' and recommended that Medicare target payment adjustments for rural areas to those areas that have access challenges.

Comment: A commenter recommended that CMS explore policies that provide Medicare coverage for services from therapy providers who furnish telehealth services to their patients as proper application of telehealth rehabilitation therapy services, particularly in underserved areas, can potentially have a dramatic impact on improving care, diminishing negative consequences, and reducing costs.

Response: The definition of a visit for purposes of Medicare home health services as set forth in § 409.48(c) specifies that a visit is an episode of personal contact with the beneficiary by

[11] See U.S. CONST. art. I, § 9 (''No money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law'').

staff of the HHA or others under arrangements with the HHA for the purpose of providing a covered service. A telephone contact or telehealth visit does not meet the definition of a visit and therefore does not count as a visit. While there is nothing to preclude an HHA from furnishing services via telehealth or other technologies that they believe promote efficiencies, those technologies are not specifically recognized and paid by Medicare under the home health benefit.

Comment: Several commenters expressed concerns with the wage index for rural areas in Maine, citing it as one of the lowest in New England. Another commenter questioned the validity of the wage index data, especially in the case of the CBSA for Albany-Schenectady-Troy, noting that in the past 5 years, this CBSA has seen its wage index reduced 5.41 percent, going from 0.8647 in 2013 to a proposed CY 2018 wage index of 0.8179.

Response: As discussed in the CY 2017 HH PPS final rule (81 FR 76721), we believe that the wage index values are reflective of the labor costs in each geographic area as they reflect the costs included on the cost reports of hospitals in those specific labor market areas. The wage index values are based on data submitted on the inpatient hospital cost reports. We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. The home health wage index is derived from the pre-floor, pre-reclassified wage index, which is calculated based on cost report data from hospitals paid under the Hospital Inpatient Prospective Payment System (IPPS). All IPPS hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. Cost reports will be rejected if Worksheet S–3 is not completed. In addition, Medicare contractors perform desk reviews on all hospitals' Worksheet S–3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. We believe that our review processes result in an accurate reflection of the applicable wages for the areas given. The processes and procedures describing how the inpatient hospital wage index is developed are discussed in the IPPS rule each year, with the most recent discussion provided in the FY 2018 IPPS final rule (82 FR 38130 through 38136 and 82 FR 38152 through 38156). Any provider type may submit comments on the hospital wage index during the annual IPPS rulemaking cycle.

Comment: A commenter stated that CMS's decision to switch from MSAs to the CBSAs for the wage index calculation has had serious financial ramifications for New York HHAs. The commenter stated that CMS's shift to the CBSA wage index designation has resulted in below trend reimbursement for New York City agencies.

Response: The MSA delineations as well as the CBSA delineations are determined by the OMB. The OMB reviews its Metropolitan Area definitions preceding each decennial census to reflect recent population changes. We believe that the OMB's CBSA designations reflect the most recent available geographic classifications and are a reasonable and appropriate way to define geographic areas for purposes of wage index values.

Comment: Several commenters opposed the fact that hospitals are given the opportunity to appeal their annual wage index and apply for geographic reclassification while HHAs in the same geographic location are not given that same privilege. The commenters believe that this lack of parity between different health care sectors further exemplifies the inadequacy of CMS's decision to continue to use the pre-floor, pre-reclassified hospital wage index to adjust home health services payment rates. Another commenter suggests that CMS include wage data from reclassified hospitals in calculating rural wage index values.

Response: We continue to believe that the regulations and statutes that govern the HH PPS do not provide a mechanism for allowing HHAs to seek geographic reclassification or to utilize the rural floor provisions that exist for IPPS hospitals. Section 4410(a) of the BBA provides that the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that state. This is the rural floor provision and it is specific to hospitals. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital's geographic classification. This reclassification provision is only applicable to hospitals as defined in section 1886(d) of the Act. In addition, we do not believe that using hospital reclassification data would be appropriate as these data are specific to the requesting hospitals and may or may not apply to a given HHA.

We continue to believe that using the pre-floor, pre-reclassified hospital wage index as the wage adjustment to the labor portion of the HH PPS rates is appropriate and reasonable.

Comment: Several commenters requested that CMS explore wholesale revision and reform of the home health wage index, including the development of a home health-specific wage index. Commenters noted that reform of the home health wage index should address the commenters' following concerns and opinions: (1) The impact on care access and financial stability of HHAs at the local level; (2) the unpredictable year-to-year swings in wage index values that are often based on inaccurate or incomplete hospital cost reports which have negatively impacted HHAs throughout the years and jeopardized access to care; (3) the inadequacy and inaccuracy of the pre-floor, pre-reclassified hospital wage index for adjusting home health costs; and (4) the labor market distortions created by reclassification of hospitals in areas in which home health labor costs are not reclassified.

Response: We appreciate the commenter's recommendation to continue exploring potential approaches for wage index reform, including collecting home health-specific wage data in order to establish a home health-specific wage index. We note that our previous attempts at either proposing or developing a home health-specific wage index were not well-received by the home health industry. In September 30, 1988 **Federal Register** notice (53 FR 38476), the Health Care Financing Administration (HCFA), as CMS was then known, implemented an HHA-specific wage index based on data received from HHAs. Subsequently, providers gave significant feedback concerning the burden that the reporting requirements posed and the accuracy of the data. As a result, the Medicare Catastrophic Coverage Act of 1988 retroactively repealed the use of an HHA-specific wage index and referenced use of the hospital wage index (see section 1895(b)(4)(C) of the Act). While this occurred many years ago, we believe that HHAs would voice similar concerns regarding the burden such reporting requirements would place on HHAs.

Consistent with our previous responses to these recurring comments (most recently published in the CY 2016 HH PPS final rule (80 FR 68654)), we also note that developing such a wage index would require a resource-intensive audit process similar to that used for IPPS hospital data, to improve the quality of the HHA cost report data in order for it to be used as part of this analysis. This audit process is quite extensive in the case of approximately

3,300 hospitals, it would be significantly more so in the case of approximately 11,000 HHAs. We believe auditing all HHA cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the IPPS wage index, would also place a burden on providers in terms of recordkeeping and completion of the cost report worksheet.

We also believe that adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors, potentially far in excess of those required under the IPPS given that there are more than three times as many HHAs as there are hospitals. Therefore, we continue to believe that, in the absence of the appropriate home health-specific wage data, using the pre-floor, pre-reclassified inpatient hospital wage data is appropriate and reasonable for the HH PPS.

Finally, CMS has conducted research on a possible alternative to the hospital wage index. CMS issued its ''Report to Congress: Plan to Reform the Medicare Wage Index'' concerning the hospital wage index, on April 11, 2012 and is available on our Wage Index Reform Web page *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html*. This report describes the concept of a commuting-based wage index (CBWI). However, implementation of a CBWI may require both statutory and regulatory changes. In addition, we believe other intermediate steps for implementation, including the collection of commuting data, may be necessary. In considering alternative methodologies for area wage adjustment, CMS would have to consider whether the benefits of such methodologies outweigh the reporting, record keeping and audit burden that would be placed on HHAs and/or other providers.

Comment: Several commenters stated that the pre-floor, pre-reclassified hospital wage index is inadequate for adjusting home health costs, particularly in states like New York, which has among the nation's highest labor costs, exacerbated, in the commenters' opinions, by their state's implementation of a phased-in $15 per-hour minimum wage hike, which they argue would be unfunded by Medicare. The commenters estimated that the minimum wage mandate, when fully phased-in, would add $2 billion in costs for that state's HHAs across all payers (Medicaid, Medicare, managed care, commercial insurance and private-pay), and would not be captured by the pre-floor, pre-reclassified hospital wage index. One commenter recommended that providers meeting higher minimum wage standards, such as HHAs, obtain additional supplemental funding to better align payments with cost trends impacting providers.

Response: Regarding minimum wage standards, we note that such increases will be reflected in future data used to create the hospital wage index to the extent that these changes to state minimum wage standards are reflected in increased wages to hospital staff.

Comment: Commenters raised issues with CMS's decision to maintain the current policy of using the pre-floor, pre-reclassified hospital wage index to adjust home health services payment rates because this resulted in volatility in the home health wage index from one year to the next. These commenters believe that what they view as unpredictable year-to-year swings in wage index values were based on inaccurate or incomplete hospital cost reports.

Response: We appreciate the commenters' concerns regarding the accuracy of the home health wage index. We utilize efficient means to ensure and review the accuracy of the hospital cost report data and resulting wage index. The home health wage index is derived from the pre-floor, pre-reclassified wage index, which is calculated based on cost report data from hospitals paid under the IPPS. All IPPS hospitals must complete the wage index survey (Worksheet S–3, Parts II and III) as part of their Medicare cost reports. Cost reports will be rejected if Worksheet S–3 is not completed. In addition, Medicare contractors perform desk reviews on all hospitals' Worksheet S–3 wage data, and we run edits on the wage data to further ensure the accuracy and validity of the wage data. We believe that our review processes result in an accurate reflection of the applicable wages for the areas given. The processes and procedures describing how the inpatient hospital wage index is developed, including a wage data verification and correction process, are discussed in the IPPS rule each year, with the most recent discussion provided in the FY 2018 IPPS final rule (82 FR 38130 through 38136, and 82 FR 38152 through 38156). Any provider type may submit comments on the hospital wage index during the annual IPPS rulemaking cycle.

Comment: A commenter recommended that CMS research the impact of instituting a population density adjustment to the labor portion of the HH PPS payments.

Response: As discussed in the CY 2017 HH PPS final rule (81 FR 76721), we do not believe that a population density adjustment is appropriate at this time. Rural HHAs continually cite the added cost of traveling from one patient to the next patient. However, urban HHAs cite the added costs associated with needed security measures and traffic congestion. The home health wage index values in rural areas are not necessarily lower than the home health wage index values in urban areas. The home health wage index reflects the wages that inpatient hospitals pay in their local geographic areas.

Final Decision: After considering the comments received in response to the CY 2018 HH PPS proposed rule, we are finalizing our proposal to use the pre-floor, pre-reclassified hospital inpatient wage index as the wage adjustment to the labor portion of the HH PPS rates. For CY 2018, the updated wage data are for the hospital cost reporting periods beginning on or after October 1, 2013 and before October 1, 2014 (FY 2014 cost report data). In addition, we are implementing the third and final year of a 0.97 percent payment reduction to account for nominal case-mix growth from CY 2012 through CY 2014 when finalizing the CY 2018 HH PPS payment rates. We note that the payment reductions to account for nominal case-mix growth from 2012 to 2014 were finalized in the CY 2016 HH PPS final rule. No additional adjustments or reductions were proposed in the CY 2018 proposed rule.

D. Payments for High-Cost Outliers Under the HH PPS

1. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount in the case of outliers because of unusual variations in the type or amount of medically necessary care. Outlier payments serve as a type of ''reinsurance'' whereby, under the HH PPS, Medicare reimburses HHAs 80 percent of their costs for outlier cases once the case exceeds an outlier threshold amount. Prior to the enactment of the Affordable Care Act, section 1895(b)(5) of the Act stipulated that projected total outlier payments could not exceed 5 percent of total projected or estimated HH payments in a given year. In the July 3, 2000 Medicare Program; Prospective Payment System for Home Health Agencies final rule (65 FR 41188 through 41190), we described the method for determining outlier payments. Under this system, outlier payments are made for episodes

whose estimated costs exceed a threshold amount for each Home Health Resource Group (HHRG). The episode's estimated cost was established as the sum of the national wage-adjusted per-visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or Partial Episode Payment (PEP) adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. The outlier payment is defined to be a proportion of the wage-adjusted estimated cost beyond the wage-adjusted threshold. The threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

In the CY 2010 HH PPS proposed rule (74 FR 40948, 40957), we stated that outlier payments increased as a percentage of total payments from 4.1 percent in CY 2005, to 5.0 percent in CY 2006, to 6.4 percent in CY 2007 and that this excessive growth in outlier payments was primarily the result of unusually high outlier payments in a few areas of the country. In that discussion, we noted that despite program integrity efforts associated with excessive outlier payments in targeted areas of the country, we discovered that outlier expenditures still exceeded the 5 percent target in CY 2007 and, in the absence of corrective measures, would continue do to so. Consequently, we assessed the appropriateness of taking action to curb outlier abuse. As described in the CY 2010 HH PPS final rule (74 FR 58080 through 58087), to mitigate possible billing vulnerabilities associated with excessive outlier payments and adhere to our statutory limit on outlier payments, we finalized an outlier policy that included a 10 percent agency-level cap on outlier payments. This cap was implemented in concert with a reduced FDL ratio of 0.67. These policies resulted in a projected target outlier pool of approximately 2.5 percent. (The previous outlier pool was 5 percent of total home health expenditures). For CY 2010, we first returned the 5 percent held for the previous target outlier pool to the national, standardized 60-day episode rates, the national per-visit rates, the LUPA add-on payment amount, and the NRS conversion factor. Then, we reduced the CY 2010 rates by 2.5 percent to account for the new outlier pool of 2.5 percent. This outlier policy was adopted for CY 2010 only.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act, and required the Secretary to reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act, and revising the language to state that the total amount of the additional payments or payment adjustments for outlier episodes may not exceed 2.5 percent of the estimated total HH PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act which capped outlier payments as a percent of total payments for each HHA at 10 percent.

As such, beginning in CY 2011, our HH PPS outlier policy is that we reduce payment rates by 5 percent and target up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. Then we reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we target up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10 percent agency-level outlier cap.

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76724), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted that the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the number of visits during an episode of care to surpass the outlier threshold and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76724), we finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and also the length of the visits provided. Using this approach, we now convert the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim will receive an outlier payment and the amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should receive outlier payments, in the CY 2017 HH PPS final rule (81 FR 76725) we also finalized the implementation of a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes. Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

2. Fixed Dollar Loss (FDL) Ratio

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of episodes that can receive outlier payments, but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes. Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower.

The FDL ratio and the loss-sharing ratio must be selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio which, we believe, preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs above the outlier threshold amount.

Simulations based on CY 2015 claims data (as of June 30, 2016) completed for the CY 2017 HH PPS final rule showed that outlier payments were estimated to represent approximately 2.84 percent of total HH PPS payments in CY 2017, and as such, we finalized a change to the FDL ratio from 0.45 to 0.55. We stated that raising the FDL ratio to 0.55, while maintaining a loss-sharing ratio of 0.80, struck an effective balance of compensating for high-cost episodes while still meeting the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments (81 FR 76726). The national, standardized 60-day episode payment amount is multiplied by the FDL ratio. That amount is wage-adjusted

to derive the wage-adjusted FDL amount, which is added to the case-mix and wage-adjusted 60-day episode payment amount to determine the outlier threshold amount that costs have to exceed before Medicare would pay 80 percent of the additional estimated costs.

Using preliminary CY 2016 claims data (as of March 17, 2017) and the proposed CY 2018 payment rates presented in section III.C. of the CY 2018 HH PPS proposed rule (82 FR 35293), we estimated that outlier payments would constitute approximately 2.47 percent of total HH PPS payments in CY 2018 under the current outlier methodology. Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we did not propose a change to the FDL ratio for CY 2018 as we believed that maintaining an FDL ratio of 0.55 with a loss-sharing ratio of 0.80 was still appropriate given the percentage of outlier payments projected for CY 2018. Likewise, we did not propose a change to the loss-sharing ratio (0.80) for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, Inpatient Rehabilitation Facility (IRF) PPS, IPPS, etc.). While we did not propose to change the FDL ratio of 0.55 for CY 2018, we noted that we would update our estimate of outlier payments as a percent of total HH PPS payments using the most current and complete year of HH PPS data (CY 2016 claims data as of June 30, 2017 or later) in this final rule.

Using updated CY 2016 claims data (as of August 18, 2017) and the final CY 2018 payment rates presented in section III.C of this final rule, we estimate that outlier payments would continue to constitute approximately 2.47 percent of total HH PPS payments in CY 2018 under the current outlier methodology. Given the statutory requirement to target up to, but no more than, 2.5 percent of total payments as outlier payments, we continue to believe that maintaining an FDL ratio of 0.55 with a loss-sharing ratio of 0.80 is still appropriate given the percentage of outlier payments projected for CY 2018.

The following is a summary of the comments received and our responses.

Comment: A commenter questioned if we would provide the CY 2018 cost-per-unit values to be used for the outlier calculation.

Response: The cost-per-unit amounts for CY 2018 are in Table 14 of this final rule. We note that in the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, we noted that the per-unit rates used to estimate an episode's cost will be updated by the home health update percentage each year, meaning we would start with the national per-visit amounts for the same calendar year when calculating the cost-per-unit used to determine the cost of an episode of care (81 FR 76727).

TABLE 14—CY 2018 COST-PER-UNIT PAYMENT RATES FOR THE CALCULATION OF OUTLIER PAYMENTS *

Visit type	CY 2018 National per-visit payment rates	Average minutes-per-visit	Cost-per-unit (1 unit = 15 minutes)
Home health aide	$64.94	63.0	$15.46
Medical social services	229.86	56.5	61.02
Occupational therapy	157.83	47.1	50.26
Physical therapy	156.76	46.6	50.46
Skilled nursing	143.40	44.8	48.01
Speech-language pathology	170.38	48.1	53.13

* These values reflect the national per visit rates for each discipline for providers who have submitted quality data; for rates applicable to those providers who did not submit quality data submitted, please see our forthcoming CY 2018 Rate Update Change Request, which will be available here: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017-Transmittals.html*.

We note that we will continue to monitor the visit length by discipline as more recent data become available, and we may propose to update the rates as needed in the future.

Comment: Several commenters stated that the changes to the outlier methodology made in the CY 2017 final rule, particularly the increase in the FDL ratio from 0.45 to 0.55, were significant and may have led to a reduction in the number of home health episodes that would qualify for outlier payment. The commenters recommended that CMS release data on the impact of this policy change on the dually eligible beneficiary population and in particular those patients with clinically complex conditions.

Response: We appreciate the commenters' concerns regarding the potential impact of the changes to the outlier policy finalized in the CY 2017 HH PPS final rule (81 FR 76727). Data reflecting the changes to the outlier policy made for CY 2017 are not yet available for analysis and assessment. However, as these updated data become available, we will evaluate for changes, analyze patterns in home health outlier payments, and monitor for any impacts, particularly for those beneficiaries with clinically complex conditions, and may include the results of such efforts in future rulemaking.

Additionally, as discussed in the CY 2017 HH PPS final rule (81 FR 76728), the goal of this policy change is to more accurately pay for outlier episodes. We noted in the CY 2017 HH PPS proposed rule that analysis indicates that a larger percentage of episodes of care for patients with a fragile overall health status will qualify for outlier payments (81 FR 43713). The outlier system is meant to help address extra costs associated with extra, and potentially unpredictable, medically necessary care. In section II.D. of the CY 2018 HH PPS proposed rule (82 FR 35275), we discussed Report to Congress: Home Health Study on Access to Care for Vulnerable Patient Populations and Subsequent Research and Analyses. We believe that this change in the outlier payment policy may ultimately serve to address some of the findings from the home health study, where margins were lower for patients with medically complex needs that typically require longer visits, thus potentially creating an incentive to treat only or primarily patients with less complex needs.

Moreover, the 2.5 percent target of outlier payments to total home health payments is a statutory requirement, as established in section 1895(b)(5) of the Act. Therefore, we modified the FDL in order to align the estimated outlier payments with the 2.5 percent target required by law.

Comment: A few commenters expressed disagreement with CMS's decision to maintain the existing 10-percent cap on outlier payments to HHAs as a purported fraud-fighting effort, suggesting that a potentially more appropriate and targeted fraud-fighting initiative will include a possible minimum provider-specific number or percent of episodes that result in LUPAs, suggesting that reporting periods with zero LUPAs could be an indicator of inappropriate provider behavior.

Response: Regarding the appropriateness of the 10 percent per-agency cap, we note that the 2.5 percent target of outlier payments to total home health payments and the 10 percent cap on outlier payments at the home health agency level are statutory requirements, as established in section 1895(b)(5) of the Act. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or increase the 2.5 percent target amount. Additionally, we appreciate the commenter's suggestion regarding alternative approaches for targeting fraud within the Medicare home health benefit. The Program for Evaluating Payment Patterns Electronic Report (PEPPER) is a comparative data report that summarizes a single provider's Medicare claims data statistics for services vulnerable to improper payments. PEPPER can support a hospital or facility's compliance efforts by identifying where its billing patterns are different from the majority of other providers in the nation. This data can help identify both potential overpayments and potential underpayments, and can provide guidance on areas in which a provider may want to focus auditing and monitoring efforts with the goal of preventing improper Medicare payments. In the HHA PEPPER, we include a metric for non-LUPA payment, which represents the count of episodes paid to the HHA that did not have a LUPA payment during the report period as a proportion of total episodes paid to the HHA during the report period (available at: *https://www.pepperresources.org/Portals/0/Documents/PEPPER/HHA/HHA_PEPPERUsersGuide_Edition2.pdf*). This measure is provided to the HHA community for review and may also be used by our Center for Program Integrity as a guide for audits and other investigative efforts.

We also note that, as described in the CY 2017 HH PPS final rule (82 FR 76727), in 2015, only about 1 percent of HHAs received 10 percent of their total HH PPS payments as outlier payments, while almost 71 percent of HHAs received less than 1 percent of their total HH PPS payments as outliers. Therefore, the 10 percent agency-level cap does not seem to significantly impact a large portion of HHAs.

Comment: Several commenters recommended that CMS conduct a more detailed analysis to determine whether the total cap of 2.5 percent of total payments as outlier payments is adequate or whether it needs to be increased for future years, particularly given the expected change in Medicare beneficiary demographics anticipated in the coming years.

Response: As established in section 1895(b)(5) of the Act, both the 2.5 percent target of outlier payments to total home health payments and the 10-percent cap on outlier payments at the home health agency level are statutory requirements. Therefore, we do not have the authority to adjust or eliminate the 10-percent cap or increase the 2.5-percent target amount. However, we will continue to evaluate for the appropriateness of those elements of the outlier policy that may be modified, including the FDL and the loss-sharing ratio. We note that other Medicare payment systems with outlier payments, such as the IRF PPS and IPPS, annually reassess the fixed-loss cost outlier threshold amount. Adjusting the outlier threshold amount in order to target the statutorily required percentage of total payments as outlier payments is standard practice.

Comment: A commenter recommended that CMS eliminate outlier payments in their entirety.

Response: We believe that section 1895(b)(5)(A) of the Act allows the Secretary the discretion as to whether or not to have an outlier policy under the HH PPS. However, we also believe that outlier payments are beneficial in that they help mitigate the incentive for HHAs to avoid patients that may have episodes of care that result in unusual variations in the type or amount of medically necessary care. The outlier system is meant to help address extra costs associated with extra, and potentially unpredictable, medically necessary care. We note that we plan to continue evaluating whether or not an outlier policy remains appropriate as well as ways to maintain an outlier policy for episodes that incur unusually high costs due to patient care needs.

Final Decision: We are finalizing no change to the FDL ratio or loss sharing ratio for CY 2018. We are maintaining an FDL ratio of 0.55 with a loss-sharing ratio of 0.80 for CY 2018. However, we will continue to monitor outlier payments and continue to explore ways to maintain an outlier policy for episodes that incur unusually high costs.

E. Proposed Implementation of the Home Health Groupings Model (HHGM) for CY 2019

We proposed case-mix methodology refinements through the implementation of the Home Health Groupings Model (HHGM). We proposed to implement the HHGM for home health periods of care beginning on or after January 1, 2019. The HHGM uses 30-day periods rather than the 60-day episode used in the current payment system, eliminates the use of the number of therapy visits provided to determine payment, and relies more heavily on clinical characteristics and other patient information (for example, diagnosis, functional level, comorbid conditions, admission source) to place patients into clinically meaningful payment categories.

We are not finalizing the implementation of the HHGM in this final rule. We received many comments from the public that we would like to take into further consideration. While commenters were generally supportive of the concept of revising the HH PPS case-mix methodology to better align payments with the costs of providing care, commenters included technical comments on various aspects of the proposed case-mix adjustment methodology under the HHGM and were most concerned about the proposed change in the unit of payment from 60 days to 30 days and such change being proposed for implementation in a non-budget neutral manner. Commenters also stated their desire for greater involvement in the development of the HHGM and the need for access to the necessary data in order to replicate and model the effects on their businesses.

We note that information continues to be available to stakeholders around this important initiative. The analyses and the ultimate development of HHGM was previously shared with both internal and external stakeholders via technical expert panels, clinical workgroups, and special open door forums. We provided high-level summaries on our case-mix methodology refinement work in the HH PPS proposed rules for CYs 2016 and 2017 (80 FR 39839, and 81 FR 76702). Additionally, a detailed technical report was posted on the CMS Web site in December 2016 and remains available, additional technical expert panel and clinical workgroup webinars were held after the posting of the technical report, and a National Provider call occurred in January 2017 to further solicit feedback from stakeholders and the general

public.[12] As many did, any provider or organization wishing to receive the necessary data to replicate and model the effects of the HHGM or study the Medicare home health benefit can submit a request through the CMS Data Request Center.[13] We note that the Home Health Agency Limited Data Set files and Research Identifiable Files are available on a quarterly and annual basis. The fourth quarter data for CY 2016 were available in mid-May of 2017. The fourth quarter files include all final action fee-for-service claims received by December 31, 2016. We also posted a HHGM Groupings Tool along with the CY 2018 HH PPS proposed rule on the HHA Center Web page, which providers can continue to use in order to replicate the HHGM methodology using their own internal data.

We also note that, in the CY 2018 HH PPS proposed rule, we assumed that behavioral responses would occur upon implementation of the HHGM. If no behavioral assumptions were made and we implemented the HHGM for CY 2018, we estimate that the 30-day payment amount needed to achieve budget neutrality would have been $1,722.29. However, because we have a continued fiduciary duty as stewards of the Medicare program to mitigate potential overpayments, if possible, we assumed behavioral responses would occur in the estimation of the 30-day payment amount. We determined that, if the HHGM were implemented for CY 2018 with assumed behavioral responses, the 30-day payment amount needed to achieve budget neutrality would have been $1,622.61. For the CY 2018 HH PPS proposed rule, we included two behavioral assumptions in our impact estimates related to the proposed implementation of the HHGM for CY 2019: (1) For LUPAs one visit under the proposed HHGM case-mix group thresholds, HHAs would provide an additional visit so the 30-day period of care becomes a non-LUPA; and (2) the highest-paying diagnosis code would be listed as primary for clinical grouping assignment. While we do not support or condone coding practices or the provision of services solely to maximize payment, we often take into account expected behavioral effects of policy changes related to rate setting. We included a LUPA behavioral assumption in our estimated impact of the HHGM based on past behavioral assumptions made under the HH PPS. As noted in the FY 2001 HH PPS final rule, the episode file showed that approximately 16 percent of episodes would have received a LUPA (65 FR 41162). However, currently, about 7 percent of all 60-day episodes receive a LUPA. For the HHGM, approximately 7 percent of 30-day periods would receive a LUPA. However, because 4.9 percent of 30-day periods of care are just one visit below the LUPA thresholds under the HHGM, we assume that for these 30-day periods, HHAs will provide an additional visit to avoid receiving a LUPA, especially in the absence of therapy thresholds and the change from a 60-day to 30-day unit of payment.

With regards to our assumption that HHAs would code the highest-paying diagnosis code as primary for the clinical grouping assignment, this assumption was based on decades of past experience under the HH PPS and other case-mix systems, such as the implementation of the diagnosis-related groups (DRGs) and the Medicare Severity (MS)-DRGs under the inpatient prospective payment system. In the FY 2008 IPPS final rule (72 FR 47176), we noted that case-mix refinements can lead to substantial unwarranted increase in payments. To address this issue when CMS transitioned from DRGs to MS–DRGs, MedPAC recommended that the Secretary project the likely effect of reporting improvements on total payments and make an offsetting adjustment to the national average base payment amounts (72 FR 47176). In the FY 2008 IPPS final rule (72 FR 47181), we summarized instances where case-mix increases resulted from documentation and coding-induced changes for the first year of the IRF PPS and in Maryland hospitals' transition to APR DRGs (estimated at around 5 percent in both instances). Therefore, we estimated that an adjustment of 4.8 percent would be necessary to maintain budget neutrality for the transition to the MS–DRGs (72 FR 47178). With regards to experience under the HH PPS, as outlined in the CY 2018 HH PPS proposed rule (82 FR 35274), between CY 2000 and 2010, total case-mix change was 23.90 percent, with 20.08 considered nominal case-mix growth, an average of approximately 2 percent nominal case-mix growth per year.

IV. Provisions of the Home Health Value-Based Purchasing (HHVBP) Model

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), we began testing the HHVBP Model on January 1, 2016. The HHVBP Model has an overall purpose of improving the quality and delivery of home health care services to Medicare beneficiaries. The specific goals of the Model are to: (1) Provide incentives for better quality care with greater efficiency; (2) study new potential quality and efficiency measures for appropriateness in the home health setting; and (3) enhance the current public reporting process.

Using the randomized selection methodology finalized in the CY 2016 HH PPS final rule, nine states were selected for inclusion in the HHVBP Model, representing each geographic area across the nation. All Medicare-certified HHAs providing services in Arizona, Florida, Iowa, Maryland, Massachusetts, Nebraska, North Carolina, Tennessee, and Washington (competing HHAs) are required to compete in the Model. Requiring all Medicare-certified HHAs providing services in the selected states to participate in the Model ensures that: (1) There is no selection bias; (2) participating HHAs are representative of HHAs nationally; and, (3) there is sufficient participation to generate meaningful results.

As finalized in the CY 2016 HH PPS final rule, the HHVBP Model will utilize the waiver authority under section 1115A(d)(1) of the Act to adjust Medicare payment rates under section 1895(b) of the Act beginning in CY 2018 based on performance on applicable measures. Payment adjustments will be increased incrementally over the course of the HHVBP Model in the following manner: (1) A maximum payment adjustment of 3 percent (upward or downward) in CY 2018; (2) a maximum payment adjustment of 5 percent (upward or downward) in CY 2019; (3) a maximum payment adjustment of 6 percent (upward or downward) in CY 2020; (4) a maximum payment adjustment of 7 percent (upward or downward) in CY 2021; and (5) a maximum payment adjustment of 8 percent (upward or downward) in CY 2022. Payment adjustments will be based on each HHA's Total Performance Score (TPS) in a given performance year (PY) on: (1) A set of measures already reported via OASIS and HHCAHPS for all patients serviced by the HHA and select claims data elements; and (2) three new measures where points are achieved for reporting data.

In the CY 2017 HH PPS final rule (81 FR 76741 through 76752), in addition to providing an update on the progress towards developing public reporting of performance under the HHVBP Model, we finalized the following changes related to the HHVBP Model:

[12] *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2017-01-18-Home-Health.html.*

[13] *https://www.resdac.org/cms-data/request/cms-data-request-center.*

- Calculating benchmarks and achievement thresholds at the state level rather than the level of the size-cohort and revising the definition for benchmark to state that benchmark refers to the mean of the top decile of Medicare-certified HHA performance on the specified quality measure during the baseline period, calculated for each state.
- Requiring a minimum of eight HHAs in a size-cohort.
- Increasing the timeframe for submitting new measure data from seven calendar days to 15 calendar days following the end of each reporting period to account for weekends and holidays.
- Removing four measures (Care Management: Types and Sources of Assistance, Prior Functioning Activities of Daily Living (ADL)/Instrumental ADL (IADL), Influenza Vaccine Data Collection Period, and Reason Pneumococcal Vaccine Not Received) from the set of applicable measures.
- Adjusting the reporting period and submission date for the Influenza Vaccination Coverage for Home Health Personnel measure from a quarterly submission to an annual submission.
- Allowing for an appeals process that includes the recalculation process finalized in the CY 2016 HH PPS final rule (80 FR 68688 through 68689), as modified, and adds a reconsideration process.

B. Quality Measures

1. Adjustment to the Minimum Number of Completed Home Health Care Consumer Assessment of Healthcare Providers and System (HHCAHPS) Surveys

The HHCAHPS survey presents home health patients with a set of standardized questions about their home health care providers and about the quality of their home health care. The survey is designed to measure the experiences of people receiving home health care from Medicare-certified home health care agencies and meet the following three broad goals to: (1) Produce comparable data on the patient's perspective that allows objective and meaningful comparisons between HHAs on domains that are important to consumers; (2) create incentives through public reporting of survey results for agencies to improve their quality of care; and (3) enhance public accountability in health care by increasing the transparency of the quality of care provided in return for public investment through public reporting.

As finalized in the CY 2016 HH PPS final rule (80 FR 68685 through 68686), if a HHA does not have a minimum of 20 episodes of care during a performance year (PY) to generate a performance score on at least five measures, that HHA would not be included in the Linear Exchange Function (LEF) and would not have a payment adjustment percentage calculated. The LEF is used to translate an HHA's Total Performance Score (TPS) into a percentage of the value-based payment adjustment earned by each HHA under the HHVBP Model. For the HHCAHPS measures, a minimum of 20 HHCAHPS completed surveys would be necessary in order for scores to be generated for the HHCAHPS quality measures that can be included in the calculation of the TPS.

However, as we stated in the CY 2018 HH PPS proposed rule (82 FR 35333), we believe that using a minimum of 40 completed HHCAHPS surveys, rather than a minimum of 20 completed HHCAHPS surveys, will better align the Model with HHCAHPS policy for the Patient Survey Star Ratings on Home Health Compare.[14] The decision to use a minimum of 40 completed surveys for these star ratings was a result of balancing two competing goals. One goal was to provide star ratings that were meaningful and minimized random variations. This goal was best served by calculating star ratings for large numbers of cases by having a larger minimum of completed HHCAHPS surveys (for example, 50 or 100 completed HHCAHPS surveys). At the same time, we also wanted to be able to provide star ratings for as many HHAs as possible. This goal was best served by using a lower minimum of completed HHCAHPS surveys (for example, 20 completed HHCAHPS surveys). We chose to balance these opposing and necessary goals by using 40 completed HHCAHPS surveys for the Patient Survey Star Ratings. Because we believe that aligning the Patient Survey Star Ratings system and the HHVBP Model provides uniformity, consistency, and standard transformability for different healthcare platforms, we proposed using a minimum of 40 instead of 20 completed HHCAHPS surveys under the HHVBP Model (82 FR 35333).

In the CY 2018 HH PPS proposed rule (82 FR 35333), we noted that we received a comment in response to the CY 2016 HH PPS proposed rule in support of using a higher minimum threshold for HHCAHPS completed surveys for the Patient Survey Star Ratings if the data are going to be used in HHVBP or any other quality assessment program. We also noted that we received public comment in response to the CY 2017 HH PPS proposed rule in support of using a higher minimum threshold for HHCAHPS completed surveys in the HHVBP Model, including a recommendation to use a minimum of 100 HHCAHPS rather than a sample size of 20 surveys (82 FR 35333). We stated in the CY 2018 HH PPS proposed rule (82 FR 35333) that we believe that proposing a minimum of 40 completed HHCAHPS surveys for the Model would be more appropriate than the higher minimums previously recommended by some commenters because it represents a balance between providing meaningful data and having sufficient numbers of HHAs with performance scores for at least 5 measures in the cohorts. Moreover, using a minimum of 40 completed HHCAHPS surveys aligns with the Patient Survey Star Ratings on Home Health Compare (82 FR 35333).

To understand the possible impact of our proposal to use a minimum of 40 HHCAHPS completed surveys, we noted in the CY 2018 HH PPS proposed rule (82 FR 35333) that HHAs may refer to the Interim Performance Reports (IPRs) issued in October 2016, January 2017 and April 2017, which analyzed 40 or more completed HHCAHPS surveys to determine each HHA's HHCAHPS quality measure scores. As a point of comparison to the minimum of 40 HHCAHPS completed surveys, these IPRs were reissued using a minimum of 20 or more completed HHCAHPS surveys and included quality measure scores, for these same time periods, calculated with HHAs that qualify for the LEF by having sufficient data for at least five measures. HHAs had the opportunity to submit a request for recalculation of the revised interim performance scores.

HHAs had an opportunity to evaluate these IPRs in light of the proposal to change to a minimum of 40 HHCAHPS completed surveys, as well as seek clarification on the difference in their reports. The participating HHAs received concurrent IPRs in July 2017 and concurrent Annual Total Performance Score and Payment Adjustment Reports, which we made available in August 2017. The concurrent reports showed one report with HHCAHPS quality measure scores calculated based on a minimum of 40 completed surveys and one report with HHCAHPS quality measure scores calculated based on a minimum of 20

[14] *Patient Survey Star Ratings https://www.medicare.gov/HomeHealthCompare/Data/Patient-Survey-Star-Ratings.html.*

completed surveys. Because the CY 2018 HH PPS proposed rule would not be finalized before the timeline for submission of recalculation and reconsideration requests, we noted HHAs would have the opportunity to submit recalculation requests for the interim performance scores based on both a minimum of 40 and 20 completed surveys, and recalculation and reconsideration requests, as applicable, for the annual total performance scores included in these reports for these thresholds in accordance with the appeals process set forth at § 484.335, which was finalized in the CY 2017 HH PPS final rule (82 FR 35333).

As discussed in the CY 2018 HH PPS proposed rule (82 FR 35333 through 35334), we analyzed the effects on participating HHAs of using the proposed 40 or more completed HHCAHPS surveys as compared to using 20 or more completed HHCAHPS surveys by examining OASIS measures submitted from January 1, 2015 through December 31, 2016, claims measures submitted from September 1, 2015 through September 30, 2016, and 12 months ending June 30, 2016 for HHCAHPS-based measures. We found that achievement thresholds, which are calculated as the median of all HHAs' performance on the specified quality measures during the 2015 baseline year for each state, would not change by more than ±1.1 percent, with the largest changes occurring in the statewide achievement thresholds for the HHCAHPS *Willingness to Recommend the Agency* measure in Arizona (+1.1 percent) and Nebraska (−1.1 percent). Benchmarks (the mean of the top decile of Medicare-certified HHA performance on the specified quality measures during the 2015 baseline year, calculated for each state) had greater potential for change, ranging down to −3.2 percent. For instance, we found that when calculated using a minimum of 40 surveys rather than a minimum of 20 surveys, there was a −2.0 percent change in the benchmark for the HHCAHPS *Willingness to Recommend the Agency* measure for Arizona and a −1.7 percent change in the benchmark for Nebraska. We also found that when calculated using a minimum of 40 surveys rather than a minimum of 20 surveys, there was a −1.7 percent change in the benchmark for the HHCAHPS *Communications between Providers and Patients measure for Arizona*, a −1.7 percent change in the benchmark for Florida, and a −3.2 percent change in the benchmark for Nebraska. Overall, the proposed change in the HHCAHPS minimum of 40 completed surveys was estimated to result in a limited percent change in the average statewide TPS for larger-volume HHAs, ranging from −0.4 through +2.2 percent. We provided estimates of the expected payment adjustment distribution based on the proposed minimum of 40 completed HHCAHPS surveys in the impact analysis of the CY 2018 HH PPS proposed rule (82 FR 35387).''

We invited public comment on our proposal to use 40 or more completed HHCAHPS surveys as the minimum to generate a quality measure score on the HHCAHPS measures, as is currently used in Home Health Compare and the Patient Survey Star Ratings. Therefore, we proposed to revise the definition of ''applicable measure'' at § 484.305 from a measure for which the competing HHA has provided 20 home health episodes of care per year to a measure for which a competing HHA has provided a minimum of 20 home health episodes of care per year for the OASIS-based measures, 20 home health episodes of care per year for the claims-based measures, or 40 completed surveys for the HHCAHPS measures. We proposed that if finalized, this policy would apply to the calculation of the benchmark and achievement thresholds and the calculation of performance scores for all Model years, beginning with PY 1.

The following is a summary of the public comments received on this proposal and our responses:

Comment: Most commenters supported CMS' proposal to adjust the minimum number of completed Home Health Care Consumer Assessment of Healthcare Providers and System (HHCAHPS) Surveys. Several of these commenters expressed that it will result in more reliable and valid data results, as well as better align with the Patient Survey Star Ratings policy. A few commenters expressed concern about the proposed change and that using a minimum of 40 completed HHCAHPS surveys will greatly reduce the number of agencies with data sufficient for Model participation. A commenter specifically requested that CMS provide a clear and separate announcement regarding the change in survey minimum, how to interpret changes in total performance scores, and how to engage in the appeals process. Finally, a few commenters were concerned that smaller volume agencies will be negatively impacted, or forced to close, given the shift from 20 to 40 completed HHCAHPS surveys.

Response: We appreciate commenters' support for our proposal to use a minimum of 40 completed HHCAHPS surveys, rather than a minimum of 20 completed HHCAHPS surveys. We continue to believe that a minimum of 40 completed HHCAHPS surveys, rather than a minimum of 20 completed HHCAHPS surveys, better aligns the Model with HHCAHPS policy for the Patient Survey Star Ratings on Home Health Compare. As discussed in the proposed rule, we believe that aligning the Patient Survey Star Ratings and the HHVBP Model will provide uniformity, consistency, and standard transformability for different healthcare platforms. While we recognize that this change could result in fewer agencies receiving a measure score on the HHCAHPS measures, we believe, as indicated in the proposed rule, that using a minimum of 40 completed HHCAHPS surveys represents an appropriate balance between providing meaningful data and having sufficient numbers of HHAs with performance scores on five other measures (for example OASIS based and claims based) to be included in the LEF. As we discuss later in this section, however, our updated analysis using full CY 2016 data found that no HHA fell below the minimum of having five measures to generate a TPS as a result of using a minimum of 40 rather than 20 completed HHCAHPs surveys.

For purposes of this final rule, we analyzed the effects on participating HHAs of using the proposed 40 or more completed HHCAHPS surveys as compared to using 20 or more completed HHCAHPS surveys by examining OASIS, claims and HHCAHPS measures from January 1, 2016 to December 31, 2016. We found that achievement thresholds will not change by more than ±1.1 percent, with the largest changes occurring in the statewide achievement thresholds for the HHCAHPS *Willingness to Recommend the Agency* measure in Arizona (+1.1 percent) and Nebraska (−1.1 percent). Benchmarks continued to have greater potential for change, ranging down to −3.1 percent. For instance, we found that when calculated using a minimum of 40 surveys rather than a minimum of 20 surveys, there was a −2.0 percent change in the benchmark for the HHCAHPS *Willingness to Recommend the Agency* measure for Arizona and a −1.7 percent change in the benchmark for Nebraska. We also found that when calculated using a minimum of 40 surveys rather than a minimum of 20 surveys, there was a −1.6 percent change in the benchmark for the HHCAHPS *Communications between Providers and*

Patients measure for Arizona, a −1.7 percent change in the benchmark for Florida, and a −3.1 percent change in the benchmark for Nebraska.

Overall, based on this updated analysis using full CY 2016 data, the proposed change in the HHCAHPS minimum of 40 completed surveys was estimated to result in a limited percent change in the average statewide TPS for larger-volume HHAs, ranging from −0.3 percent through +1.8 percent and the majority of the states were close to zero. Additionally, the updated analysis using full CY 2016 data found that there were no Medicare-certified HHAs in the selected states that fell below the minimum of having five measures to generate a TPS for CY 2018 as a result of using a minimum of 40 rather than 20 completed HHCAHPs surveys.

To provide HHAs with information on the effects of using a minimum of 40 completed HHCAHPS surveys, rather than a minimum of 20 completed HHCAHPS surveys, we reissued the October 2016, January 2017 and April 2017 IPRs, which analyzed 40 or more completed HHCAHPS surveys, so that they could be recalculated with HHAs that have 20 or more completed HHCAHPS surveys. Moreover, CMS provided HHAs with concurrent IPRs in July 2017 and concurrent Annual Total Performance Score and Payment Adjustment Reports in August 2017 to show one report with HHCAHPS quality measure scores calculated based on a minimum of 40 completed surveys and one report with HHCAHPS quality measure scores calculated based on a minimum of 20 completed surveys. HHAs also had the opportunity to submit recalculation requests for the interim performance scores and recalculation and reconsideration requests, as applicable, for the annual total performance scores, in accordance with the process set forth at § 484.335. Additionally, we provided a number of webinars and other information on the interpretation of the quality measure scores and the Total Performance Scores and on the appeals process. More specifically, we provided all HHAs with a questions and answers document on the use of HHCAHPS measures in HHVBP Model performance reports when the reissued and concurrent IPRs were made available. These reports and communications provided points of comparison, clarification and information on the potential impact of using a minimum of 40 completed HHCAHPS surveys, rather than a minimum of 20 completed HHCAHPS surveys, to generate a quality measure score on the HHCAHPS measures. CMS notes that no recalculation requests on the reissued and concurrent IPRs were received and no recalculation or reconsideration requests on the concurrent Annual Reports were received that related to our proposal to change to the minimum of 40 completed HHCAHPS surveys.

The change from a minimum of 20 completed HHCAHPS surveys to a minimum of 40 completed HHCAHPS surveys was not intended to negatively impact smaller agencies. We do not believe smaller HHAs will be disadvantaged by this change to a minimum of 40, because given their exemption from HHCAHPS reporting requirements, it is unlikely they would be measured on HHCAHPS under the Model and they can still compete on other measures.

We will continue to monitor the impacts of using a minimum of 40 completed HHCAHPS surveys, rather than a minimum of 20 completed HHCAHPS surveys, for purposes of receiving a performance score for any of the HHCAHPS measures.

Comment: A commenter suggested that because one negative survey might affect a score based on a minimum of 20 completed HHCAHPS surveys, removing the lowest and highest HHCAHPS for HHAs may be an effective method to align with the average customer response.

Response: We believe this comment is outside of the scope of the proposed methodology change in the CY 2018 HH PPS proposed rule to use a minimum of 40 completed HHCAHPS surveys rather than a minimum of 20 completed HHCAHPS surveys. However, we note that we believe each HHCAHPS survey may be an important avenue for public quality reporting and continued improvement within the HHA environment.

Final Decision: For the reasons stated previously and in consideration of the comments received, we are finalizing our proposal to amend the definition of ''applicable measure'' to mean a measure for which a competing HHA has provided a minimum of 40 completed surveys for HHCAHPS measures, for purposes of receiving a performance score for any of the HHCAHPS measures, beginning with PY1. In addition, we are finalizing a few minor technical edits to the regulation at § 484.305 to replace the colon and spell out ''twenty'' and ''forty'' (rather than ''20'' and ''40'').

2. Removal of One OASIS-Based Measure Beginning With Performance Year 3

In the CY 2016 HH PPS final rule, we finalized a set of quality measures in Figure 4a: Final PY1 Measures and Figure 4b: Final PY1 new measures (80 FR 68671 through 68673) for the HHVBP Model to be used in PY 1, referred to as the starter set.

The measures were selected for the Model using the following guiding principles: (1) Use a broad measure set that captures the complexity of the services HHAs provide; (2) Incorporate the flexibility for future inclusion of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT) measures that cut across post-acute care settings; (3) Develop 'second generation' (of the HHVBP Model) measures of patient outcomes, health and functional status, shared decision making, and patient activation; (4) Include a balance of process, outcome and patient experience measures; (5) Advance the ability to measure cost and value; (6) Add measures for appropriateness or overuse; and (7) Promote infrastructure investments. This set of quality measures encompasses the multiple National Quality Strategy (NQS) domains [15] (80 FR 68668). The NQS domains include six priority areas identified in the CY 2016 HH PPS final rule (80 FR 68668) as the CMS Framework for Quality Measurement Mapping. These areas are: (1) Clinical quality of care; (2) care coordination; (3) population & community health; (4) person- and caregiver-centered experience and outcomes; (5) safety; and (6) efficiency and cost reduction. Figures 4a and 4b of the CY 2016 HH PPS final rule (80 FR 68671 through 68673) identified 15 outcome measures (five from the HHCAHPS, eight from Outcome and Assessment Information Set (OASIS), and two from the Chronic Care Warehouse (claims)), and nine process measures (six from OASIS, and three new measures, which were not previously reported in the home health setting).

In the CY 2017 HH PPS final rule (81 FR 76743 through 76747), we removed the following four measures from the measure set for PY 1 and subsequent performance years: (1) Care Management: Types and Sources of Assistance; (2) Prior Functioning ADL/IADL; (3) Influenza Vaccine Data Collection Period: Does this episode of care include any dates on or between October 1 and March 31?; and (4) Reason Pneumococcal Vaccine Not Received, for the reasons discussed in that final rule.

For PY 3, we proposed to remove one OASIS-based measure, Drug Education

[15] 2015 Annual Report to Congress, *http://www.ahrq.gov/workingforquality/reports/annual-reports/nqs2015annlrpt.htm.*

on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures (82 FR 35334). We stated in the CY 2018 HH PPS proposed rule that, as part of our ongoing monitoring efforts, we found that based on the standard metrics of measure performance, many providers have achieved full performance on the Drug Education measure. For example, for the January 2017 IPRs (which covered the 12-month period of October 1, 2015 through September 30, 2016), the average value for this measure across all participating HHAs was 95.69 percent from October 2015 through September 2016. When looking at September 2016, the mean value on this measure across all participating HHAs had increased to 97.8 percent. In addition, we noted that there are few HHAs with poor performance on the measure. Based on the January 2017 IPRs, across all participating HHAs, the 10th percentile was 89 percent and the 5th percentile was 81.8 percent, but only 1.8 percent of HHAs had a value below 70 percent on the measure. We stated in the CY 2018 HH PPS proposed rule (82 FR 35334) that we believe that removing this measure would be consistent with our policy, as noted in the CY 2017 HH PPS final rule (81 FR 76746), that when a measure has achieved full performance, we may propose the removal of the measure in future rulemaking. In addition, our contractor's Technical Expert Panel (TEP), which consists of 11 panelists with expertise in home health care and quality measures, expressed concern that the Drug Education measure does not capture whether the education provided by the HHA was meaningful.

We presented the revised set of applicable measures, reflecting our proposal to remove the OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, in Table 43 of the CY 2018 HH PPS proposed rule. We stated that this measure set would be applicable to PY3 and each subsequent performance year until such time that another set of applicable measures, or changes to this measure set, are proposed and finalized in future rulemaking (82 FR 35334 through 35336).

We invited public comment on the proposal to remove one OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures for PY3 and subsequent performance years and Table 43 of the CY 2018 HH PPS proposed rule. The following is a summary of the public comments received on this proposal and our responses:

Comment: Several commenters expressed support for removing the OASIS-based quality measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures as it has ''topped out.''

Response: We appreciate the support regarding the proposed removal of the ''Drug Education'' measure from the HHVBP Model's set of applicable measures because it has ''topped out''. We are finalizing the removal of the ''Drug Education'' measure as most providers have achieved full performance on the measure.

Comment: Several commenters provided feedback regarding the measure set more generally and some were outside of the scope of the proposed change. A commenter recommended that CMS consider assigning 50 percent of the ''Star Rating'' and HHVBP performance to claims-based measures and Patient Satisfaction, as the commenter believed that these measures are difficult or impossible to manipulate, and then assign the other 50 percent to OASIS-based self-reported measures. A commenter expressed concern that the measure set for the HHVBP Model mainly requires improvement in patient functioning and that this conflicts directly with the *Jimmo* v. *Sebelius settlement.*[16] Another commenter recommended replacing the *Pneumococcal Polysaccharide Vaccine Ever Received* (NQF#0525) because the measure no longer reflects current recommendations of the Advisory Committee for Immunization Practice (ACIP).

Response: We appreciate the comments on the measures methodology and, as discussed in the CY 2016 HH PPS final rule (80 FR 68669) and CY 2017 HH PPS final rule (81 FR 76747), acknowledge that skilled care may be necessary to improve a patient's current condition, to maintain the patient's current condition, or to prevent or slow further deterioration of the patient's condition, as was clarified through the provisions revised as part of *Jimmo* v. *Sebelius* settlement. As stated in those rules, this settlement agreement pertains only to the clarification of CMS's manual guidance on coverage standards, not payment measures like those at issue here, and expressly does not pertain to or prevent the implementation of new regulations, including new regulations pertaining to the HHVBP Model. We refer readers to the CY 2016 HH PPS final rule (80 FR 68669 through 68670) for additional discussion of our analyses of measure selection, including our analyses of existing measures relating to improvement and stabilization. As discussed in that rule, the HHVBP Model is designed such that any measures determined to be good indicators of quality will be considered for use in the HHVBP Model in future years and may be added through the rulemaking process. As discussed in prior years, we will continue to seek and consider input we have received on the measure set for the HHVBP Model.

Final Decision: We are finalizing our proposal to remove the OASIS-based measure, Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care, from the set of applicable measures for PY3 and subsequent years, as reflected in Table 15. Table 15 identifies the applicable measures set for PY3 and each subsequent performance year until such time that another set of applicable measures, or changes to this measure set, are proposed and finalized in future rulemaking.

TABLE 15—MEASURE SET FOR THE HHVBP MODEL* BEGINNING PY 3

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Clinical Quality of Care.	Improvement in Ambulation-Locomotion.	Outcome	NQF0167	OASIS (M1860).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in ambulation/locomotion at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.

[16] *Jimmo* v. *Sebelius* Settlement Agreement Fact Sheet: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Jimmo-FactSheet.pdf.*

TABLE 15—MEASURE SET FOR THE HHVBP MODEL* BEGINNING PY 3—Continued

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Clinical Quality of Care.	Improvement in Bed Transferring.	Outcome	NQF0175	OASIS (M1850).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bed transferring at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care.	Improvement in Bathing.	Outcome	NQF0174	OASIS (M1830).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in bathing at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Clinical Quality of Care.	Improvement in Dyspnea.	Outcome	NA	OASIS (M1400).	Number of home health episodes of care where the discharge assessment indicates less dyspnea at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Communication & Care Coordination.	Discharged to Community.	Outcome	NA	OASIS (M2420).	Number of home health episodes where the assessment completed at the discharge indicates the patient remained in the community after discharge.	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Efficiency & Cost Reduction.	Acute Care Hospitalization: Unplanned Hospitalization during first 60 days of Home Health.	Outcome	NQF0171	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for an unplanned admission to an acute care hospital in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Efficiency & Cost Reduction.	Emergency Department Use without Hospitalization.	Outcome	NQF0173	CCW (Claims)	Number of home health stays for patients who have a Medicare claim for outpatient emergency department use and no claims for acute care hospitalization in the 60 days following the start of the home health stay.	Number of home health stays that begin during the 12-month observation period. A home health stay is a sequence of home health payment episodes separated from other home health payment episodes by at least 60 days.
Patient Safety	Improvement in Pain Interfering with Activity.	Outcome	NQF0177	OASIS (M1242).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less frequent pain at discharge than at the start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient Safety	Improvement in Management of Oral Medications.	Outcome	NQF0176	OASIS (M2020).	Number of home health episodes of care where the value recorded on the discharge assessment indicates less impairment in taking oral medications correctly at discharge than at start (or resumption) of care.	Number of home health episodes of care ending with a discharge during the reporting period, other than those covered by generic or measure-specific exclusions.
Population/Community Health.	Influenza Immunization Received for Current Flu Season.	Process	NQF0522	OASIS (M1046).	Number of home health episodes during which patients (a) received vaccination from the HHA or (b) had received vaccination from HHA during earlier episode of care, or (c) was determined to have received vaccination from another provider.	Number of home health episodes of care ending with discharge, or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Population/Community Health.	Pneumococcal Polysaccharide Vaccine Ever Received.	Process	NQF0525	OASIS (M1051).	Number of home health episodes during which patients were determined to have ever received Pneumococcal Polysaccharide Vaccine (PPV).	Number of home health episodes of care ending with discharge or transfer to inpatient facility during the reporting period, other than those covered by generic or measure-specific exclusions.
Patient & Caregiver-Centered Experience.	Care of Patients	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Communications between Providers and Patients.	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Specific Care Issues.	Outcome		CAHPS	NA	NA.
Patient & Caregiver-Centered Experience.	Overall rating of home health care.	Outcome		CAHPS	NA	NA.

TABLE 15—MEASURE SET FOR THE HHVBP MODEL* BEGINNING PY 3—Continued

NQS domains	Measure title	Measure type	Identifier	Data source	Numerator	Denominator
Patient & Caregiver-Centered Experience.	Willingness to recommend the agency.	Outcome		CAHPS	NA	NA.
Population/Community Health.	Influenza Vaccination Coverage for Home Health Care Personnel.	Process	NQF0431 (Used in other care settings, not Home Health).	Reported by HHAs through Web Portal.	Healthcare personnel in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year: a) received an influenza vaccination administered at the healthcare facility, or reported in writing or provided documentation that influenza vaccination was received elsewhere: or b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other components of the vaccine or history of Guillain-Barre Syndrome within 6 weeks after a previous influenza vaccination; or c) declined influenza vaccination; or d) persons with unknown vaccination status or who do not otherwise meet any of the definitions of the above-mentioned numerator categories.	Number of healthcare personnel who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact.
Population/Community Health.	Herpes zoster (Shingles) vaccination: Has the patient ever received the shingles vaccination?	Process	NA	Reported by HHAs through Web Portal.	Total number of Medicare beneficiaries aged 60 years and over who report having ever received zoster vaccine (shingles vaccine).	Total number of Medicare beneficiaries aged 60 years and over receiving services from the HHA.
Communication & Care Coordination.	Advance Care Plan.	Process	NQF0326	Reported by HHAs through Web Portal.	Patients who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	All patients aged 65 years and older.

* **Notes:** For more detailed information on the measures utilizing OASIS refer to the *OASIS–C1/ICD–9, Changed Items & Data Collection Resources* dated September 3, 2014 available at *www.oasisanswers.com/LiteratureRetrieve.aspx?ID=215074*. For NQF endorsed measures see The NQF Quality Positioning System available at *http://www.qualityforum.org/QPS*. For non-NQF measures using OASIS see links for data tables related to OASIS measures at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*. For information on HHCAHPS measures see *https://homehealthcahps.org/SurveyandProtocols/SurveyMaterials.aspx*.

C. Quality Measures for Future Consideration

The CY 2016 HH PPS final rule discusses the HHVBP Model design, the guiding principles to select measures, and the six priority areas of the National Quality Strategy (NQS) we considered for the Model (80 FR 68656 through 68678). Under the HHVBP Model, any measures we determine to be good indicators of quality will be considered for use in the HHVBP Model in future years, and may be added or removed through the rulemaking process. To further our commitment to objectively assess HHVBP quality measures, we are utilizing an implementation contractor that invited a group of measure experts to provide advice on the adjustment of the current measure set for consideration. The contractor convened a technical expert panel (TEP) consisting of 11 panelists with expertise in home health care and quality measures that met on September 7, 2016, in Baltimore, Maryland and via conference call on December 2, 2016. The TEP discussed developing a composite total change in ADL/IADL measure; a composite functional decline measure; a measure to capture when an HHA correctly identifies the patient's need for mental and behavioral health supervision; and a measure to identify if a caregiver is able to provide the patient's mental or behavioral health supervision, to align with § 409.45(b)(3)(iii) and the Medicare Benefit Policy Manual (Pub. 100–02), Chapter 7, Section 20.2. We discussed each of these potential measures in further detail in the CY 2018 HH PPS proposed rule (82 FR 35336 through 35340), and also discuss in this section of this final rule. While any new measures would be proposed for use in future rulemaking, we solicited comment on these potential measures now to inform measure development and selection.

As noted in the CY 2017 HH PPS final rule (81 FR 76747), we received several comments expressing concern that the measures under the Model do not reflect the patient population served under the Medicare Home Health benefit as the outcome measures focus on a patient's clinical improvement and do not address patients with chronic illnesses; deteriorating neurological, pulmonary, cardiac, and other conditions; and some with terminal illness. The commenters opined that the value of including stabilization measures in the HHVBP Model is readily apparent as it aligns the Model with the Medicare Home Health benefit. Commenters also expressed concerns that improvement is not always the goal for each patient and

that stabilization is a reasonable clinical goal for some patients. Commenters suggested the addition of stabilization or maintenance measures be considered for the HHVBP Model. Many commenters objected to the use of improvement measures in the HHVBP Model. We did not receive any specific measures for future consideration as part of those comments. In the CY 2018 HH PPS proposed rule (82 FR 35336 through 35340), we identified measures that we are considering for possible inclusion under the Model in future rulemaking and sought input from the public on the measures described, as well as any input about the development or construction of the measures and their features or methodologies. We are also including the description of these possible measures in this final rule in the subsections that follow.

1. Total Change in ADL/IADL Performance by HHA Patients

The measure set finalized in the CY 2016 HH PPS final rule included Change in Daily Activity Function as Measured by the Activity Measure for Post-Acute Care (AM–PAC) (NQF #0430). However, the measure was removed in the CY 2017 HH PPS final rule and never used in the HHVBP Model because the measure required use of a proprietary data collection instrument in the home health environment. We stated in the CY 2018 HH PPS proposed rule that we were considering replacing Change in Daily Activity Function as Measured by AM–PAC (NQF #0430) with a composite total ADL/IADL change performance measure. During the September 2016 TEP meeting, an alternative to the Change in Daily Activity Function measure was presented. The TEP requested that a composite Total ADL/IADL Change measure be investigated empirically. This measure was discussed as part of the follow-up conference call, and the TEP supported continued development of the measure in the HHVBP Model as a way of including a measure that captures all three potential outcomes for home health patients: stabilization; decline; and improvement. They provided input on the technical specifications of the potential composite measure, including the feasibility of implementing the measure and the overall measure reliability and validity. We noted in the CY 2018 HH PPS proposed rule that we reviewed this suggested alternative and believe this measure would provide actionable and transparent information that would support HHA efforts to improve care and prevent functional decline for all patients across a broad range of patient functional outcomes. The measure would also improve accountability during an episode of care when the patient is directly under the HHA's care.

We noted in the CY 2018 HH PPS proposed rule that the name of this potential composite measure could be *Total Change in ADL/IADL Performance by HHA Patients.* The measure would report the average, normalized, total improved functioning across the 11 ADL/IADL items on the current OASIS–C2 instrument. The measure is calculated by comparing scores from the start-of-care/resumption of care to scores at discharge. For each item the patient's discharge assessed performance score is subtracted from the patient's start of care/resumption of care assessed performance score, and then divided by the maximum improvement value based on the number of response options for that item. These values are summed into a total normalized change score that can range from −11 (that is, for an episode where there is maximum decline on all 11 items used in the measure) to +11 (that is, for an episode where there is the maximum improvement on all 11 items). An HHA's score on the measure is based on its average across all eligible episodes. Patients who are independent on all 11 ADL/IADL items at Start of Care (SOC)/Resumption of Care (ROC) would also be included in the measure. The HHA's observed score on the measure is the average of the normalized total scores for all eligible episodes for its patients during the reporting period.

The following 11 ADLs/IADL-related items from OASIS–C2 items were included in developing a composite measure:

ADL OASIS–C2 items related to Self-Care:

- M1800 (Grooming).
- M1810 (Upper body dressing).
- M1820 (Lower body dressing).
- M1845 (Toileting hygiene).
- M1870 (Eating).

ADL OASIS–C2 items related to Mobility:

- M1840 (Toilet transferring).
- M1840 (Bed transferring).
- M1860 (Ambulation).

Other IADLs OASIS items:

- M1880 (Light meal preparation).
- M1890 (Telephone use).
- M2020 (Oral medication management).

Based on these identified measures, we would risk-adjust using OASIS–C2 items to account for case-mix variation and other factors that affect functional decline but are outside the influence of the HHA. The risk-adjustment model uses an ordinary least squares (OLS) [17] [18] regression framework because the outcome measure (normalized change in ADL/IADL performance) is a continuous variable.

The prediction model for this outcome measure was derived using the predicted values from the 11 individual outcomes that are currently used to risk adjust these 11 individual quality measures. Of the 11 values tested, the 8 identified in the proposed rule were found to be statistically related to the *Total Change in ADL/IADL Performance by HHA Patients* measure at $p < 0.0001$ level and would be used in the prediction model that we are considering proposing to use to risk adjust the HHA's observed value for this potential future measure. The prediction model for this outcome measure uses predicted values from the following individual outcomes (**NOTE:** The primary source OASIS item is listed in parenthesis after the name of the quality measure):

- Improvement in Upper Body Dressing (M1810).
- Improvement in Management of Oral Medications (M2020).
- Improvement in Bed Transferring (M1850).
- Improvement in Ambulation/Locomotion (M1860).
- Improvement in Grooming (M1800).
- Improvement in Toileting Hygiene (M1845).
- Discharged to the Community (M2420).
- Improvement in Toileting Transfer (M1840).

Two predictive models, one based on predicted values from CY 2014 and one from CY 2015, were computed. The correlations at the episode level between observed and predicted values for the target outcome measure *Total Change in ADL/IADL Performance by HHA Patients* are shown in Table 16.

[17] Fox, John (1997). Applied Regression Analysis, Linear Models, and Related\Methods/Edition 1, 1997, SAGE.

[18] Greene, William H. (2017). Econometric analysis (8th ed.). New Jersey: Pearson. ISBN 978–0134461366.

TABLE 16—CORRELATIONS AT THE EPISODE LEVEL BETWEEN OBSERVED AND PREDICTED VALUES FOR THE TARGET OUTCOME MEASURE TOTAL CHANGE IN ADL/IADL PERFORMANCE BY HHA PATIENTS

Data group	Correlation	Significance (p <)	r2 (Coeff. Determination) %
CY2014, National	0.5022	0.0001	25.22
CY2014, HHVBP states	0.5094	0.0001	25.95
CY2015, National	0.5011	0.0001	25.11
CY2015, HHVBP states	0.5076	0.0001	25.76

The results in Table 16 suggest that either model would account for 25 percent or more of the variability in the outcome measure. These models could be considered very strong predictive models for the target outcome measure. Although the analysis supports developing a composite measure, the analysis assumes that the OASIS–C2 items identified to be used in the composite measure do not change. However, we recognize that OASIS–C2 items could be removed or added in any given year. We expect to conduct an additional analysis, in advance of any future proposal, to assess whether changes to OASIS–C2 items that are removed or added could significantly impact a HHA's ability to address several measures to improve its overall score in the composite measure. We solicited public comments on whether or not to include a composite total ADL/IADL change performance measure in the set of applicable measures, the name of any such measure, the risk adjustment method, and whether we should conduct an analysis of the impact of removal/addition of OASIS–C2 items.

2. Composite Functional Decline Measure

The second measure we are considering for possible inclusion under the Model in future rulemaking is a *Composite Functional Decline Measure* that could be the percentage of episodes where there was decline on one or more of the eight ADL items used in the measure. As noted in the CY 2018 HH PPS proposed rule and this final rule, we received comments on the CY 2017 HH PPS proposed rule suggesting that we consider the addition of stabilization or maintenance measures. We stated in the CY 2018 HH PPS proposed rule that to address this suggestion, we are considering a composite functional decline measure because the existing functional stabilization measures, taken individually, are topped out, with HHA level means of 95 percent or higher. This type of composite functional decline measure is similar to the composite ADL decline measure that is used in the Skilled Nursing Facility (SNF) Quality Reporting program (QRP).[19] The SNF QRP measure is constructed from four ADL items: Bed mobility; transfer; eating; and toileting.

An HHVBP composite functional decline measure could provide actionable and transparent information that could support HHA efforts to improve care and prevent functional decline for all patients, including those for whom improvement in functional status is not a realistic care goal. We noted in the CY 2018 HH PPS proposed rule that this concept was discussed during the TEP meeting on September 7, 2016, with a follow-up conference call held on December 2, 2016. The TEP supported the inclusion of measures of stabilization and decline in the HHVBP Model, as well as further development of the composite functional decline measure. They provided input on the technical specifications of the potential composite measure, including the feasibility of implementing the measure and the overall measure reliability and validity.

When calculating the composite functional decline measure, we noted that we could use the following 8 existing OASIS–C2 items:

- Ambulation/Locomotion (M1860).
- Bed Transferring (M1840).
- Toilet Transferring (M1840).
- Bathing (M1830).
- Toilet Hygiene (M1845).
- Lower Body Dressing (M1820).
- Upper Body Dressing (M1810).
- Grooming (M1800).

We noted that the measure could be defined as 1 if there is decline reported in one or more of these items between the Start of Care and the Discharge assessments and zero if no decline is reported on any of these items. As with other OASIS-based measures, a performance score for the measure would only be calculated for HHAs that have 20 or more episodes of care during a performance year.

The measure could be risk-adjusted using OASIS–C2 items to account for case-mix variation and other factors that affect functional decline but are outside of the influence of the HHA. The risk-adjustment model uses a logistic regression framework. The model includes a large number of patient clinical conditions and other characteristics measured at start of care. A logistic regression model is estimated to predict whether the patient will have a length of stay of greater than 60 days. The predicted probability of a length of stay of greater than 60 days is used, along with other patient characteristics, to construct a logistic regression model to predict the probability of decline in any of eight ADLs. This model is used to estimate the predicted percent of ADL decline at the HHA level. To calculate case-mix adjusted values, the observed value of the measure is adjusted by the difference between the HHA predicted percent and the national predicted percent. The risk-adjustment model reduces the adjusted difference between HHAs that serve a disproportionate number of longer-stay patients and those that serve patients with more typical lengths of stay of one episode.

Across all participating HHAs in the HHVBP Model, for HHAs that had less than 20 percent of episodes lasting more than 60 days, the average on the functional decline measure was 8.08 percent. This increased to 11.08 percent for HHAs with 20 percent to 40 percent of episodes lasting more than 60 days, 14.23 percent for HHAs with 40 percent to 60 percent of episodes lasting more than 60 days, and 20.59 percent for HHAs with more than 60 percent of episodes lasting more than 60 days. This finding suggests that, in addition to focusing on prevention of functional decline, we should also attempt to better predict a patient's functional trajectory and potentially stratify the population to exclude those on a likely downward trajectory. However, in spite of this finding, the inclusion of a measure that rewards providers for avoiding functional decline has the advantage of diversifying the set of measures for the HHVBP model. We solicited public

[19] "Long-stay Nursing Home Care: Percent of Residents Whose Need for help with Activities of Daily Living has Increased." *https://www.qualitymeasures.ahrq.gov/summaries/summary/50060.*

comments on whether or not to include a composite functional decline measure in the set of applicable measures, the name of any such measure, the risk adjustment method, and whether we should conduct an analysis of the impact of removal/addition of OASIS–C2 items.

3. Behavioral Health Measures

Although we did not receive comments or suggestions through the rulemaking process for the HHVBP Model regarding behavioral or mental health measures, we noted in the CY 2018 HH PPS proposed rule that we recognize that the Model does not include such measures. The OASIS–C2 collects several items related to behavioral and mental health (M1700 Cognitive Functioning; M1710 Confusion Frequency; M1720 Anxiety; M1730 Depression Screening; M1740 Cognitive, Behavioral, and Psychiatric Symptoms; M1745 Frequency of Disruptive Behavior Symptoms; and M1750 Psychiatric Nursing Services). These items are used to compute both Improvement and Process measures as well as Potentially Avoidable Events. The inclusion of behavioral health measures is important for care transformation and improvement activities as many persons served by the Home Health program may have behavioral health needs.

The TEP made several suggestions during the December 2016 conference call as to whether the focus of a behavioral or mental health measure could be identifying whether a patient needed mental or behavioral health assistance compared to the supervision of the patient or advocacy assistance. The TEP supported the supervision type measure due to its opportunity for potential improvement. In further analyses, we identified two underlying components to outcomes for providing assistance. We developed a method, described in the following section, to identify patients who have or do not have needs for mental or behavioral health supervision. We noted that we are considering further refining this method by identifying the involvement of the caregiver in addressing the patient's mental or behavioral health supervision needs as an important outcome measure, and we solicited comment on whether this is an appropriate factor or feature that we should consider in developing such a measure in future rulemaking.

a. HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision

We stated in the CY 2018 HH PPS proposed rule that we are considering adding a *HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision* measure to the HHVBP Model in the future to capture a patient's need for mental or behavioral health supervision based on an identifier. This identifier is based on information from existing Neuro/Emotional/Behavioral Status OASIS items, along with other indicators of mental/behavioral health problems to identify a patient in need of supervisory assistance. The outcome measure assesses whether the HHA correctly identifies whether or not the patient needs mental or behavioral health supervision based on the OASIS SOC/ROC assessment item M2102f, Types and Sources of Assistance: Supervision and Safety.

A composite Mental/Behavioral Health measure could be a dichotomous measure that reports the percentage of episodes of care where the HHA correctly identifies: (a) Patients who need mental or behavioral health supervision; and (b) patients who do not need mental or behavioral health supervision. The numerator could be a combination of two values: (1) The number of episodes of care where the HHA correctly identifies patients who need mental or behavioral health supervision; plus (2) the number of episodes of care where the HHA correctly identifies patients who do not need mental or behavioral health supervision. The denominator is all episodes of care.

The composite measure requires that a patient's need for mental or behavioral health supervision be identified. The following algorithm was designed to identify if a patient was in need of mental or behavioral health supervision. If the patient met any of the following conditions, the patient was identified by the algorithm as in need of mental or behavioral health supervision:

- Was discharged from a psychiatric hospital prior to entering home health care (M1000 = 6).
- Is diagnosed as having chronic mental behavioral problems (M1021 and M1023).
- Is diagnosed with a mental illness (M1021 and M1023).
- Is cognitively impaired (M1700 ≥ 2).
- Is confused (M1710 ≥ 2).
- Is identified as having a memory deficit (M1740 = 1).
- Is identified as having impaired decision-making (M1740 = 2).
- Is identified as being verbally disruptive (M1740 = 3).
- Is identified as being physically aggressive (M1740 = 4).
- Is identified as exhibiting disruptive, infantile, or inappropriate behaviors (M1740 = 5).
- Is identified as being delusional (M1740 = 6).
- Has a frequency of disruptive symptoms (M1745 ≥ 2).

The measure also requires that the HHA identify if the patient is in need of mental or behavioral health supervision. This requirement is based on the SOC/ROC code for M2102f, Types and Sources of Assistance: Supervision and Safety. If the HHA codes a value of zero, then the HHA has identified this patient as not needing mental or behavioral health supervision. If the HHA codes another value for M2102f, Types and Sources of Assistance: Supervision and Safety, then the HHA has identified this patient as needing mental or behavioral health supervision. The outcome measure is defined as the agreement between the algorithm's identification of a patient's need for mental or behavioral health supervision and the HHA's coding of this need. That is, if—

- The algorithm identifies the patient as not in need of mental or behavioral health supervision and the HHA identifies the patient as not in need of mental or behavioral health supervision; or
- The algorithm identifies the patient as in need of mental or behavioral health supervision and the HHA identifies the patient as in need of mental or behavioral health supervision; then
- The outcome is coded as 1, successful.

As with other OASIS-based measures, a performance score for the measure would only be calculated for HHAs that have 20 or more episodes of care during a performance year.

The measure is risk-adjusted using OASIS–C2 items to account for case-mix variation and other factors that affect functional decline but are outside the influence of the HHA. The risk-adjustment model uses a logistic regression framework. The model includes a large number of patient clinical conditions and other characteristics measured at the start of care. To calculate case-mix adjusted values, the observed value of the measure is adjusted by the difference between the HHA predicted percent and the national predicted percent.

The prediction model for this outcome measure uses 39 risk factors [20] with each risk factor statistically significant at p<0.0001. The correlation for the model between observed and predicted values as estimated by Somers' D [21] is 0.427, that yields an estimated coefficient of determination (r2) value based on the Tau-a [22] of 0.201. This suggests that the variability in the model accounts for (predicts) approximately 20 percent of the variability in the outcome measure. The best statistic for evaluating the power of a prediction model that is derived using logistic regression is the c-statistic.[23] This statistic identifies the overall accuracy of prediction by comparing observed and predicted value pairs to the proportion of the time that both predict the outcome in the same direction with 0.500 being a coin-flip. The discussed prediction model has a c-statistic equal to 0.713, which is considered to be good. Using data from CY 2015, the episode-level mean for the HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision measure is 61.98 percent, nationally, and 62.98 percent for the HHVBP states.

b. Caregiver Can/Does Provide for Patient's Mental or Behavioral Health Supervision Need

We stated in the CY 2018 HH PPS proposed rule that we are considering including under the Model in future rulemaking a *Caregiver Can/Does Provide for Patient's Mental or Behavioral Health Supervision Need* measure that would encourage HHAs to ensure that patients who need mental or behavioral health supervision are receiving such care from the patient's caregivers, and would be a realistic care goal.

When considering how to develop a measure to determine whether or not the caregiver can/does provide the patient's mental or behavioral health supervision, we would create an identifier of a patient's need for mental or behavioral health supervision. This identifier is based on the same algorithm described in the previous section from existing Neuro/Emotional/Behavioral Status OASIS items along with other indicators of mental/behavioral health problems to identify a patient in need of supervisory assistance. The outcome measure is whether the HHA correctly identifies this patient as having the need for mental or behavioral health supervision based on the OASIS SOC/ROC assessment item M2102f, Types and Sources of Assistance: Supervision and Safety.

The measure could be a dichotomous measure that reports the percentage of episodes where patients with identified mental or behavioral health supervision needs have their needs met or could have their needs met by the patient's caregiver with additional training (if needed) and support by the HHA. The numerator is the intersection of the number of episodes of care where: (1) The patient needs mental or behavioral health supervision; and (2) these patients have their needs met or could have their needs met by the patient's caregiver with additional training (if needed) and support by the HHA. By intersection, we mean that, for the numerator to equal one, a patient has to need mental or behavioral health supervision and has to have these needs met by his or her caregiver, or could have their needs met by the caregiver with additional training and/or support by the HHA. The denominator is all episodes of care. The algorithm discussed previously for *HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision* could also be used to first identify if a patient was in need of mental or behavioral health supervision.

To identify whether caregivers are able to provide supervisory care or, with training, could be able to provide supervisory care for these patients, we could use the SOC/ROC code for M2102f, Types and Sources of Assistance: Supervision and Safety. If the HHA codes a value of 1 (Non-agency caregiver(s) currently provide assistance) or 2 (Non-agency caregiver(s) need training/supportive services to provide assistance), then the measure identifies that a caregiver does or could provide supervision to a patient who has been identified as needing mental or behavioral health supervision.

The outcome measure is defined as the agreement between the algorithm's identification of a patient's need for mental or behavioral health supervision and the availability of supervision from the patient's caregiver(s). That is, if—

- The algorithm identifies the patient as in need of mental or behavioral health supervision and there is documentation that the patient's caregiver(s) do or could provide this supervision; then
- The outcome is coded as 1, successful.

As with other OASIS-based measures, a performance score for the measure would only be calculated for HHAs that have 20 or more episodes during a performance year. We would use the same methodology to risk-adjust by using OASIS–C2 items and the prediction model described previously. The prediction model for this outcome measure uses 55 risk factors with each risk factor significant at p <0.0001. The correlation for the model between observed and predicted values as estimated by Somers' D is 0.672, that yields an estimated coefficient of determination (r2) value based on the Tau-a of 0.205. This suggests that the variability in the model accounts for (predicts) approximately 20 percent of the variability in the outcome measure. The best statistic for evaluating the power of a prediction model that is derived using logistic regression is the c-statistic. This statistic identifies the overall accuracy of prediction by comparing observed and predicted value pairs to the proportion of the time that both predict the outcome in the same direction with 0.500 being a coin-flip. The prediction model has a c-statistic equal to 0.836, which is considered to be extremely strong.

We noted in the CY 2018 HH PPS proposed rule that we are considering whether the HHA Correctly Identifies Patient's Need for Mental or Behavioral Health Supervision measure or the Caregiver Can/Does Provide for Patient's Mental or Behavioral Health

[20] ''Home Health Quality Initiative: Quality Measures'' *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*

[21] Somers' D is a statistic that is based on the concept of concordant vs. discordant pairs for two related values. In this case, if both the observed and predicted values are higher than the average or if both values are less than the average, then the pair of numbers is considered concordant. However, if one value is higher than average and the other is lower than average—or vice versa, then the pair of values is considered discordant. The Somer's D is (# of concordant pairs—# of discordant pairs)/total # of pairs. The higher the ratio, the stronger the concordance between the two set of values.

[22] The Kendall Tau-a assumes that if there is a correlation between two variables, then sorting the variables based on one of the values will result in ordering the second variable. It uses the same concept of concordant pairs in Somers' D but a different formula: t = [(4P)/[(n) (n–1)]—1 where p = # of concordant pairs and n = # of pairs. This correlation method reduces the effect of outlier values as the values are essentially ranked.

[23] The C-statistic (sometimes called the ''concordance'' statistic or C-index) is a measure of goodness of fit for binary outcomes in a logistic regression model. In clinical studies, the C-statistic gives the probability a randomly selected patient who experienced an event (for example, a disease or condition) had a higher risk score than a patient who had not experienced the event. It is equal to the area under the Receiver Operating Characteristic (ROC) curve and ranges from 0.5 to 1.

- A value below 0.5 indicates a very poor model.
- A value of 0.5 means that the model is no better than predicting an outcome than random chance.
- Values over 0.7 indicate a good model.
- Values over 0.8 indicate a strong model.

Supervision Need measure would be most meaningful to include in the Model. We also noted that we were considering the interactions between the Home Health Grouping Model (HHGM) proposal on quality measures discussed in section III. of the proposed rule and the HHVBP Model for the quality measures discussed in section IV.B of the proposed rule. We solicited public comments on the methodologies, analyses used to test the quality measure, and issues described in this section for future measure considerations. We noted that we will continue to share analyses as they become available with participating HHAs during future webinars.

The following is a summary of the public comments received on the ''Quality Measures for Future Consideration'' and our responses:

Comment: We received several comments from stakeholders offering their input on the quality measures discussed. Many were receptive to the development of new measures. Some commenters supported the development of composite measures, but believed improvement should not be the sole focus of any measure as they indicated that many patients benefit greatly from skilled home health services but are not likely to improve on these measures. While many commenters were in support of the inclusion of measures that capture an agency's ability to identify mental or behavioral health needs and identify whether a caregiver is available to provide behavioral supervision, they cautioned CMS that home health providers should not be made responsible for determining behavioral health diagnoses outside of a simple recognition of need. MedPAC was one of a few commenters that did not support developing new process measures, such as the described measure concepts of correctly identifying the patient's need for mental and behavioral health supervision, and identifying if a caregiver is able to provide the patient's mental or behavioral health supervision. MedPAC indicated that while it believes that improving a patient's functional ability is a goal of home health care, it has some degree of concern that the 'composite total change in ADL/IADL measure' and the 'composite functional decline measure' represent reporting elements completely within the control of the home health agency. MedPAC recommended that if CMS includes these measures, it may also want to consider and propose ways that such data could be independently audited or otherwise verified. Another commenter opposed the addition of a composite functional decline measure as they believe it rewards agencies that have selective admission practices of refusing patients that are likely to decline toward end of life, and also opposed the inclusion of behavioral health measures as they believe that they may discourage agencies from accepting patients when there are behavioral health issues or few local resources.

Response: We appreciate the comments on the discussion of the measures that we are considering for possible inclusion in the Model and will take the recommendations into consideration as we determine whether or not to include new measures in future rulemaking.

Comment: In response to our solicitation of public comment, we also received a few comments that were outside the scope of discussion of the specific future quality measures that we are considering, as discussed in the proposed rule. A commenter recommended that CMS develop and implement HHVBP policies in alignment with Congressional activity supporting one national approach to VBP for home care services. Another commenter recommended that CMS factor quality metrics into HHVBP that not only relate to health outcomes, but also that are within the control of the home health care provider, adequately measuring the quality of care provided. Another commenter recommended that CMS ensure that value-based home health purchasing models incorporate a shared definition of value that incorporates the patient and caregiver voice. A few commenters questioned the level of payment at risk under the Model, and believed that placing up to eight percent of HHA payment at risk for performance is too much. A few commenters questioned the geographic participation criteria for the Model and recommended including voluntary participation by interested HHAs in non-participating states.

Response: We appreciate the comment to align home health VBP policies with Congressional activity supporting a national approach to VBP home care services. We also appreciate the comments that recommend adequately measuring the quality of care provided and for CMS to ensure that value-based home health purchasing models incorporate a shared definition of value that incorporates the patient and caregiver voice. As an Innovation Center model, we are closely monitoring the quality measures and will address any needed adjustments through future rulemaking. With respect to the comments regarding the level of payment at risk under the Model, as discussed in the CY 2016 HH PPS final rule (80 FR 68687), competing HHAs that provide the highest quality of care and that receive the maximum upward adjustment will improve their financial viability that could ensure that the vulnerable population that they serve has access to high quality care. Only HHAs that provide very poor quality of care, relative to the cohort they compete within, would be subject to the highest downward payment adjustments. We appreciate the desire for interested HHAs in non-participating states to participate in the Model, but do not plan to re-open the Model to additional participants at this time.

We appreciate the comments on potential new quality measures and intend to continue to provide opportunities for stakeholder input as we consider additional measures for possible inclusion in the HHVBP Model's applicable measure set. We will continue to collect and analyze data as we consider whether to propose any additional measures in future rulemaking.

V. Updates to the Home Health Care Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

Section 1895(b)(3)(B)(v)(II) of the Act requires that for 2007 and subsequent years, each HHA submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data in accordance with this clause, the Secretary is directed to reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP and (except in 2018) further reduction of the increase by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the Home Health PPS for a year being less than payment rates for the preceding year.

We use the terminology ''CY [year] HH QRP'' to refer to the calendar year for which the HH QRP requirements applicable to that calendar year must be met in order for an HHA to avoid a 2 percentage point reduction to its market

basket percentage increase under section 1895(b)(3)(B)(v)(I) of the Act when calculating the payment rates applicable to it for that calendar year.

The Improving Medicare Post-Acute Care Transformation Act of 2014 (Pub. L. 113–185, enacted on October 6, 2014) (IMPACT Act) amended Title XVIII of the Act, in part, by adding new section 1899B of the Act, entitled ''Standardized Post-Acute Care Assessment Data for Quality, Payment, and Discharge Planning,'' and by enacting new data reporting requirements for certain post-acute care (PAC) providers, including Home Health Agencies (HHAs). Specifically, new sections 1899B(a)(1)(A)(ii) and (iii) of the Act require HHAs, Inpatient Rehabilitation Facilities (IRFs), Long Term Care Hospitals (LTCHs) and Skilled Nursing Facilities (SNFs), under each of their respective quality reporting program (which, for HHAs, is found at section 1895(b)(3)(B)(v) of the Act), to report data on quality measures specified under section 1899B(c)(1) of the Act for at least five domains, and data on resource use and other measures specified under section 1899B(d)(1) of the Act for at least three domains. Section 1899B(a)(1)(A)(i) of the Act further requires each of these PAC providers to report under its respective quality reporting program standardized patient assessment data in accordance with subsection (b) for at least the quality measures specified under subsection (c)(1) and that is with respect to five specific categories: Functional status; cognitive function and mental status; special services, treatments, and interventions; medical conditions and co-morbidities; and impairments. All of the data that must be reported in accordance with section 1899B(a)(1)(A) of the Act must be standardized and interoperable, so as to allow for the exchange of the information among PAC providers and other providers, as well as for the use of such data to enable access to longitudinal information and to facilitate coordinated care. We refer readers to the CY 2016 HH PPS final rule (80 FR 68690 through 68692) for additional information on the IMPACT Act and its applicability to HHAs.

B. General Considerations Used for the Selection of Quality Measures for the HH QRP

We refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68698) for a detailed discussion of the considerations we apply in measure selection for the HH QRP, such as alignment with the CMS Quality Strategy,[24] which incorporates the three broad aims of the National Quality Strategy.[25] As part of our consideration for measures for use in the HH QRP, we review and evaluate measures that have been implemented in other programs and take into account measures that have been endorsed by NQF for provider settings other than the home health setting. We have previously adopted measures with the term ''Application of'' in the names of those measures. We have received questions pertaining to the term ''application'' and clarified in the proposed rule that when we refer to a measure as an ''Application of'' the measure, we mean that the measure would be used in a setting other than the setting for which it was endorsed by the NQF. For example, in the FY 2016 SNF PPS Rule (80 FR 46440 through 46444) we adopted An Application of the Measure Percent of Residents with Experiencing Falls with Major Injury (Long Stay) (NQF #0674), which is endorsed for the Nursing Home setting but not the SNF setting. For such measures, we stated that we intend to seek NQF endorsement for the home health setting, and if the NQF endorses one or more of them, we would update the title of the measure to remove the reference to ''Application of.''

We received comments on the considerations we apply in our measure selection and on other topics related to measures used in the HH QRP.

Comment: Some commenters supported the standardization of measures and data across HHAs, LTCHs, IRFs, and SNFs so that CMS can make comparisons between them, but cautioned that such standardization could compromise the validity of the data. These commenters stated that the home is different than institutional settings because the patient has a greater role in determining how, when, and if certain interventions are provided, and that individual skill, cognitive and functional ability, and financial resources affect the ability of home health patients to safely manage their health care needs, interventions, and medication regimens. Other commenters expressed concerns about the reliability and validity of cross-setting measures due to the unique characteristics of the home health setting and emphasized caution in interpreting measure rates.

Response: We appreciate the support for standardization to enable comparisons across post-acute care providers. We also recognize the uniqueness of the home setting, including patients' capacity to directly and independently manage their environment and health care needs, such as medications and treatments. However, we disagree that patients are limited in their freedom to help set their goals and preferences when receiving care services within LTCHs, IRFs or SNFs. In our measure development and alignment work, we continuously assess and account for the unique characteristics of home health patients including the use of risk-adjustment models that account for differences in cognitive and functional ability. Further, we are mindful that regardless of where services are rendered, risk adjustment is generally applied to characteristics of the individual rather than the provider setting.

All of the measures we proposed to adopt for the HH QRP were tested for reliability and/or validity, and we believe that the results of that testing support our conclusion that the measures are sufficiently reliable and valid to warrant their adoption in the HH QRP. The results of our reliability and validity testing for these measures may be found in the Measure Specifications for Measures Proposed in CY 2018 HH QRP Final Rule, posted on the CMS HH QRP Web page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html*. We will continue to test, monitor and validate these measures as part of measure maintenance.

Comment: One commenter suggested that the claims-based measures be weighted more than OASIS measures in order to control for inflated outcomes. Another commenter was concerned that OASIS measure data can be manipulated and suggested the HH QRP should only use claims-based measures because they are more objective.

Response: We wish to clarify that we do not weight home health measures in the home health quality reporting program. However, we believe that the commenter is concerned about the gaming on behalf of home health agencies. We believe that the collection of both claims-based and OASIS based measures is appropriate for the program. Claims-based data can be limited because they are associated with billing and do not always provide a complete picture of the patient's health assessment status. OASIS fills in those gaps by giving us additional information about care processes and outcomes that are furnished to HHA patients.

[24] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[25] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

Although we recognize that OASIS assessments are, by their nature, more subjective than claims, we require HHAs to attest to the accuracy of the data submitted on each OASIS assessment.

C. Accounting for Social Risk Factors in the HH QRP

In the CY 2018 HH PPS proposed rule (82 FR 35341 through 35342), we discussed accounting for social risk factors in the HH QRP. We understand that social risk factors such as income, education, race and ethnicity, employment, disability, community resources, and social support (certain factors of which are also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) play a major role in health. One of our core objectives is to improve beneficiary outcomes including reducing health disparities, and we want to ensure that all beneficiaries, including those with social risk factors, receive high quality care. In addition, we seek to ensure that the quality of care furnished by providers and suppliers is assessed as fairly as possible under our programs while ensuring that beneficiaries have adequate access to excellent care.

We have been reviewing reports prepared by the Office of the Assistant Secretary for Planning and Evaluation (ASPE [26]) and the National Academies of Sciences, Engineering, and Medicine on the issue of measuring and accounting for social risk factors in CMS' quality measurement and payment programs, and considering options on how to address the issue in these programs. On December 21, 2016, ASPE submitted a Report to Congress on a study it was required to conduct under section 2(d) of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. The study analyzed the effects of certain social risk factors of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[27] The report also included considerations for strategies to account for social risk factors in these programs. In a January 10, 2017 report released by The National Academies of Sciences, Engineering, and Medicine, that body provided various potential methods for measuring and accounting for social risk factors, including stratified public reporting.[28]

In addition, the NQF undertook a 2-year trial period in which new measures, measures undergoing maintenance review, and measures endorsed with the condition that they enter the trial period were assessed to determine whether risk adjustment for selected social risk factors was appropriate for these measures. Measures from the HH QRP, Rehospitalization During the First 30 Days of Home Health (NQF# 2380), and Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health (NQF# 2505) were included in this trial. This trial entailed temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. Since the publication of the CY 2018 HH PPS proposed rule, the National Quality Forum (NQF) has concluded their initial trial on risk adjustment for quality measures. Based on the findings from the initial trial, NQF will continue its work to evaluate the impact of social risk factor adjustment on intermediate outcome and outcome measures for an additional 3 years. The extension of this work will allow NQF to determine further how to effectively account for social risk factors through risk adjustment and other strategies in quality measurement.

As we continue to consider the analyses and recommendations from these reports, we are continuing to work with stakeholders in this process. As we have previously communicated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities or minimize incentives to improve the outcomes for disadvantaged populations. Keeping this concern in mind, while we sought input on this topic previously, we continue to seek public comment on whether we should account for social risk factors in measures in the HH QRP, and if so, what method or combination of methods would be most appropriate for accounting for social risk factors. Examples of methods include: confidential reporting to providers of measure rates stratified by social risk factors, public reporting of stratified measure rates, and potential risk adjustment of a particular measure as appropriate based on data and evidence.

In addition, in the CY 2018 HH PPS proposed rule (82 FR 35341 through 35342), we sought public comment on which social risk factors might be most appropriate for reporting stratified measure scores and potential risk adjustment of a particular measure. Examples of social risk factors include, but are not limited to, dual eligibility/low-income subsidy, race and ethnicity, and geographic area of residence. We also sought comments on which of these factors, including current data sources where this information would be available, could be used alone or in combination, and whether other data should be collected to better capture the effects of social risk. We will take commenters' input into consideration as we continue to assess the appropriateness and feasibility of accounting for social risk factors in the HH QRP. We note that to the extent we consider making any changes we would propose them through future notice and comment rulemaking.

We look forward to working with stakeholders as we consider the issue of accounting for social risk factors and reducing health disparities in CMS programs. Of note, implementing any of the methods previously stated will be taken into consideration in the context of how this and other CMS programs operate (for example, data submission methods, availability of data, statistical considerations relating to reliability of data calculations, among others), so we also sought comment on operational considerations. We are committed to ensuring that beneficiaries have access to and receive excellent care, and that the quality of care furnished by providers and suppliers is assessed fairly in CMS programs. This section of this final rule includes a discussion of the comments we received on this topic, along with our responses.

Comment: Commenters were generally supportive of accounting for social risk factors in the HH QRP quality measures. Many commenters stated that there was evidence demonstrating that these factors can have substantial influence on patient health outcomes. Some commenters who supported accounting for social risk factors noted that these factors are outside the control of the provider and were concerned that without risk adjustment, differences in quality scores may reflect differences in patient populations rather than differences in quality.

A few other commenters, while acknowledging the influence of social risk factors on health outcomes, cautioned against adjusting for them in quality measurement due to the potential for unintended consequences.

[26] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[27] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[28] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

These commenters expressed concern over the possibility that risk- adjusted measures may remove incentives for quality improvement among facilities that serve higher levels of underserved populations.

Regarding risk adjustment methodology, some commenters made specific recommendations regarding the type of risk adjustment that must be used. Commenters stated that any risk stratification must be considered on a measure-by-measure basis, and that measures that are broadly within the control of the provider and reflective of direct care, such as pressure ulcers, must not be stratified. The commenters stated that social risk factor adjustment be used only on outcome measures, not process measures. One commenter alternately suggested using socioeconomic factors to stratify, rather than adjust, measure results. Multiple commenters recommended that we conduct further research and testing of risk-adjustment methods. A commenter suggested that CMS use Social Risk Factors, Social Determinants of Health or Distressed Communities Index scores within the HH QRP. Some commenters suggested the formation of a TEP to further refine the use of such data.

In addition to supporting race and ethnicity, dual eligibility status, and geographical location, commenters suggested additional risk factors, including: Patient-level factors such as lack of personal resources, education level, and employment. Some commenters also suggested community resources and other factors such as access to adequate food, medications, living conditions (including living alone), and lack of an adequate support system or caregiver availability. Several encouraged the development of measures that reflect person-centered domains to improve the focus on outcomes for disadvantaged populations.

A few commenters provided feedback on confidential and public reporting of data adjusted for social risk factors. A commenter suggested that CMS start with confidential reporting and, once there has been opportunity for HHAs to review and understand their results, CMS could transition to public reporting.

Response: We thank commenters for their suggestions. As we have previously stated, we are concerned about holding providers to different standards for the outcomes of their patients with social risk factors because we do not want to mask potential disparities. We believe that the path forward must incentivize improvements in health outcomes for disadvantaged populations while ensuring that beneficiaries have adequate access to excellent care. Also, based on the findings from the initial trial, NQF will continue its work to evaluate the impact of social risk factor adjustment on intermediate outcome and outcome measures for an additional three years. The extension of this work will allow NQF to determine further how to effectively account for social risk factors through risk adjustment and other strategies in quality measurement. We await recommendations of the NQF trial to further inform our efforts.

We will consider all suggestions as we continue to assess each measure and the overall HH QRP. We intend to explore options including but not limited to measure stratification by social risk factors in a consistent manner across several quality reporting programs, informed by considerations of stratification methods described in IX.A.13 of the preamble of the FY 2018 IPPS/LTCH PPS final rule. We thank commenters for this important feedback and will continue to consider options to account for social risk factors that will allow us to address disparities and potentially incentivize improvement in care for patients and beneficiaries. We will also consider providing feedback to providers on outcomes for individuals with social risk factors in confidential reports.

D. Removal of OASIS Items

In the CY 2018 HH PPS proposed rule (82 FR 35342) we proposed to remove 247 data elements from 35 OASIS items collected at specific time points during a home health episode. These data elements are not used in the calculation of quality measures already adopted in the HH QRP, nor are they being used for previously established purposes unrelated to the HH QRP, including payment, survey, the HH VBP Model or care planning. We included list of the 35 OASIS items we proposed to remove, in part or in their entirety, in Table 45 of the proposed rule (82 FR 35342 and 35343) and also made them available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html*. Subsequent to issuing the proposed rule, we discovered that we had inadvertently included three OASIS items in Table 45 that are used either for payment or for the HH QRP. Those items are M1200 Vision (used for payment), M2030 Management of Injectable Medications (used for payment), and M1730 Depression Screening (used in the HH QRP). Accordingly, we will not be removing these items from the OASIS.

Comment: Many commenters supported our proposal to remove items from OASIS. Most of these commenters agreed that items not used for the purposes of determining patient outcomes or the quality of care should be removed.

Response: We appreciate the support for our proposal to remove items from OASIS.

Comment: One commenter noted that OASIS Item M2250 (Plan of Care Synopsis) is proposed for removal and questioned whether OASIS Item M2401 (Intervention Synopsis) will continue to be collected.

Response: We proposed to remove OASIS Item M2250 because it is not used for the HH QRP or for any other purpose. OASIS Item M2401 is used in the calculation of the quality measure Diabetic Foot Care and Patient Education Implemented (NQF #0519), which we adopted in the CY 2010 HH PPS final rule (74 FR 58096), and will therefore continue to be collected at the time point of Transfer to an Inpatient Facility and Discharge from Agency.

Comment: One commenter questioned if there is another OASIS version that will be implemented so that a beneficiary's Medicare Beneficiary Identifier (MBI) can be provided in the OASIS.

Response: Effective January 1, 2018 the OASIS–C2 will be able to accommodate the MBI which is an alternative Medicare Beneficiary Identifier that we are adopting to replace the Social Security number (SSN)-based Health Insurance Claim Number (HICN) in an effort to prevent identity theft in the Medicare population. Instructions for reporting OASIS Item M0063 (Medicare Beneficiary Number) can be found in the OASIS–C2 Guidance Manual: Effective January 1, 2018 at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/OASIS-C2-Guidance-Manual-Effective_1_1_18.pdf*.

Comment: A few commenters raised concerns about the overall burden associated with CMS' proposals, noting that if all proposed new assessment items are finalized, the new assessment items could be more burdensome to collect than the one being removed.

Response: We appreciate the comments and as more fully discussed in section V.H. of this final rule, we have decided not to finalize the standardized patient assessment data elements proposed for three of the five categories under § 1899B(b)(1)(B) of the Act: Cognitive Function and Mental

Status; Special Services, Treatments, and Interventions; and Impairments.

Final Decision: After consideration of the comments received, we are finalizing the removal of 235 data elements from 33 OASIS items collected at specific time points during a home health episode, effective with all HHA assessments on or after January 1, 2019. As previously explained, we will continue to collect OASIS items M1200, M2030 and M1730. Table 17 lists the OASIS items and data elements to be removed and they can also be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html*.

TABLE 17—ITEMS TO BE REMOVED FROM OASIS EFFECTIVE JANUARY 1, 2019

OASIS item	Specific time point					
	Start of care	Resumption of care	Follow-up	Transfer to an inpatient facility	Death at home	Discharge from agency
M0903				1	1	1
M1011	6	6	6			
M1017	6	6				
M1018	6	6				
M1025	12	12	12			
M1034	1	1				
M1036	4	4				
M1210	1	1				
M1220	1	1				
M1230	1	1				1
M1240	1	1				
M1300	1	1				
M1302	1	1				
M1320	1	1				1
M1322						1
M1332						1
M1350	1	1				
M1410	3	3				
M1501				1		1
M1511				5		5
M1610						1
M1615	1	1				1
M1750	1	1				
M1880	1	1				1
M1890	1	1				1
M1900	4	4				
M2030						1
M2040	2	2				
M2102 *	6	6				** 3
M2110	1	1				
M2250	7	7				
M2310				*** 15		*** 15
M2430				20		
Total	70	70	18	42	1	34

* M2102 row f to remain collected at Start of Care, Resumption of Care and Discharge from Agency as part of the HH VBP program.
** M2102 rows a, c, d to remain collected at Discharge from Agency for survey purposes.
*** M2310 responses 1, 10, OTH, UK to remain collected at Transfer to an Inpatient Facility and Discharge from Agency for survey purposes.

E. Collection of Standardized Patient Assessment Data Under the HH QRP

1. Definition of Standardized Patient Assessment Data

Section 1895(b)(3)(B)(v)(IV)(bb) of the Act requires that beginning with the CY 2019 HH QRP, HHAs report standardized patient assessment data required under section 1899B(b)(1) of the Act. For purposes of meeting this requirement, section 1895(b)(3)(B)(v)(IV)(cc) of the Act requires that a HHA submit the standardized patient assessment data required under section 1899B(b)(1) of the Act in the form and manner, and at the time, as specified by the Secretary.

Section 1899B(b)(1)(B) of the Act describes standardized patient assessment data as data required for at least the quality measures described in sections 1899B(c)(1) of the Act and that is with respect to the following categories:

- Functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider.
- Cognitive function, such as ability to express and understand ideas, and mental status, such as depression and dementia.
- Special services, treatments and interventions such as the need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition.
- Medical conditions and comorbidities such as diabetes, congestive heart failure and pressure ulcers.
- Impairments, such as incontinence and an impaired ability to hear, see or swallow.
- Other categories deemed necessary and appropriate by the Secretary.

As required under section 1899B(b)(1)(A) of the Act, the standardized patient assessment data must be reported at least for the beginning of the home health episode (for example, HH start of care/resumption of care) and end of episode

(discharge), but the Secretary may require the data to be reported more frequently.

In the CY 2018 HH PPS proposed rule (82 FR 35343), we proposed to define the standardized patient assessment data that HHAs must report under the HH QRP, as well as the requirements for the reporting of these data. The collection of standardized patient assessment data is critical to our efforts to drive improvement in healthcare quality across the four post-acute care (PAC) settings to which the IMPACT Act applies. We noted that we intend to use these data for a number of purposes, including facilitating their exchange and longitudinal use among healthcare providers to enable high quality care and outcomes through care coordination, as well as for quality measure calculation, and identifying comorbidities that might increase the medical complexity of a particular admission.

HHAs are currently required to report patient assessment data through the Outcome and Assessment Information Set (OASIS) by responding to an identical set of assessment questions using an identical set of response options (we refer to a solitary question/response option as a data element and we refer to a group of questions/responses as data elements), both of which incorporate an identical set of definitions and standards. The primary purpose of the identical questions and response options is to ensure that we collect a set of standardized data elements across HHAs, which we can then use for a number of purposes, including HH payment and measure calculation for the HH QRP.

LTCHs, IRFs, and SNFs are also required to report patient assessment data through their applicable PAC assessment instruments, and they do so by responding to identical assessment questions developed for their respective settings using an identical set of response options (which incorporate an identical set of definitions and standards). Like the OASIS, the questions and response options for each of these other PAC assessment instruments are standardized across the PAC provider type to which the PAC assessment instrument applies. However, the assessment questions and response options in the four PAC assessment instruments are not currently standardized with each other. As a result, questions and response options that appear on the OASIS cannot be readily compared with questions and response options that appear, for example, on the Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF–PAI), which is the PAC assessment instrument used by IRFs. This is true even when the questions and response options are similar. This lack of standardization across the four PAC provider types has limited our ability to compare one PAC provider type with another for purposes such as care coordination and quality improvement.

To achieve a level of standardization across HHAs, LTCHs, IRFs, and SNFs that enables us to make comparisons between them, we proposed to define ''standardized patient assessment data'' as patient or resident assessment questions and response options that are identical in all four PAC assessment instruments, and to which identical standards and definitions apply.

We stated in the proposed rule that standardizing the questions and response options across the four PAC assessment instruments is an essential step in making that data interoperable, allowing it to be shared electronically, or otherwise, between PAC provider types. It will enable the data to be comparable for various purposes, including the development of cross-setting quality measures and to inform payment models that take into account patient characteristics rather than setting, as described in the IMPACT Act.

We did not receive any specific comments on the proposed definition.

Final Decision: We are finalizing as proposed our definition of standardized patient assessment data.

2. General Considerations Used for the Selection of Standardized Patient Assessment Data

As part of our effort to identify appropriate standardized patient assessment data for purposes of collecting under the HH QRP, we sought input from the general public, stakeholder community, and subject matter experts on items that would enable person-centered, high quality health care, as well as access to longitudinal information to facilitate coordinated care and improved beneficiary outcomes.

To identify optimal data elements for standardization, our data element contractor organized teams of researchers for each category, with each team working with a group of advisors made up of clinicians and academic researchers with expertise in PAC. Information-gathering activities were used to identify data elements, as well as key themes related to the categories described in section 1899B(b)(1)(B) of the Act. In January and February 2016, our data element contractor also conducted provider focus groups for each of the four PAC provider types, and a focus group for consumers that included current or former PAC patients and residents, caregivers, ombudsmen, and patient advocacy group representatives. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Focus Group 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*.

Our data element contractor also assembled a 16-member TEP that met on April 7 and 8, 2016, and January 5 and 6, 2017, in Baltimore, Maryland, to provide expert input on data elements that are currently in each PAC assessment instrument, as well as data elements that could be standardized. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data TEP Summary Reports 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*.

As part of the environmental scan, data elements currently in the four existing PAC assessment instruments were examined to see if any could be considered for proposal as standardized patient assessment data. Specifically, this evaluation included consideration of data elements in OASIS–C2 (effective January 2017); IRF–PAI, v1.4 (effective October 2016); LCDS, v3.00 (effective April 2016); and MDS 3.0, v1.14 (effective October 2016). Data elements in the standardized assessment instrument that we tested in the Post-Acute Care Payment Reform Demonstration (PAC PRD)—the Continuity Assessment Record and public reporting Evaluation (CARE)—were also considered. A literature search was also conducted to determine whether we could propose to adopt additional data elements as standardized patient assessment data.

Additionally, we held four Special Open Door Forums (SODFs) on October 27, 2015; May 12, 2016; September 15, 2016; and December 8, 2016, to present data elements we were considering and to solicit input. At each SODF, some stakeholders provided immediate input, and all were invited to submit additional comments via the CMS IMPACT Mailbox: *PACQualityInitiative@cms.hhs.gov*.

We also convened a meeting with federal agency subject matter experts (SMEs) on May 13, 2016. In addition, a public comment period was open from August 12 to September 12, 2016 to solicit comments on detailed candidate data element descriptions, data collection methods, and coding methods. The IMPACT Act Public Comment Summary Report containing the public comments (summarized and verbatim) and our responses 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 specifically sought to identify standardized patient assessment data that we could feasibly incorporate into the LTCH, IRF, SNF, and HHA assessment instruments and that have the following attributes: (1) Being supported by current science; (2) testing well in terms of their reliability and validity, consistent with findings from the Post-Acute Care Payment Reform Demonstration (PAC PRD); (3) the potential to be shared (for example, through interoperable means) among PAC and other provider types to facilitate efficient care coordination and improved beneficiary outcomes; (4) the potential to inform the development of quality, resource use and other measures, as well as future payment methodologies that could more directly take into account individual beneficiary health characteristics; and (5) the ability to be used by practitioners to inform their clinical decision and care planning activities. We also applied the same considerations that we apply to quality measures, including the CMS Quality Strategy which is framed using the three broad aims of the National Quality Strategy.

3. Policy for Retaining HH QRP Measures and Standardized Patient Assessment Data

In the CY 2017 HH PPS final rule (81 FR 76755 through 76756), we adopted a policy that will allow for any quality measure adopted for use in the HH QRP to remain in effect until the measure is removed, suspended, or replaced. For further information on how measures are considered for removal, suspension or replacement, we refer readers to the CY 2017 HH PPS final rule (81 FR 76755 through 76756). We proposed to apply this same policy to the standardized patient assessment data that we adopt for the HH QRP.

Comment: Several commenters supported this proposal.

Response: We appreciate the commenters' support.

Final Decision: We are finalizing that our policy for retaining HH QRP measures will apply to the standardized patient assessment data that we adopt for the HH QRP.

4. Policy for Adopting Changes to HH QRP Measures and Application of That Policy to Standardized Patient Assessment Data

In the CY 2017 HH PPS final rule (81 FR 76756), we adopted a subregulatory process to incorporate updates to HH quality measure specifications that do not substantively change the nature of the measure. We noted that substantive changes will be proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a nonsubstantive change and the subregulatory process for nonsubstantive changes, we refer readers to the CY 2017 HH PPS final rule (81 FR 76756). We proposed to apply this policy to the standardized patient assessment data that we adopt for the HH QRP. We invited public comment on this proposal.

Comment: One commenter requested that we propose to adopt all substantive changes to measures only after soliciting input from a technical expert panel of home health clinical leaders, holding a Special Open Door Forum to explain the changes under consideration, and allowing stakeholders to submit meaningful comments on those potential changes.

Response: We agree that input from both technical experts and the public is critical to the measure development process, and we generally solicit both types of input when we consider whether to propose substantive updates to measures. We also solicit input in other ways, such as through open door forums and solicitations for public comment, and often engage in these activities prior to proposing substantive updates through the rulemaking process. Finally, the rulemaking process itself gives the public an additional opportunity to comment on the substantive updates to measures under consideration.

Final Decision: After consideration of the public comments, we are finalizing that we will apply our policy for adopting changes to HH QRP measures to the standardized patient assessment data that we adopt for the HH QRP.

5. Quality Measures Previously Finalized for the HH QRP

The HH QRP currently has 23 measures, as outlined in Table 18.

TABLE 18—MEASURES CURRENTLY ADOPTED FOR THE HH QRP

Short name	Measure name & data source
OASIS-based	
Pressure Ulcers	Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (NQF # 0678).* +
DRR	Drug Regimen Review Conducted with Follow-Up for Identified Issues-Post Acute Care (PAC) Home Health Quality Reporting Program. +
Ambulation	Improvement in Ambulation/Locomotion (NQF #0167).
Bathing	Improvement in Bathing (NQF #0174).
Dyspnea	Improvement in Dyspnea.
Oral Medications	Improvement in Management of Oral Medication (NQF #0176).
Pain	Improvement in Pain Interfering with Activity (NQF #0177).
Surgical Wounds	Improvement in Status of Surgical Wounds (NQF #0178).
Bed Transferring	Improvement in Bed Transferring (NQF # 0175).
Timely Care	Timely Initiation Of Care (NQF # 0526).
Depression Assessment	Depression Assessment Conducted.
Influenza	Influenza Immunization Received for Current Flu Season (NQF #0522).
PPV	Pneumococcal Polysaccharide Vaccine Ever Received (NQF #0525).
Falls Risk	Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537).
Diabetic Foot Care	Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care (NQF #0519).
Drug Education	Drug Education on All Medications Provided to Patient/Caregiver during All Episodes of Care.
Claims-based	
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP). +

TABLE 18—MEASURES CURRENTLY ADOPTED FOR THE HH QRP—Continued

Short name	Measure name & data source
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP). +
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Home Health Quality Reporting Program. +
ACH	Acute Care Hospitalization During the First 60 Days of Home Health (NQF #0171).
ED Use	Emergency Department Use without Hospitalization During the First 60 Days of Home Health (NQF #0173).
Rehospitalization	Rehospitalization During the First 30 Days of Home Health (NQF #2380).
ED Use without Readmission	Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health (NQF #2505).
HHCAHPs-based	
Professional Care	How often the home health team gave care in a professional way.
Communication	How well did the home health team communicate with patients.
Team Discussion	Did the home health team discuss medicines, pain, and home safety with patients.
Overall Rating	How do patients rate the overall care from the home health agency.
Willing to Recommend	Will patients recommend the home health agency to friends and family.

*Not currently NQF-endorsed for the home health setting.

The data collection period will begin with CY 2017 Q1&2 reporting for CY 2018 APU determination, followed by the previously established HH QRP use of 12 months (July 1, 2017–June 30, 2018) of CY 2017 reporting for CY 2019 APU determination. Subsequent years will be based on the HH July 1–June 30 timeframe for APU purposes. For claims data, the performance period will use rolling CY claims for subsequent reporting purposes.

F. New HH QRP Quality Measures Beginning With the CY 2020 HH QRP

In the CY 2018 HH PPS proposed rule (82 FR 35345) we proposed that beginning with the CY 2020 HH QRP, in addition to the quality measures we are retaining under our policy described in section V.B. of this final rule, we would replace the current pressure ulcer measure entitled Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) with a modified version of the measure and adopt one measure on patient falls and one measure on assessment of patient functional status. We also proposed to characterize the data elements described in this section as standardized patient assessment data under section 1899B(b)(1)(B) of the Act that must be reported by HHAs under the HH QRP through the OASIS. The new measures that we proposed to adopt are as follows:

- Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
- Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674).
- 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).

The measures are described in more detail as follows:

1. Replacing the Current Pressure Ulcer Quality Measure, Entitled Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), With a Modified Pressure Ulcer Measure, Entitled Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury

a. Measure Background

We proposed to remove the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), from the HH QRP measure set and to replace it with a modified version of that measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP. The change in the measure name is to reduce confusion about the new modified measure. The modified version differs from the current version of the measure because it includes new or worsened unstageable pressure ulcers, including deep tissue injuries (DTIs), in the measure numerator. The proposed modified version of the measure also contained updated specifications intended to eliminate redundancies in the assessment items needed for its calculation and to reduce the potential for underestimating the frequency of pressure ulcers. The modified version of the measure would satisfy the IMPACT Act domain of ''Skin integrity and changes in skin integrity.''

b. Measure Importance

As described in the CY 2016 HH PPS final rule (80 FR 68697), pressure ulcers are high-cost adverse events and are an important measure of quality. For information on the history and rationale for the relevance, importance, and applicability of having a pressure ulcer measure in the HH QRP, we referred readers to the CY 2016 HH PPS final rule (80 FR 68697 to 68700.

We proposed to adopt a modified version of the current pressure ulcer measure because unstageable pressure ulcers, including DTIs, are similar to Stage 2, Stage 3, and Stage 4 pressure ulcers in that they represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating and painful and are often an avoidable outcome of medical care.[29 30 31 32 33 34] Studies show that most pressure ulcers can be avoided and can also be healed in acute, post-acute, and long term care settings with appropriate medical care.[35] Furthermore, some studies indicate that DTIs, if managed using appropriate care, can be resolved without deteriorating into a worsened pressure ulcer.[36 37]

While there are few studies that provide information regarding the incidence of unstageable pressure ulcers in PAC settings, an analysis conducted by our measure development contractor indicated that adding unstageable pressure ulcers to the quality measure numerator would result in a higher

[29] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' *Nurs N Z* 19(10): 20–24.

[30] Gorzoni, M.L. and S.L. Pires (2011). ''Deaths in nursing homes.'' *Rev Assoc Med Bras* 57(3): 327–331.

[31] Thomas, J.M., et al. (2013). ''Systematic review: health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality.'' *J Am Geriatr Soc* 61(6): 902–911.

[32] White-Chu, E.F., et al. (2011). ''Pressure ulcers in long-term care.'' *Clin Geriatr Med* 27(2): 241–258.

[33] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med.* 2001;135 (8 Part 2), 744–51.

[34] Bennet, G, Dealy, C Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging*, 33(3):230–235.

[35] Black, Joyce M., et al. ''Pressure ulcers: avoidable or unavoidable? Results of the national pressure ulcer advisory panel consensus conference.'' *Ostomy-Wound Management* 57.2 (2011): 24.

[36] Sullivan, R. (2013). A Two-year Retrospective Review of Suspected Deep Tissue Injury Evolution in Adult Acute Care Patients. Ostomy Wound Management 59(9) http://www.o-wm.com/article/two-year-retrospective-review-suspected-deep-tissue-injury-evolution-adult-acute-care-patien.

[37] Posthauer, ME, Zulkowski, K. (2005). Special to OWM: The NPUAP Dual Mission Conference: Reaching Consensus on Staging and Deep Tissue Injury. Ostomy Wound Management 51(4) http://www.o-wm.com/content/the-npuap-dual-mission-conference-reaching-consensus-staging-and-deep-tissue-injury.

percentage of patients with new or worsened pressure ulcers in HHA settings and increase the variability of measure scores. A higher percentage indicates lower quality. This increased variability serves to improve the measure by improving the ability of the measure to distinguish between high and low quality home health agencies.

We have found in the testing of this measure that given the low prevalence of pressure ulcers in the home health setting, the addition of unstageable ulcers to this measure could enhance variability. Analysis of 2015 OASIS data found that in approximately 1.2 percent, or more than 70,000 episodes, of patients had an unstageable ulcer upon admission. Patients in more than 13,000 episodes were discharged with an unstageable ulcer. In addition, unstageable ulcers due to slough/eschar worsened between admission and discharge in approximately 5,000 episodes of care. In conclusion, the inclusion of unstageable pressure ulcers, including DTIs, in the numerator of this measure is expected to increase measure scores and variability in measure scores, thereby improving the ability to discriminate among poor- and high-performing HHAs.

Testing shows similar results in other PAC settings. For example, in SNFs, using data from Quarter 4 2015 through Quarter 3 2016, the mean score on the currently implemented pressure ulcer measure is 1.75 percent, compared with 2.58 percent in the proposed measure. In the proposed measure, the SNF mean score is 2.58 percent; the 25th and 75th percentiles are 0.65 percent and 3.70 percent, respectively; and 20.32 percent of facilities have perfect scores. In LTCHs, using data from Quarter 1 through Quarter 4 2015, the mean score on the currently implemented pressure ulcer measure is 1.95 percent, compared with 3.73 percent in the proposed measure. In the proposed measure, the LTCH mean score is 3.73 percent; the 25th and 75th percentiles are 1.53 percent and 4.89 percent, respectively; and 5.46 percent of facilities have perfect scores. In IRFs, using data from Quarter 4 2016, the mean score on the currently implemented pressure ulcer measure is 0.64 percent, compared with 1.46 percent in the proposed measure. In the proposed measure, the IRF mean score is 1.46 percent and the 25th and 75th percentiles are 0 percent and 2.27 percent, respectively. The inclusion of unstageable pressure ulcers, including DTIs, in the numerator of this measure is expected to increase measure scores and variability in measure scores, thereby improving the ability to distinguish between poor and high performing HHAs.

This increased variability of scores across quarters and deciles may improve the ability of the measure to distinguish between high and low performing providers across PAC settings.

c. Stakeholder Feedback

Our measure development contractor sought input from subject matter experts, including Technical Expert Panels (TEPs), over the course of several years on various skin integrity topics and specifically those associated with the inclusion of unstageable pressure ulcers including DTIs. Most recently, on July 18, 2016, a TEP convened by our measure development contractor provided input on the technical specifications of this proposed quality measure, including the feasibility of implementing the proposed measure's updates across PAC settings. The TEP supported the use of the proposed measure across PAC settings, including the use of different data elements for measure calculation. The TEP supported the updates to the measure across PAC settings, including the inclusion in the numerator of unstageable pressure ulcers due to slough and/or eschar that are new or worsened, new unstageable pressure ulcers due to a non-removable dressing or device, and new DTIs. The TEP recommended supplying additional guidance to providers regarding each type of unstageable pressure ulcer. This support was in agreement with earlier TEP meetings, held on June 13, and November 15, 2013, which had recommended that CMS update the specifications for the pressure ulcer measure to include unstageable pressure ulcers in the numerator.[38] [39] Exploratory data analysis conducted by our measure development contractor suggests that the addition of unstageable pressure ulcers, including DTIs, will increase the observed incidence of new or worsened pressure ulcers at the facility level and may improve the ability of the proposed quality measure to discriminate between poor- and high-performing agencies.

We solicited stakeholder feedback on this proposed measure by means of a public comment period held from October 17 through November 17, 2016. In general, we received considerable support for the proposed measure. A few commenters supported all of the changes to the current pressure ulcer measure that resulted in the proposed measure, with one commenter noting the significance of the work to align the pressure ulcer quality measure specifications across the PAC settings. Many commenters supported the inclusion of unstageable pressure ulcers due to slough/eschar, due to non-removable dressing/device, and DTIs in the proposed quality measure. Other commenters did not support the inclusion of DTIs in the proposed quality measure because they stated that there is no universally accepted definition for this type of skin injury.

Some commenters provided feedback on the data elements used to calculate the proposed quality measure. We believe that these data elements will promote facilitation of cross-setting quality comparison as required under the IMPACT Act, alignment between quality measures and payment, reduction in redundancies in assessment items, and prevention of inappropriate underestimation of pressure ulcers. The currently implemented pressure ulcer measure is calculated using retrospective data elements that assess the number of new or worsened pressure ulcers at each stage, while the proposed measure is calculated using data elements that assess the current number of unhealed pressure ulcers at each stage, and the number of these that were present upon admission, which are subtracted from the current number at that stage. Some commenters did not support the data elements that will be used to calculate the proposed measure, and requested further testing of these data elements. Other commenters supported the use of these data elements stating that these data elements simplified the measure calculation process.

The public comment summary report for the proposed measure is available on the CMS Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

[38] Schwartz, M., Nguyen, K.H., Swinson Evans, T.M., Ignaczak, M.K., Thaker, S., and Bernard, S.L.: Development of a Cross-Setting Quality Measure for Pressure Ulcers: OY2 Information Gathering, Final Report. Centers for Medicare & Medicaid Services, November 2013. Available: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Quality-Measure-for-Pressure-Ulcers-Information-Gathering-Final-Report.pdf.*

[39] Schwartz, M., Ignaczak, M.K., Swinson Evans, T.M., Thaker, S., and Smith, L.: The Development of a Cross-Setting Pressure Ulcer Quality Measure: Summary Report on November 15, 2013, Technical Expert Panel Follow-Up Webinar. Centers for Medicare & Medicaid Services, January 2014. Available: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-of-a-Cross-Setting-Pressure-Ulcer-Quality-Measure-Summary-Report-on-November-15-2013-Technical-Expert-Pa.pdf.*

The NQF-convened Measures Application Partnership (MAP) Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup met on December 14 and 15, 2016, and provided us input about this proposed measure. The NQF-convened MAP PAC/LTC workgroup provided a recommendation of ''support for rulemaking'' for use of the proposed measure in the HH QRP. The MAP Coordinating Committee met on January 24 and 25, 2017, and provided a recommendation of ''conditional support for rulemaking'' for use of the proposed measure in the HH QRP. The MAP's conditions of support include that, as a part of measure implementation, we provide guidance on the correct collection and calculation of the measure result, as well as guidance on public reporting Web sites explaining the impact of the specification changes on the measure result. The MAP's conditions also specify that CMS continue analyzing the proposed measure to investigate unexpected results reported in public comment. We stated in the proposed rule that we intend to fulfill these conditions by offering additional training opportunities and educational materials in advance of public reporting, and by continuing to monitor and analyze the proposed measure. We currently provide private provider feedback reports as well as a Quarterly Quality Measure report that allows HHAs to track their measure outcomes for quality improvement purposes. Aside from those reports, we conduct internal monitoring and evaluation of our measures to ensure that the measures are performing as they were intended to perform during the development of the measure. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452.*

We reviewed the NQF's consensus endorsed measures and were unable to identify any home health measures that address changes in skin integrity related to pressure ulcers. Therefore, based on the evidence previously discussed, we proposed to adopt the quality measure entitled, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, for the HH QRP beginning with the CY 2020 HH QRP. We noted that we plan to submit the proposed measure to the NQF for endorsement consideration as soon as feasible.

d. Data Collection

The data for this quality measure will be collected using the OASIS data set, which is currently submitted by HHAs through the Quality Improvement and Evaluation System (QIES) Assessment Submission and Processing (ASAP) System. While the inclusion of unstageable wounds in the proposed measure results in a measure calculation methodology that is different from the methodology used to calculate the current pressure ulcer measure, the data elements needed to calculate the proposed measure are already included on the OASIS data set. In addition, our proposal to eliminate duplicative data elements that were used in calculation of the current pressure ulcer measure will result in an overall reduced reporting burden for HHAs for the proposed measure. For more information on OASIS data set submission using the QIES ASAP System, we refer readers to *https://www.qtso.com/.*

For technical information about this proposed measure, including information about the measure calculation and the standardized patient assessment data elements used to calculate this measure, we refer readers to the document titled *Finalized Specifications for HH QRP Quality Measures and Standardized Patient Assessment Data Elements*, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

We proposed that HHAs will begin reporting the proposed pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, which will replace the current pressure ulcer measure, with data collection beginning with respect to admissions and discharges occurring on or after January 1, 2019.

We solicited public comment on our proposal to remove the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and replace it with a modified version of that measure, entitled, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP.

Comment: Several commenters supported the proposed replacement of the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of that measure entitled, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. One of these commenters noted that this measure will increase the number of identified pressure ulcers.

One commenter supported the proposed measure calculation approach because it does not include pressure ulcers that were present at the time of admission, and noted that a pressure ulcer that is present on admission is only included in the measure if it subsequently worsens during the home health episode of care.

Response: We appreciate the commenters' support.

Comment: A few commenters suggested that we make additional refinements to the proposed measure before we adopt it for the HH QRP; however, these commenters did not specifically describe any proposed refinements. One commenter stated generally that the measure was not fully developed. Another commenter expressed concerns about the differences between the specifications for this measure in the SNF setting related to other PAC settings, including the home health setting. A few commenters additionally commented on the reliability and validity of the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury. Some commenters requested that additional testing analyses be conducted prior to the implementation of this measure, and others recommended that we conduct additional testing to determine the applicability of this measure for its use in the home health setting. One commenter encouraged CMS to continue to test the measure to ensure it collects accurate data.

Response: We believe that the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure is a fully developed measure that is standardized across the PAC settings, including in the SNF setting. Testing results for this measure indicated increased observed pressure ulcer scores in the LTCH, IRF, SNF and HH patient populations when the unstageable ulcers were included, compared with the previously implemented pressure ulcer measure. Specifically, an analysis conducted by the measure development contractor, using data from October through December 2016, showed mean scores increasing by 2.03 percentage points in home health, with the addition of unstageable pressure ulcers in the measure. The changes in the proposed measure also increased the variability of measures scores.

Further, the reliability and validity of the M0300/M1311 data elements used to calculate this quality measure have been tested in several ways. The MDS 3.0 pilot test showed good reliability in the SNF setting, and we believe that the results are applicable to other post-acute care providers, including HHAs, because the data elements are

standardized across the LTCH, IRF, SNF, and HH settings. Testing conducted to evaluate our ability to derive the measure's numerator from the M0300 data elements revealed that accuracy improved. The M0300 data elements are standardized with the M1311 data elements used in OASIS, and we are able to determine that we can also reliably use M1311 data elements to calculate the measure. Additionally, with regard to the reliability of the pressure ulcer data elements, the average gold-standard to gold-standard kappa statistic was 0.905. The average gold-standard to facility-nurse kappa statistic was 0.937. These kappa scores indicate ''almost perfect'' agreement using the Landis and Koch standard for strength of agreement.[40]

A main difference between the current and proposed pressure ulcer measures is that the proposed measure includes unstageable pressure ulcers, including DTIs, in the numerator of the quality measure, resulting in increased scores in all settings. By including pressure ulcers that were not included in the numerator of the current pressure ulcer measure, the scores on the proposed measure are higher and the risk of the measure being ''topped-out'' is lower.

To assess the construct validity of this measure, or the degree to which the measure assesses what it claims or purports to be assessing, our measure contractor sought input from TEPs over the course of several years. Most recently, on July 18, 2016, a TEP supported the inclusion in the numerator of unstageable pressure ulcers due to slough and/or eschar that are new or worsened, new unstageable pressure ulcers/injuries due to a non-removable dressing or device, and new DTIs. The measure testing activities were presented to TEP members for their input on the reliability, validity, and feasibility of the proposed measure and the changes. The TEP members supported the measure construct.

We intend to continue to perform reliability and validity testing to ensure that that the measure demonstrates scientific acceptability (including reliability and validity) and meets the goals of the HH QRP. Further, while we intend to validate the data collected to ensure data accuracy, we note that providers are expected to submit accurate data. Finally, as with all measure development and implementation, we will provide training and guidance prior to implementation of the measure to promote consistency in the interpretation of the measure.

Comment: A few commenters suggested that we monitor the measure for unintended consequences such as surveillance bias, suggesting that this could affect measure performance.

Response: We appreciate the comments pertaining to unintended consequences, including potential bias in reporting the number and stage of pressure ulcers, which could affect measure performance. We intend to monitor measure results and item-level responses on an ongoing basis to identify potential biases or other issues.

Comment: Some commenters expressed concerns pertaining to the importance of appropriate documentation of unstageable pressure ulcers, including deep tissue injuries (DTIs). One commenter commented that the definition of pressure ulcers included in the measure may be too subjective to collect reliable, accurate measure data across post-acute care providers, citing DTIs specifically. This commenter added that, as a result, the measure could provide misleading portrayals of HH performance.

Response: We appreciate the comments pertaining to the concerns related to appropriate documentation and definition of unstageable pressure ulcers. We interpret the commenters' comment regarding appropriate documentation of unstageable pressure ulcers in the medical record to mean that as a result of this measure, providers should ensure such documentation is incorporated into the medical record. We note that accurate assessment and documentation of all patient assessment findings is customary for ensuring quality care.

We agree that unstageable pressure ulcers should be appropriately documented, but disagree that the definition of pressure ulcers used in the measure may be too subjective to allow for accurate and reliable data capture in post-acute care settings. The definitions of the pressure-related ulcers and injuries used in this measure are standardized and, while all healthcare assessment information can invoke clinical subjectivity, we believe that the definitions provided in our guidance manuals, which align with nationally recognized definitions, enables the collection of data in a reliable manner. We are also confident, based on the reliability testing results previously explained, that the measure can accurately assess HHA performance. Further, we intend to provide training to HHAs to ensure that they understand how to properly report it.

Comment: Some commenters requested training, help desk support, and guidance in completing the items that will be used to calculate the proposed measure. One commenter also recommended that CMS conduct training on steps HHAs can take to improve quality.

Response: We are currently engaged in efforts to provide educational activities related to the HH QRP, including training events and responses to questions submitted to the Help Desk, which will include information to help HHAs understand how to complete and code the pressure ulcer. Such educational and training information is part of our ongoing strategy to ensure successful implementation of the HH QRP, and ultimately quality improvement. Recordings of previous trainings are available on the CMS YouTube Web site at *https://www.youtube.com/user/CMSHHSgov/featured,* and we will continue to make recordings of trainings available there. We invite HHAs to submit specific inquiries related to the coding of the OASIS through our help desk, *HHQualityQuestions@cms.hhs.gov*. Additionally, a Frequently Asked Questions document is provided quarterly for the HH QRP, in the Downloads section of the HH Quality Reporting FAQs Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HH-Quality-Reporting/HH-Quality-Reporting-FAQs-.html*. These FAQ documents are updated to reflect current guidance related to the HH QRP, including data submission deadlines and training materials.

Comment: One commenter noted the proposed measure requires HHAs to count the number of unhealed pressure ulcers at each stage and subtract the number present upon admission. While the commenter agreed that excluding pressure ulcers that are present on admission is an appropriate improvement to the measure, the commenter cautioned that it adds complexity to the coding process. Other commenters stated that this information may be difficult for providers to capture because of the new data elements used to calculate the new measure.

Response: We disagree that the proposed measure will require HHAs to make adjustments to their coding processes because HHAs already submit the data to calculate the modified measure. Additionally, the assessment does not require HHAs to tally or count the number of unhealed pressure ulcers. We perform that calculation for

[40] Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. Biometrics 33(1), 159–174. Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. Biometrics 33(1), 159–174.

purposes of calculating the measure rates.

Comment: Several commenters recommended that CMS attain NQF endorsement of the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure prior to implementation.

Response: While this measure is not currently -endorsed by a consensus-based entity, which is currently the National Quality Forum (NQF), we believe that this measure possess the attributes necessary for such endorsement, including the measure's applicability, face validity and feasibility, and its reliability and validity as derived from the national testing. Therefore, we believe that this measure is appropriate for adoption into the HH QRP. However, we intend to submit this measure to NQF for consideration for its consideration for endorsement as soon as feasible.

Comment: A few commenters provided feedback on the use of the term ''pressure injury''. Commenters encouraged CMS to use the terminology recommended by NPUAP and to align with their staging definitions, which will assist providers to be more standardized.

Response: We have integrated the current language of NPUAP terminology for coding the patient and resident assessment instruments, especially in light of the recent updates made by the NPUAP to their Pressure Ulcer Staging System. The NPUAP announced a change in terminology to use the term ''pressure injury'' in April 2016.[41] A TEP held by our measure development contractor on July 15, 2016, was supportive of using the term ''pressure injury.'' Some members of the TEP stated that the term ''injury'' is not associated with blame or harm by an entity, that ''injury'' may be a more inclusive term than ''ulcer'', and that the term ''pressure injury'' may be more easily and positively understood by patients, residents, and family members than ''pressure ulcer.'' The TEP recommended training for providers and consumers regarding any change in terminology. This change will be accompanied by additional training and guidance for providers, patients, or residents to clarify any confusion.

Comment: One commenter suggested that the burden of replacing the current measure with the modified pressure ulcer measure will be greater than the burden associated with reporting the current pressure ulcer measure. The commenter encouraged CMS to streamline reporting and reduce duplicative efforts. The commenter further commented that CMS should review the total number of data points, including the OASIS measure set, to eliminate HHA documentation and administrative burden.

Response: We appreciate the commenter's feedback. We do not believe that the reporting of the proposed measure will impose a new burden on HHAs because the measure is calculated using data elements that are currently included in OASIS that HHAs already submit. As we continue to refine and modify the OASIS, we will continue to evaluate and avoid any unnecessary burden associated with the implementation of the HH QRP.

Final Decision: After consideration of the comments received, we are finalizing our proposal to replace the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), with a modified version of that measure entitled, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, effective with the CY 2020 HH QRP.

2. Addressing the IMPACT Act Domain of Functional Status, Cognitive Function, and Changes in Function and Cognitive Function: 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)

a. Measure Background

Sections 1899B(c)(1)(A) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(ii) is January 1, 2019 for HHAs, and October 1, 2016 for SNFs, IRFs and LTCHs), the Secretary specify a quality measure to address the domain of ''Functional status, cognitive function, and changes in function and cognitive function.'' We proposed to adopt 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) for the HH QRP, beginning with the CY 2020 program year. This is a process measure that reports the percentage of patients with an admission and discharge functional assessment and treatment goal that addresses function. The treatment goal provides evidence that a care plan with a goal has been established for the HH patient.

The National Committee on Vital and Health Statistics' Subcommittee on Health,[42] noted that ''information on functional status is becoming increasingly essential for fostering healthy people and a healthy population. Achieving optimal health and well-being for Americans requires an understanding across the life span of the effects of people's health conditions on their ability to do basic activities and participate in life situations in other words, their functional status.'' This is supported by research showing that patient and resident functioning is associated with important outcomes such as discharge destination and length of stay in inpatient settings,[43] as well as the risk of nursing home placement and hospitalization of older adults living in the community.[44] For example, many patients who utilize HH services may be at risk for a decline in function due to limited mobility and ambulation.[45] Thus, impairment in function activities such as self-care and mobility is highly prevalent in HH patients. For example, in 98 percent of the over six million HH episodes in 2015, the patient had at least one limitation or was not completely independent in self-care activities such as grooming, upper and lower body dressing, bathing, toilet hygiene, and/or feeding/eating.[46]

The primary goal of home health care is to provide restorative care when improvement is expected, maintain function and health status if improvement is not expected, slow the rate of functional decline to avoid institutionalization in an acute or post-acute setting, and/or facilitate transition to end-of-life care as appropriate.[47] [48]

[41] National Pressure Ulcer Advisory Panel (NPUAP) announces a change in terminology from pressure ulcer to pressure injury and updates the stages of pressure injury √ The National Pressure Ulcer Advisory Panel—NPUAP. (2016, April 13), from *http://www.npuap.org/national-pressure-ulcer-advisory-panel-npuap-announces-a-change-in-terminology-from-pressure-ulcer-to-pressure-injury-and-updates-the-stages-of-pressure-injury/.*

[42] Subcommittee on Health National Committee on Vital and Health Statistics, ''Classifying and Reporting Functional Status'' (2001).

[43] Reistetter TA, Graham JE, Granger CV, Deutsch A, Ottenbacher KJ. Utility of Functional Status for Classifying Community Versus Institutional Discharges after Inpatient Rehabilitation for Stroke. Archives of Physical Medicine and Rehabilitation, 2010; 91:345–350.

[44] Miller EA, Weissert WG. Predicting Elderly People's Risk for Nursing Home Placement, Hospitalization, Functional Impairment, and Mortality: A Synthesis. Medical Care Research and Review, 57; 3: 259–297.

[45] Kortebein, P., Ferrando, A., Lombebeida, J., Wolfe, R., & Evans, W.J. (2007). Effect of 10 days of bed rest on skeletal muscle in health adults. JAMA; 297(16):1772–4.

[47] Riggs, J.S. & Madigan, E.A. (2012). Describing variation in home health care episodes for patients with heart failure. Home Health Care Management and Practice, 24(3): 146–152.

[48] Ellenbecker, C.H., Samia, L., Cushman, M.J., & Alster, K (2008). Patient safety and quality: an evidence-based handbook for nurses. Rockville (MD): agency for healthcare research and quality (US); 2008 Apr. Chapter 13.

Home health care can positively impact functional outcomes. In stroke patients, home-based rehabilitation programs administered by home health clinicians significantly improved ADL function and gait performance.[49] Home health services, delivered by a registered nurse, positively impacted patient Quality of Life (QOL) and clinical outcomes, including significant improvement in dressing lower body, bathing meal preparation, shopping, and housekeeping. For some home health patients, achieving independence within the living environment and improved community mobility might be the goal of care. For others, the goal of care might be to slow the rate of functional decline to avoid institutionalization.[50]

Patients' functional status is associated with important patient outcomes, so measuring and monitoring the patients' extent of engaging in self-care and mobility is valuable. Functional decline among the elderly;[51] and chronic illness comorbidities, such as chronic pain among the older adult population[52 53] are associated with decreases in self-sufficiency and patient activation (defined as the patient's knowledge and confidence in self-managing their health). Impaired mobility, frailty, and low physical activity are associated with institutionalization,[54] higher risk of falls and falls-related hip fracture and death,[55 56] greater risk of under nutrition,[57] higher rates of inpatient admission from the emergency department,[58] and higher prevalence of hypertension and diabetes.[59]

In addition, the assessment of functional ability and provision of treatment plans directed toward improving or maintaining functional ability could impact health care costs. Providing comprehensive home health care, which includes improving or maintaining functional ability for frail elderly adults, can reduce the likelihood of hospital readmissions or emergency department visits, leading to reduced health care service expenditures.[60 61 62] Reducing preventable rehospitalizations, which made up approximately 17 percent of Medicare's $102.6 billion in 2004 hospital payments, creates the potential for large health care cost savings.[63 64]

Further, improving and maintaining functional ability in individuals with high needs, defined as those with three or more chronic conditions, may also account for an increase in healthcare savings. Adults with three or more chronic conditions have nearly four times the average annual per-person spending for health care services and prescription medications than the average for all U.S. adults, and high needs adults with limitations in their ability to perform ADLs, have even higher average annual health care expenditures.[65] High needs individuals with functional limitations spend, on average, $21,021 on annual health care services, whereas the average annual health care expenditures for all U.S. adults are approximately $4,845.45.

b. Measure Importance

The majority of individuals who receive PAC services, including care provided by HHAs, SNFs, IRFs, and LTCHs, have functional limitations, and many of these individuals are at risk for further decline in function due to limited mobility and ambulation.[66] The patient populations treated by HHAs, SNFs, IRFs, and LTCHs vary in terms of their functional abilities. For example, for home health patients, achieving independence within the home environment and promoting community mobility may be the goal of care. For other home health patients, the goal of care may be to slow the rate of functional decline in order to allow the person to remain at home and avoid institutionalization.[67] The clinical practice guideline Assessment of Physical Function[68] recommends that clinicians document functional status at baseline and over time to validate capacity, decline, or progress. Therefore, assessment of functional status at admission and discharge, as well as establishing a functional goal for discharge as part of the care plan is an

[44] Miller EA, Weissert WG. Predicting Elderly People's Risk for Nursing Home Placement, Hospitalization, Functional Impairment, and Mortality: A Synthesis. Medical Care Research and Review, 57; 3: 259–297.

[45] Kortebein, P., Ferrando, A., Lombebeida, J., Wolfe, R., & Evans, W.J. (2007). Effect of 10 days of bed rest on skeletal muscle in health adults. JAMA; 297(16):1772–4.

[47] Riggs, J.S. & Madigan, E.A. (2012). Describing variation in home health care episodes for patients with heart failure. Home Health Care Management and Practice, 24(3): 146–152.

[48] Ellenbecker, C.H., Samia, L., Cushman, M.J., & Alster, K (2008). Patient safety and quality: an evidence-based handbook for nurses. Rockville (MD): agency for healthcare research and quality (US); 2008 Apr. Chapter 13.

[49] Asiri, F.Y., Marchetti, G.F., Ellis, J.L., Otis, L., Sparto, P.J., Watzlaf, V., & Whitney, S.L. (2014). Predictors of functional and gait outcomes for persons poststroke undergoing home-based rehabilitation. Journal of Stroke and Cerebrovascular Diseases: The Official Journal of National Stroke Association, 23(7), 1856–1864. *https://doi.org/10.1016/j.jstrokecerebrovasdis.2014.02.025.*

[50] Ellenbecker, C.H., Samia, L., Cushman, M.J., & Alster, K (2008). Patient safety and quality: an evidence-based handbook for nurses. Rockville (MD): agency for healthcare research and quality (US); 2008 Apr. Chapter 13.

[51] Gleason, K.T., Tanner, E.K., Boyd, C. M., Saczynski, J.S., & Szanton, S. L. (2016). Factors associated with patient activation in an older adult population with functional difficulties. Patient Education and Counseling, 99(8), 1421–1426.

between difficulties in daily activities and falling: loco-check as a self-assessment of fall risk. Interactive Journal of Medical Research, 5(2), e20. *https://doi.org/10.2196/ijmr.5590.*

[56] Zaslavsky, O., Zelber-Sagi, S., Gray, S. L., LaCroix, A. Z., Brunner, R.L., Wallace, R.B., . . . Woods, N.F. (2016). Comparison of Frailty Phenotypes for Prediction of Mortality, Incident Falls, and Hip Fracture in Older Women. Journal of the American Geriatrics Society, 64(9), 1858–1862. *https://doi.org/10.1111/jgs.14233.*

[57] 57 van der Pols-Vijlbrief, R., Wijnhoven, H.A. H., Bosmans, J.E., Twisk, J.W.R., & Visser, M. (2016). Targeting the underlying causes of undernutrition. Cost-effectiveness of a multifactorial personalized intervention in community-dwelling older adults: A randomized controlled trial. Clinical Nutrition (Edinburgh, Scotland). *https://doi.org/10.1016/j.clnu.2016.09.030.*

[58] Hominick, K., McLeod, V., & Rockwood, K. (2016). Characteristics of older adults admitted to hospital versus those discharged home, in emergency department patients referred to internal medicine. Canadian Geriatrics Journal 202F;: CGJ, 19(1), 9–14. *https://doi.org/10.5770/cgj.19.195.*

[59] Halaweh, H., Willen, C., Grimby-Ekman, A., & Svantesson, U. (2015). Physical activity and health-related quality of life among community dwelling elderly. J Clin Med Res, 7(11), 845–52.

[60] Hirth, V., Baskins, J., & Dever-Bumba, M. (2009). Program of all-inclusive care (PACE): Past, present, and future. Journal of the American Medical Directors Association, 10, 155–160.

[61] Mukamel, D.B., Fortinsky, R.H., White, A., Harrington, C., White, L.M., & Ngo-Metzger, Q. (2014). The policy implications of the cost structure of home health agencies. Medicare & Medicaid Research Review, 4(1). *https://doi.org/10.5600/mmrr2014-004-01-a03.*

[62] Meunier, M.J., Brant, J.M., Audet, S., Dickerson, D., Gransbery, K., & Ciemins, E.L. (2016). Life after PACE (Program of All-Inclusive Care for the Elderly): A retrospective/prospective, qualitative analysis of the impact of closing a nurse practitioner centered PACE site. Journal of the American Association of Nurse Practitioners. *https://doi.org/10.1002/2327-6924.12379.*

[63] Jencks, S.F., Williams, M.V., and Coleman, E.A. (2009). Rehospitalizations among patients in the Medicare fee-for-service program. New England Journal of Medicine; 360(14):1418–28.

[64] Tao, H., Ellenbecker, C.H., Chen, J., Zhan, L., & Dalton, J. (2012). The influence of social environmental factors on rehospitalization among patients receiving home health care services. ANS. Advances in Nursing Science, 35(4), 346–358. *https://doi.org/10.1097/ANS.0b013e318271d2ad.*

[65] Hayes, S.L., Salzberg, C.A., McCarthy, D., Radley, DC, Abrams, M.K., Shah, T., and Anderson, G.F. (2016). High-Need, High-Cost Patients: Who are they and how do they use health care—A population-based comparison of demographics, health care use, and expenditures. The Commonwealth Fund.

[66] Kortebein P, Ferrando A, Lombebeida J, Wolfe R, Evans WJ. Effect of 10 days of bed rest on skeletal muscle in health adults. JAMA; 297(16):1772–4.

[67] Ellenbecker CH, Samia L, Cushman MJ, Alster K. Patient safety and quality in home health care. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Vol 1.

[68] Kresevic DM. Assessment of physical function. In: Boltz M, Capezuti E, Fulmer T, Zwicker D, editor(s). Evidence-based geriatric nursing protocols for best practice. 4th ed. New York (NY): Springer Publishing Company; 2012. p. 89–103.

important aspect of patient or resident care across PAC settings.

Currently, functional assessment data are collected by all four PAC providers, yet data collection has employed different assessment instruments, scales, and item definitions. The data cover similar topics, but are not standardized across PAC settings. The different sets of functional assessment items coupled with different rating scales makes communication about patient and resident functioning challenging when patients and residents transition from one type of setting to another. Collection of standardized functional assessment data across HHAs, SNFs, IRFs, and LTCHs using common data items will establish a common language for patient and resident functioning, which may facilitate communication and care coordination as patients and residents transition from one type of provider to another. The collection of standardized functional status data may also help improve patient functioning during an episode of care by ensuring that basic daily activities are assessed for all PAC residents at the start and end of care, and that at least one functional goal is established.

The functional assessment items included in the proposed functional status quality measure were originally developed and tested as part of the Post-Acute Care Payment Reform Demonstration version of the Continuity Assessment Record and Evaluation (CARE) Item Set, which was designed to standardize the assessment of a person's status, including functional status, across acute and post-acute settings (HHAs, SNFs, IRFs, and LTCHs). The functional status items in the CARE Item Set are daily activities that clinicians typically assess at the time of admission and/or discharge to determine patient or resident needs, evaluate patient or resident progress, and prepare patients, residents, and their families for a transition to home or to another setting.

The development of the CARE Item Set and a description and rationale for each item is described in a report entitled ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set: Volume 1 of 3.'' [69] Reliability and validity testing were conducted as part of CMS's Post-Acute Care Payment Reform Demonstration (PAC–PRD), and we concluded that the functional status items have acceptable reliability and validity. Testing for the functional assessment items concluded that the items were able to evaluate all patients on basic self-care and mobility activities, regardless of functional level or PAC setting. A description of the testing methodology and results are available in several reports, including the report entitled ''The Development and Testing of the Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report On Reliability Testing: Volume 2 of 3'' [70] and the report entitled ''The Development and Testing of The Continuity Assessment Record And Evaluation (CARE) Item Set: Final Report on Care Item Set and Current Assessment Comparisons: Volume 3 of 3.'' [71] These reports are available on our Post-Acute Care Quality Initiatives Web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.*

Additional testing of these functional assessment items was conducted in a small field test occurring in 2016–2017, capturing data from 12 HHAs. Preliminary data results yielded moderate to substantial reliability for the self-care and mobility data items. More information about testing design and results can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html.*

The functional status quality measure we proposed to adopt beginning with the CY 2020 HH QRP is a process quality measure that is an application of the NQF-endorsed quality measure, the Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631). This quality measure reports the percent of patients with both an admission and a discharge functional assessment and a functional treatment goal.

This process measure requires the collection of admission and discharge functional status data by clinicians using standardized patient assessment data elements, which assess specific functional activities, such as self-care and mobility activities. The self-care and mobility function activities are coded using a 6-level rating scale that indicates the patient's level of independence with the activity at both admission and discharge. A higher score indicates more independence. These functional assessment data elements will be collected at Start or Resumption of Care (SOC/ROC) and discharge.

For this quality measure, there must be documentation at the time of admission (SOC) that at least one activity performance (function) goal is recorded for at least one of the standardized self-care or mobility function items using the 6-level rating scale. This indicates that an activity goal(s) has been established. Following this initial assessment, the clinical best practice will be to ensure that the patient's care plan reflected and included a plan to achieve such activity goal(s). At the time of discharge, goal setting and establishment of a care plan to achieve the goal, is reassessed using the same 6-level rating scale, allowing for the ability to evaluate success in achieving the patient's activity performance goals.

To the extent that a patient has an unplanned discharge, for example, transfer to an acute care facility, the collection of discharge functional status data may not be feasible. Therefore, for patients with unplanned discharges, admission functional status data and at least one treatment goal must be reported, but discharge functional status data are not required to be reported.

c. Stakeholder Feedback

Our measures contractor convened a TEP on October 17 and October 18, 2016. The TEP was composed of a diverse group of stakeholders with HH, PAC, and functional assessment expertise. The panel provided input on the technical specifications of this proposed measure, including the feasibility of implementing the measure, as well as the overall measure of reliability and validity. The TEP additionally provided feedback on the clinical assessment items used to calculate the measure. The TEP reviewed the measure ''Percent of Long-Term Care Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF 2631)'' for potential application to the home health setting. Overall they were supportive of a functional process measure, noting it could have the positive effect of focusing clinician attention on functional status and goals. A summary of the TEP proceedings is available on the PAC Quality Initiatives Downloads and Videos Web page at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/post-acute-care-quality-initiatives/impact-act-of-2014/impact-act-downloads-and-videos.html.*

[69] Barbara Gage et al., ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI International, 2012).

[70] Ibid.

[71] Ibid.

We also solicited stakeholder feedback on the development of this measure through a public comment period held from November 4, 2016 through December 5, 2016. Several stakeholders and organizations supported this measure for implementation and for measure standardization. Some commenters also provided feedback on the standardized patient assessment data elements used to calculate the proposed quality measure. Commenters offered suggestions, including providing education regarding the difference in measure scales for the standardized items relative to current OASIS functional items, and guidance on the type of clinical staff input needed to appropriately complete new functional assessment items. Commenters also addressed the feasibility of collecting data for the individual standardized self-care and mobility items in the home health setting. Finally, commenters noted the importance of appropriate goal setting when functional improvement for a patient may not be feasible. The public comment summary report for the proposed measure is available on the CMS Web site at *https://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 NQF-convened MAP met on December 14 and 15, 2016, and provided input on the use of this proposed measure in the HH QRP. The MAP recommended ''conditional support for rulemaking'' for this measure. MAP members noted the measure will drive care coordination and improve transitions by encouraging the use of standardized functional assessment items across PAC settings, but recommended submission to the NQF for endorsement to include the home health setting. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2017/02/MAP_2017_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

We reviewed the NQF's consensus endorsed measures and were unable to identify any home health measures that address functional assessment and treatment goals that that address function. However, we were able to identify five functional measures in home health that assess functional activities only, without a treatment goal. These measures are: (1) Improvement in Ambulation/Locomotion (NQF #0167); (2) Improvement in Bathing (NQF #0174); (3) Improvement in Bed Transfer (NQF #0175); (4) Improvement in Management of Oral Medications (NQF # 0176); and (5) Improvement in Pain Interfering with Activity (NQF #0177). Our review determined that these setting-specific measures are not appropriate to meet the specified IMPACT Act domain as they do not include standardized items or are not included for various other PAC populations. Specifically—

- The items used to collect data for the current home health measures are less specific, leading to broader measure results, whereas the standardized patient assessment data items used for the proposed measure assess core activities such as rolling in bed, walking a specified distance, or wheelchair capability.
- The item coding responses are more detailed when compared to the non-standardized OASIS item responses, allowing for more granular data for the measure.
- The proposed functional measure will capture a patient's discharge goal at admission into home health; this detail is not captured in the existing endorsed HH function measures.

Therefore, based on the evidence discussed previously, we proposed to adopt the quality measure entitled, 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), for the HH QRP beginning with the CY 2020 HH QRP. We noted that we plan to submit the proposed measure to the NQF for endorsement consideration as soon as is feasible.

For technical information about the proposed measure, including information about the measure calculation and the standardized patient assessment data elements used to calculate this measure, we referred readers to the document titled, *Final Specifications for HH QRP Quality Measures and Standardized Patient Assessment Data,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

d. Data Collection

For purposes of assessment data collection, we proposed to add new functional status items to the OASIS, to be collected at SOC/ROC and discharge. These items will assess specific self-care and mobility activities, and will be based on functional items included in the PAC–PRD version of the CARE Item Set. More information pertaining to item testing is available on our Post-Acute Care Quality Initiatives Web page at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.*

To allow HHAs to fulfill the requirements of the Home Health Agency Conditions of Participation (HHA CoPs) (82 FR 4509), we proposed to add a subset of the functional assessment items to the OASIS, with collection of these items at Follow-Up (FU). The collection of these assessment items at FU by HHAs will allow them to fulfill the requirements outlined in the HHA CoPs that suggest that the collection of a patient's current health, including functional status, be collected on the comprehensive assessment.

This new subset of functional status items are standardized across PAC settings and support the proposed standardized measure. They are organized into two functional domains: Self-Care and Mobility. Each domain includes dimensions of these functional constructs that are relevant for home health patients. The proposed function items that we proposed to add to the OASIS for purposes of the calculation of this proposed quality measure would not duplicate existing items currently collected in that assessment instrument for other purposes. The current OASIS function items evaluate current ability, whereas the proposed functional items would evaluate an individual's usual performance at the time of admission and at the time of discharge for goal setting purposes. Additionally, we noted that there are several key differences between the existing and new proposed function items that may result in variation in the patient assessment results including: (1) The data collection and associated data collection instructions; (2) the rating scales used to score a resident's level of independence; and (3) the item definitions. A description of these differences is provided with the measure specifications available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

Because of the differences between the current function assessment items (OASIS C–2) and the proposed function assessment items that we would collect for purposes of calculating the proposed measure, we would require that HHAs submit data on both sets of items. Data collection for the new proposed function items do not substitute for the data collection under the current OASIS ADL and IADL items, and as discussed previously, we do not believe that the

items are duplicative. However, we solicited comment on opportunities to streamline reporting to avoid duplication and minimize burden.

We proposed that data for the proposed quality measure would be collected through the OASIS, which HHAs currently submit through the QIES ASAP system. We referred readers to section V.F.2 of the proposed rule (82 FR 35345 through 35353) for more information on the proposed data collection and submission timeline for this proposed quality measure. We noted that if this measure is finalized, we intended to provide initial confidential feedback to home health agencies, prior to the public reporting of this measure.

We solicited public comment on our proposal to adopt 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).

Comment: A number of commenters supported the proposed 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). MedPAC acknowledged the value of a functional status quality measure that would be standardized with other functional status quality measures across the four PAC settings.

Response: We appreciate the commenters' support of the measure.

Comment: Some commenters suggested that CMS refine the measure and conduct additional testing for home health setting applicability before adopting it Other commenters recommended that we provide training and give HHAs time to adjust their workflow to both accommodate the new measure and the removal of duplicative data elements in the OASIS. Further, a few commenters expressed concern over the addition of the items used to calculate the proposed process quality measure, claiming that the items will be duplicative and that the legacy items must be removed from the OASIS–C2 assessment instrument to limit provider burden. Commenters also requested that CMS consider the additional resources providers will need to accommodate item set changes and encouraged ongoing education efforts for new data elements.

Response: The items for this measure were rigorously tested in the Post-Acute Care Payment Reform Demonstration (PAC PRD). Based on testing from the PAC PRD, the inter-rater reliability of the items needed to calculate this measure was favorable, with items' kappa scores between 0.59 and 0.80. This is important for measuring progress in some of the most complex cases treated in post-acute care settings. The data elements developed to calculate this proposed process measure were also tested in a comprehensive field test of existing and potential OASIS data elements and found to be feasible with acceptable levels of inter-rater reliability, as described at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/OASIS-Data-Sets.html.*

Although HHAs will need to incorporate the data on this measure into their workflow, we do not believe that these data elements are duplicative of other data already collected. The items needed to calculate the proposed measure different assessment scales, coding options for those with medical complexities, and have different definitions for items and activities, and the proposed measure's data elements evaluate usual performance in various manners. Further, to reduce potential burden associated with collecting the proposed measure, we have included several mechanisms to reduce the number of items that apply to any one patient. For example, there are gateway questions pertaining to walking and wheelchair mobility that allow the clinician to skip items that ask if the patient does not walk or does not use a wheelchair, respectively.

Comment: Commenters provided feedback on the reliability and validity of the items necessary to calculate the function process measure. Some of these commenters expressed concern that the proposed function measure has not undergone testing and validation in the home health setting or may not be applicable for home health setting as in the facility-based post-acute care settings. One of these commenter expressed concern that the scales used to assess the items for the proposed process quality measure and the current OASIS functional assessment items are different, which could affect the items' reliability and validity. Another commenter raised concern with the difference in timeframe allowed for data collection when compared to other OASIS items.

Response: In the PAC PRD, the functional activity items (self-care and mobility) were tested sufficiently in HHAs and with sufficient patients to support reliability. The functional assessment items were compared to other functional assessment instrument data (including OASIS functional assessment items), as part of the PAC–PRD analyses with positive results. The inter-rater reliability of the functional activity items has been tested and the results have been favorable with items' kappa scores between .59 and .80. We also conducted analyses of the internal consistency of the function data analyses which indicate moderate to substantial agreement suggesting sufficient reliability for the items used to calculate the proposed process quality measure.

We acknowledge that the scale for the items used to calculate the proposed quality measure vary from the scales that are used in current OASIS–C2 items. The scale used to assess the items for the proposed process quality measure assesses independence in functional activities (a higher score indicates greater independence). We believe that the 6-level scale will allow us to better distinguish change at the highest and lowest levels of patient functioning by documenting minimal change from no change at the low end of the scale.[72] The PAC PRD supported the use of the scale in HHAs with both the alpha testing and beta testing reinforcing the clinical logic and consistency of language for the functional assessment items. The items in section GG were developed with input from clinicians and stakeholders to better measure the change in function, regardless of the severity of the individual's impairment.

The items used to calculate the proposed process quality measure are standardized across the four PAC settings, based on the need for data to reflect the patient's status at the time of SOC/ROC and EOC. We are currently conducting testing across the four PAC settings to align the most appropriate time frame of data collection at admission/SOC and at discharge/EOC.

A full description of the analyses and the results are provided in the report, The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set and Current Assessment Comparisons Volume 3 of 3, and the report is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/CARE-Item-Set-and-B-CARE.html.* Additional testing of the Section GG items with the OASIS functional items was recently completed

[72] Barbara Gage *et al.,* ''The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on the Development of the CARE Item Set'' (RTI International, 2012).

and will to continue to help inform guidance for HH providers.

Comment: One commenter suggested that the OASIS should include an assessment of Instrumental Activities of Daily Living (IADL) as a part of functional assessment.

Response: We appreciate the commenter's recommendation and will take it into consideration in future measure refinement work.

Comment: Commenters expressed concern about different clinical staff assessing functional status and setting functional goals across PAC settings, noting that in some settings, such as SNFs, licensed physical therapists typically assess function and set functional goals, whereas in HHAs, nurses typically perform that assessment. Commenters noted that setting a goal will pose a challenge for nurses in the home health setting.

Response: We are unclear why the commenters believe that goal setting will be more difficult in the home health setting than in other settings. The goals being assessed through the measure are intended to be set by patients, not clinicians. In addition, the original testing of the assessment items used for the proposed measure included a wide variety of clinicians to assess item collection, coding and reliability. For more information on testing results, we refer readers to the PAC PRD final report located at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/The-Development-and-Testing-of-the-Continuity-Assessment-Record-and-Evaluation-CARE-Item-Set-Final-Report-on-the-Development-of-the-CARE-Item-Set-Volume-1-of-3.pdf.*

Final Decision: After consideration of the comments received, we are finalizing, as proposed, the adoption of the measure entitled the 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) for the HH QRP beginning with the CY 2020 program year.

3. Addressing the IMPACT Act Domain of ''Incidence of Major Falls'' Measure: Percent of Residents Experiencing One or More Falls With Major Injury

a. Measure Background

Section 1899B(c)(1)(D) of the Act requires that no later than the specified application date (which under section 1899B(a)(1)(E)(i)(IV) of the Act is January 1, 2019 for HHAs, and October 1, 2016 for SNFs, IRFs and LTCHs), the Secretary specify a measure to address the domain of incidence of major falls, including falls with major injury. We proposed to adopt the measure, Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0674), for which we would begin to collect data on January 1, 2019 for the CY 2020 HH QRP to meet this requirement. This proposed outcome measure reports the percentage of patients who have experienced falls with major injury during episodes ending in a 3-month period.

b. Measure Importance

Falls affect an estimated 6 to 12 million older adults each year and are the leading cause of both fatal injury and nonfatal hospital admissions.[73] [74] Within the home health population, the risk of falling is significant as approximately one third of individuals over the age of 65 experienced at least one fall annually.[75] Major fall-related injuries among older community-dwelling adults are a growing health concern within the United States [76] [77] because they can have high medical and cost implications for the Medicare community.[78] In 2013, the direct medical cost for falls in older adults was $34 billion [79] and is projected to increase to over $101 billion by 2030 due to the aging population.[80]

Evidence from various studies indicates that implementing effective fall prevention interventions and minimizing the impact of falls that do occur reduces overall costs, emergency department visits, hospital readmissions, and overall Medicare resource utilization.[81] [82] [83] [84] In the 2006 Home Assessments and Modification study, a home visit by an occupational therapist or home care worker to identify and mitigate potential home hazards and risky behavior, resulted in a 46 percent reduction in fall rates for those receiving the intervention compared to controls.[85] Overall, patients participating in interventions experienced improved quality of life due to reduced morbidity, improved functional ability and mobility, reduced number of falls and injurious falls, and a decrease in the fear of falling.[86] [87] Falls also represent a significant cost burden to Medicare. Each year, 2.8 million older people are treated in Emergency Departments for fall related injuries and over 800,000 require hospitalization.[88] Adjusted to 2015 dollars, nationally, direct medical costs for nonfatal fall related injuries in older adults were over $31.3 billion.[89] Additional health care costs (in 2010 dollars) can range from $3,500 for a fall without serious injury to $27,000 for a

[73] Bohl, A.A., Phelan, E.A., Fishman, P.A., & Harris, J R. (2012). How are the costs of care for medical falls distributed? The costs of medical falls by component of cost, timing, and injury severity. The Gerontologist, 52(5): 664–675.

[74] National Council on Aging (2015). Falls Prevention Fact Sheet. Retrieved from *https://www.ncoa.org/wp-content/;uploads/Fact-Sheet_Falls-Prevention.pdf.*

[75] Avin G.K., Hanke A.T., Kirk-Sanche, N., McDonough M.C., Shubert E.T., Hardage, J.,& Hartley, G. (2015). Management of Falls in Community-Dwelling Older Adults: Clinical Guidance Statement From the Academy of Geriatric Physical Therapy of the American Physical Therapy Association. Physical Therapy, 95(6), 815–834. doi:10.2522/ptj.20140415.

[76] Hester, A.L. & Wei, F. (2013). Falls in the community: State of the science. Clinical Interventions in Aging, 8:675–679.

[77] Orces, C.H. & Alamgir, H. (2014). Trends in fall-related injuries among older adults treated in emergency departments in the USA. Injury Prevention, 20: 421–423.

[78] Liu, S.W., Obermeyer, Z., Chang, Y., & Shankar, K.N. (2015). Frequency of ED revisits and death among older adults after a fall. American Journal of Emergency Medicine, 33(8), 1012–1018. doi:10.1016/j.ajem.2015.04.023.

[79] Centers for Disease Control and Prevention (2015b). Important facts about falls. *http://www.cdc.gov/homeandrecreationalsafety/falls/adultfalls.html.* Accessed April 19, 2016.

[80] Houry, D., Florence, C. Bladwin, G., Stevens, J., & McClure, R. (2015). The CDC Injury Center's response to the growing public health problem of falls among older adults. American Journal of Lifestyle Medicine, 10(1), 74–77.

[81] Bamgbade, S., & Dearmon, V. (2016). Fall prevention for older adults receiving home healthcare. Home Healthcare Now, 34(2), 68–75.

[82] Carande-Kulis, V., Stevens, J.A., Florence, C.S., Beattie, B.L., & Arias, I. (2015). A cost–benefit analysis of three older adult fall prevention interventions. Journal of Safety Research, 52, 65–70. doi:10.1016/j.jsr.2014.12.007.

[83] Cohen, A.M., Miller, J., Shi, X., Sandhu, J., & Lipsitz, A. (2015). Prevention program lowered the risk of falls and decreased claims for long-term care services among elder participants. Health Affairs, 34(6), 971–977.

[84] Howland, J., Shankar, K.N., Peterson, E.W., & Taylor, A.A. (2015). Savings in acute care costs if all older adults treated for fall-related injuries completed matter of balance. Injury Epidemiology, 2(25), 1–7.

[85] Pighills AC, Torgerson DJ, Sheldon TA, Drummond AE, Bland JM. Environmental assessment and modification to prevent falls in older people. Journal of the American Geriatrics Society. 2011;59(1):26–33.

[86] Chase, C.A., Mann, K., Wasek, S., & Arbesman, M. (2012). Systematic review of the effect of home modification and fall prevention programs on falls and the performance of community-dwelling older adults. American Journal of Occupational Therapy, 66(3), 284–291.

[87] Patil, R., Uusi-Rasi, K., Tokola, K., Karinkanta, S., Kannus, P., & Sievanen, H. (2015). Effects of a Multimodal Exercise Program on Physical Function, Falls, and Injuries in Older Women: A 2-Year Community-Based, Randomized Controlled Trial. Journal of the American Geriatrics Society, 63(7), 1306–1313.

[88] Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. Web–based Injury Statistics Query and Reporting System (WISQARS) [online]. Accessed August 5, 2016.

[89] Burns ER, Stevens JA, Lee R. The direct costs of fatal and non-fatal falls among older adults—United States. J Safety Res 2016;58:99–103.

fall with a serious injury.[90] Between 1988 and 2005, fractures accounted for 84 percent of hospitalizations for fall-related injuries among older adults.[91] Researchers evaluated the cost of fall-related hospitalizations among older adults using the 2011 Texas Hospital Inpatient Discharge Data and determined that the average cost for fall-related hip fractures was $61,715 for individuals 50 and older living in metropolitan areas and $55,366 for those living nonmetropolitan areas.[92]

To meet the IMPACT Act provision requiring the development of a standardized quality measure for the domain of Incidence of Major Falls (sections 1899B(c)(1)(D) of the Act), we proposed the standardized measure, The Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674). We noted that this quality measure is NQF-endorsed and has been successfully implemented in the Nursing Home Quality Initiative for nursing facility long-stay residents since 2011, demonstrating the measure is feasible, appropriate for assessing PAC quality of care, and could be used as a platform for standardized quality measure development. This quality measure is standardized across PAC settings and contains items that are collected uniformly in each setting's assessment instruments (that is, MDS, IRF–PAI, and LCDS). Further, an application of the quality measure was adopted for use in the LTCH QRP in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50874 through 50877), revised in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50290 through 50291), and adopted to fulfill IMPACT Act requirements in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49736 through 49739). Data collection began in April 1, 2016 for LTCHs, and October 1, 2016 for SNFs and IRFs.

More information on the NQF-endorsed quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) is available at *http://www.qualityforum.org/QPS/0674.*

c. Stakeholder Feedback

A TEP convened by our measure development contractor provided input on the technical specifications of an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), including the feasibility of implementing the measure across PAC settings. The TEP was supportive of the implementation of this measure across PAC settings and was also supportive of our efforts to standardize this measure for cross-setting development. More information about this TEP can be found at *https://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, we solicited public comment on this measure from September 19, 2016, through October 14, 2016. Overall, commenters were generally supportive of the measure, but raised concerns about the attribution given that home health clinicians are not present in the home at all times and recommended risk-adjusting the measure. The summary of this public comment period can be found at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/post-acute-care-quality-initiatives/impact-act-of-2014/impact-act-downloads-and-videos.html.*

Finally, we presented this measure to the NQF-convened MAP on December 14, 2016. The MAP conditionally supported the use of an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) in the HH QRP as a cross-setting quality measure. The MAP highlighted the clinical significance of falls with major injury, while noting potential difficulties in collecting falls data and more limited action ability in the home health setting. The MAP suggested that CMS explore stratification of measure rates by referral origin when public reporting. More information about the MAP's recommendations for this measure is available at *http://www.qualityforum.org/Publications/2017/02/MAP_2017_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.* We solicited public comment on the stratification of the proposed measure, specifically on the measure rates for public reporting. The quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) is not currently endorsed for the home health setting. We reviewed the NQF's consensus endorsed measures and were unable to identify any NQF-endorsed cross-setting quality measures for that setting that are focused on falls with major injury. We found one falls-related measure in home health titled, Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate (NQF #0537).

We noted that we are also aware of one NQF-endorsed measure, Falls with Injury (NQF #0202), which is a measure designed for adult acute inpatient and rehabilitation patients capturing ''all documented patient falls with an injury level of minor or greater on eligible unit types in a calendar quarter, reported as injury falls per 100 days.'' [93] After careful review, we determined that these measures are not appropriate to meet the IMPACT Act domain of incidence of major falls. Specifically—

- NQF #0202 includes minor injuries in the numerator definition. Including all falls in an outcome measure could result in providers limiting activity for individuals at higher risk for falls.
- NQF #0537 is a process-based measure of HHAs' efforts to assess the risk for any fall, but not actual falls.
- Neither measure is standardized across PAC settings.

We are unaware of any other cross-setting quality measures for falls with major injury that have been endorsed or adopted by another consensus organization for the Home health setting. Therefore, based on the evidence discussed previously, we proposed to adopt the quality measure entitled, An Application of the Measure Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674), for the HH QRP beginning with the CY 2020 HH QRP. We noted in the proposed rule that we plan to submit the proposed measure to the NQF for endorsement consideration as soon as it is feasible.

d. Data Collection

For purposes of assessment data collection, we proposed to add two new falls-related items to the OASIS. The proposed falls with major injury item used to calculate the proposed quality measure does not duplicate existing items currently collected in the OASIS. We proposed to add two standardized items to the OASIS for collection at EOC, which comprises the Discharge from Agency, Death at Home, and Transfer to an Inpatient Facility time

[90] Wu S, Keeler EB, Rubenstein LZ, Maglione MA, Shekelle PG. A cost-effectiveness analysis of a proposed national falls prevention program. Clin Geriatr Med. 2010;26(4): 751–66.

[91] Orces, C.H. & Alamgir, H. (2014). Trends in fall-related injuries among older adults treated in emergency departments in the USA. Injury Prevention, 20: 421–423.

[92] Towne, S.D., Ory, M.G., & Smith, M.L. (2014). Cost of fall-related hospitalizations among older adults: Environmental comparisons from the 2011 Texas hospital inpatient discharge data. Population Health Management, 17(6), 351–356.

[93] American Nurses Association (2014, April 9). Falls with injury. Retrieved from *http://www.qualityforum.org/QPS/0202.*

points: J1800 and J1900. The first item (J1800) is a gateway item that asks whether the patient has experienced any falls since admission/resumption of care (prior assessment). If the answer to J1800 is yes, the next item (J1900) asks for the number of falls with: (a) No injury, (b) injury (except major), and (c) major injury. The measure is calculated using data reported for J1900C (number of falls with major injury). This measure would be calculated at the time of discharge (see 82 FR 35351). For technical information about this proposed measure, including information pertaining to measure calculation and the standardized patient assessment data element used to calculate this measure, we referred readers to the document titled, *Final Specifications for HH QRP Quality Measures and Standardized Patient Assessment Data,* available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

We proposed that data for the proposed quality measure would be collected through the OASIS, which HHAs currently submit through the QIES ASAP system. We referred readers to section V.I.4 of the proposed rule for more information on the proposed data collection and submission timeline for this proposed quality measure.

We solicited public comments on our proposal to adopt an application of the quality measure, the Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674) beginning with the CY 2020 HH QRP.

Comment: A few commenters supported the proposed measure, Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (NQF #0674), noting that it aligned with measures in other post-acute care settings.

Response: We appreciate the commenters' support of the proposed measures.

Comment: Several commenters suggested that CMS further refine and test Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (NQF #0674), to determine HHA setting applicability before adopting it for the HH QRP. Other commenters recommended that we provide training and time for HHAs to accommodate the new measures into their workflow. One commenter recommended that we review the impact of new measures on high needs beneficiaries.

Response: This measure is fully developed and testing of this measure is based on a comprehensive field test of the items used to calculate this measure. Further, feedback from clinicians suggested that the items used to calculate this measure are feasible to collect in a Home health setting, reinforcing the measure testing by CMS and their measure contractor. Therefore, by way of testing results and consensus vetting, we believe that this measure is applicable to a home health setting.

With respect to training, we intend to engage in multiple activities including updating our manual and conducting training sessions, to ensure that HHAs understand how to properly report the measure.

Comment: A few commenters addressed the administrative burden of the measure, specifically focusing on the addition of items used in its calculation to the OASIS. Specifically, one of these commenters encouraged CMS to review the overall number of OASIS data elements and measures. The same commenter noted that HHAs already are evaluated on a falls measure, ''Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate''.

Response: This proposed measure is an outcome measure that we are adopting to satisfy the measure domain, Incidence of Major Falls, required by the IMPACT Act. The process measure, ''Multifactor Fall Risk Assessment Conducted for All Patients Who Can Ambulate'', is a measure that assesses falls risk rather than the outcome of a major fall. That measure is not aligned across post-acute care settings and therefore does not meet the requirements of the IMPACT Act.

Pertaining to the administrative burden, the proposed measure, ''Falls with Major Injury,'' requires a total of two items to be added to the OASIS, which were considered feasible for collection in post-acute care settings. We believe these items add minimally to the quality reporting burden.

Comment: Several commenters noted that the home health setting is unique from facility-based care, making it difficult to assess or prevent patient falls. Commenters noted that home health staff are not with their patients around the clock, unlike facility-based care, and that patients may refuse or decline to follow staff recommendations on falls prevention.

Response: Assessing the incidence of major falls, which is associated with morbidity, mortality, and high costs, is required under the IMPACT Act and is also one of our major priorities for improving the quality of patient care. In order to ensure that this measure is appropriate for a home health setting, we examined fall risk and prevalence among the cohort of home health patients by means of an analysis using 2015 OASIS data. In nearly 32 percent of the 5.3 million episodes with relevant data, the patient had a history of falls, defined as two or more falls, or any fall with an injury, in the previous 12 months. For the more than 6.1 million episodes where the patient received a multi-factor falls risk assessment using a standardized, validated assessment tool, the patient was found to have falls risk 93 percent of the time. Additionally, there were nearly 100,000 instances documented where a patient required emergency care for an injury due to a fall. Our environmental scan identified evidence-based strategies that can and have been applied in the home health setting to reduce falls risk. Therefore, we believe that a measure of this type is important for both providers and individuals, to support person-centered care to properly assess for the risk of falling accompanied by a major injury to support proper care planning. In addition to meeting the requirements of the IMPACT Act, this measure will address the current gap in the HH QRP measure set for this type of injurious fall.

Comment: Several commenters recommended that this measure be risk-adjusted for the purpose of public-reporting, and that unadjusted rates be shared with providers via confidential feedback only. Commenters additionally suggested that there may be unintended consequences without risk adjustment such that HHAs may be hesitant to accept higher falls' risk patients for fear of the financial impact. The commenters stated that this may potentially limit the value of comparison amongst HHAs. According to one of these commenters, without risk adjustment, the measure could present a distorted correlation between the rate of major injuries related to falls and the quality of care provided by the agency. This will limit comparisons among home health agencies. Another commenter noted that stratifying results for public reporting may not be feasible given sample sizes and will not be a substitute for risk-adjustment.

Response: While we acknowledge that various patient characteristics can elevate the risk for falls, falls with major injury are considered to be 'never events. A never event is a serious reportable event. For that reason, we do not believe we should risk adjust the proposed measure. Risk adjusting for falls with major injury could unintentionally lead to insufficient risk prevention by the provider. The need for risk assessment, based on varying

risk factors among residents, does not remove the obligation of providers to minimize that risk.

Comment: Many commenters noted that the falls measure is not endorsed by NQF for the home health setting and encouraged CMS to pursue NQF endorsement.

Response: While this measure is not currently NQF-endorsed, we recognize that the NQF endorsement process is an important part of measure development and we plan to submit this measure for NQF endorsement consideration as soon as feasible.

Final Decision: After consideration of the comments received, we are finalizing as proposed the measure Percent of Residents Experiencing One or More Falls with Major Injury for adoption in the HH QRP beginning with the CY 2020 program year.

G. HH QRP Quality Measures and Measure Concepts Under Consideration for Future Years

We solicited public comment on the importance, relevance, appropriateness, and applicability of each of the quality measures listed in Table 19 for use in future years in the HH QRP.

TABLE 19—HH QRP QUALITY MEASURES UNDER CONSIDERATION FOR FUTURE YEARS

IMPACT Act domain	Functional status, cognitive function, and changes in function and cognitive function
Measures	A. Application of NQF #2633—Change in Self-Care Score for Medical Rehabilitation Patients. B. Application of NQF #2634—Change in Mobility Score for Medical Rehabilitation Patients. C. Application of NQF #2635—Discharge Self-Care Score for Medical Rehabilitation Patients. D. Application of NQF #2636—Discharge Mobility Score for Medical Rehabilitation Patients.

We noted that we are considering four measures that will assess a change in functional outcomes such as self-care and mobility across a HH episode. These measures would be standardized to measures finalized in other PAC quality reporting programs, such as the IRF QRP. We solicited feedback on the importance, relevance, appropriateness, and applicability of these measure constructs.

Based on input from stakeholders, we have identified additional concept areas for potential future measure development for the HH QRP. These include claims-based within stay potentially preventable hospitalization measures. The potentially preventable within-stay hospitalization measures will look at the percentage of HH episodes in which patients were admitted to an acute care hospital or seen in an emergency department for a potentially preventable condition during an HH episode. We solicited feedback on the importance, relevance, appropriateness, and applicability of these measure constructs.

In alignment with the requirements of the IMPACT Act to develop quality measures and standardize data for comparative purposes, we believe that evaluating outcomes across the post-acute settings using standardized data is an important priority. Therefore, in addition to proposing a process-based measure for the domain of ''Functional status, cognitive function, and changes in function and cognitive function'', included in the proposed rule, we noted that we also intended to develop outcomes-based quality measures, including functional status and other quality outcome measures to further satisfy this domain.

Comment: Three commenters expressed general support for the measures under consideration for future years. These commenters stated that measures should be tested in the home health setting prior to being finalized, highlighting that the home setting is different than other standardized institutional care settings and presents unique challenges to caregivers and beneficiaries. One of the commenters stated that the measurement domains are critically important in the home health setting and highly relevant, especially for patients whose goal is improvement, adding that the relevance, appropriateness, and applicability can only be discussed after validity and reliability testing is completed in the home health setting. Another commenter suggested leveraging changes in quality measures as an effort to safeguard the delivery of therapy services and ensure accountability on the part of the provider.

Response: We appreciate the recommendations and comments. We agree that all future measures should be adequately tested and found reliable for the home health setting.

Comment: Commenters supported the development of functional status measures. MedPAC also supported measures that cut-across sectors, as long as they are standardized, and noted they would support the self-care and mobility measure concepts for HHAs based on the IRF measure specifications, as long as CMS ensured that the measures are aligned across PAC settings. A few commenters recommended that functional measures may assess for beneficiaries who do not have the goal of improvement. Other commenters noted that stabilization measures are appropriate for quality improvement initiatives as they closely align with the goal of HH services to help patients maintain their current level of function or when possible to improve it. Another commenter suggested closely monitoring functional status measures to determine the impact of other reforms, such as changes to the payment approaches, to determine the impact of these changes on patient outcomes.

Response: We appreciate the comments from MedPAC and others. We agree that the maintenance of function and avoidance or reduction in functional decline are appropriate goals for HH patients. We appreciate all recommendations and will take these comments into consideration as we consider measures for future rulemaking.

Comment: Three commenters specifically supported the potentially preventable within-stay hospitalization measure. MedPAC supported the development of a claims-based, potentially preventable hospitalization measure, adding that measuring potentially preventable hospitalizations holds providers accountable only for conditions that generally could have been managed by the HHA.

Response: We appreciate the comments from MedPAC and others pertaining to the potentially preventable within-stay hospitalization measure under consideration for future implementation in the HH QRP. We note that appropriately assessing hospital readmissions as an outcome is important, acknowledge the importance of avoiding unintended consequences that may arise from such assessments, and will take into consideration the commenters' recommendations.

Comment: Commenters had suggestions for other measures that could be added to the HH QRP.

Response: We appreciate the commenters' recommendations and will

take them into account in our future measure development work.

1. IMPACT Act Implementation Update

As a result of the input and suggestions provided by technical experts at the TEPs held by our measure developer, we noted in the proposed rule that we are engaging in additional development work for two measures that will satisfy section 1899B(c)(1)(E) of the Act, including performing additional testing. We noted that we intended to specify these measures under section 1899B(c)(1)(E) of the Act no later than January 1, 2019 and we intend to propose to adopt them for the CY 2021 HH QRP, with data collection beginning on or about January 1, 2020.

We did not receive any comments on this update.

H. Standardized Patient Assessment Data

1. Standardized Patient Assessment Data Reporting for the CY 2019 HH QRP

Section 1895(b)(3)(B)(v)(IV)(bb) of the Act requires that for calendar years beginning on or after January 1, 2019, HHAs submit to the Secretary standardized patient assessment data required under section 1899B(b)(1) of the Act.

In the CY 2018 HH PPS proposed rule (82 FR 35351) we proposed that the current pressure ulcer measure, Application of Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), be replaced with the proposed pressure ulcer measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, beginning with the CY 2020 HH QRP. The current pressure ulcer measure will remain in the HH QRP until that time. Accordingly, for the requirement that HHAs report standardized patient assessment data for the CY 2019 HH QRP, we proposed that the data elements used to calculate that measure meet the definition of standardized patient assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1895(b)(3)(b)(v)(IV)(aa) of the Act for the beginning of the HH episode (for example, HH start of care/resumption of care), as well as the end of the HH episode (discharges) occurring during the first two quarters of CY 2018 will also satisfy the requirement to report standardized patient assessment data beginning with the CY 2019 HH QRP.

The collection of assessment data pertaining to skin integrity, specifically pressure related wounds, is important for multiple reasons. Clinical decision making, care planning, and quality improvement all depend on reliable assessment data collection. Pressure related wounds represent poor outcomes, are a serious medical condition that can result in death and disability, are debilitating and painful, and are often avoidable.[94 95 96 97 98 99] Pressure related wounds are considered healthcare acquired conditions.

As we noted, the data elements needed to calculate the current pressure ulcer measure are already included on the OASIS data set and reported by HHAs, and exhibit validity and reliability for use across PAC providers. Item reliability for these data elements was also tested for the nursing home setting during implementation of MDS 3.0. Testing results are from the RAND Development and Validation of MDS 3.0 project.[100] The RAND pilot test of the MDS 3.0 data elements showed good reliability and are applicable to the OASIS because the data elements tested are the same as those used in the OASIS Data Set. Across the pressure ulcer data elements, the average gold-standard nurse to gold-standard nurse kappa statistic was 0.905. The average gold-standard nurse to facility-nurse kappa statistic was 0.937. Data elements used to risk adjust this quality measure were also tested under this same pilot test, and the gold-standard to gold-standard kappa statistic, or percent agreement (where kappa statistic not available), ranged from 0.91 to 0.99 for these data elements. These kappa scores indicate ''almost perfect'' agreement using the Landis and Koch standard for strength of agreement.[101]

The data elements used to calculate the current pressure ulcer measure received public comment on several occasions, including when that measure was proposed in the CY 2016 HH PPS (80 FR 68623). Further, they were discussed in the past by TEPs held by our measure development contractor on June 13 and November 15, 2013, and recently by a TEP on July 18, 2016. TEP members supported the measure and its cross-setting use in PAC. The report, Technical Expert Panel Summary Report: Refinement of the Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678) Quality Measure for Skilled Nursing Facilities (SNFs), Inpatient Rehabilitation Facilities (HHAs), Long-Term Care Hospitals (LTCHs), and Home Health Agencies (HHAs), is available at and *https://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: Some commenters supported reporting the data elements already implemented in the HH QRP to fulfill the requirement to report standardized patient assessment data for the CY 2019 HH QRP. Specifically, the commenters supported the use of data elements used in calculation of the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678) to fulfill this requirement. However, one commenter recommended that CMS implement such measures after public deliberation and discussion. A commenter suggested that CMS adopt the same policies in this CY 2018 HH PPS final rule as it adopted for IRFs, SNFs and LTCHs in the other final rules issued this year.

Response: We appreciate the support and where possible we have aligned with the other settings. We affirm that as we continue to implement measures, such as the pressure ulcer quality measure, we will continue to engage the public both during the measure development phase and through the rulemaking process.

Final Decision: After consideration of the public comments received, we are finalizing as proposed that the data elements currently reported by HHAs to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678),to meet the definition of standardized patient assessment data with respect to medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act,

[94] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' *Nurs N Z* 19(10): 20–24.

[95] Gorzoni, M.L. and S.L. Pires (2011). ''Deaths in nursing homes.'' *Rev Assoc Med Bras* 57(3): 327–331.

[96] Thomas, J.M., *et al.* (2013). ''Systematic review: Health-related characteristics of elderly hospitalized adults and nursing home residents associated with short-term mortality.'' *J Am Geriatr Soc* 61(6): 902–911.

[97] White-Chu, E.F., *et al.* (2011). ''Pressure ulcers in long-term care.'' *Clin Geriatr Med* 27(2): 241–258.

[98] Bates-Jensen BM. Quality indicators for prevention and management of pressure ulcers in vulnerable elders. *Ann Int Med.* 2001;135 (8 Part 2), 744–51.

[99] Bennet, G, Dealy, C Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging,* 33(3):230–235.

[100] Saliba, D., & Buchanan, J. (2008, April). *Development and validation of a revised nursing home assessment tool: MDS 3.0.* Contract No. 500–00–0027/Task Order #2. Santa Monica, CA: Rand Corporation. Retrieved from *http://www.cms.hhs.gov/NursingHomeQualityInits/Downloads/MDS30FinalReport.pdf.*

[101] Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. *Biometrics* 33(1), 159–174.

and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act beginning with the CY 2019 HH QRP.

2. Standardized Patient Assessment Data Reporting Beginning With the CY 2020 HH QRP

In the CY 2018 HH PPS proposed rule (82 FR 35355 through 35371), we described our proposals for the reporting of standardized patient assessment data by HHAs beginning with the CY 2020 HH QRP. LTCHs, IRFs, and SNFs are also required to report standardized patient assessment data through their applicable PAC assessment instruments, and they do so by responding to identical assessment questions developed for their respective settings using an identical set of response options (which incorporate an identical set of definitions and standards). We proposed that HHAs will be required to report these data at admission (SOC/ROC) and discharge beginning on January 1, 2019, with the exception of three data elements (Brief Interview of Mental Status (BIMS), Hearing, and Vision) that will be required at SOC/ROC only. Following the initial reporting year (which will be based on 6 months of data) for the CY 2020 HH QRP, subsequent years for the HH QRP would be based on a full calendar year of such data reporting.

In selecting the data elements, we carefully weighed the balance of burden in assessment-based data collection and aimed to minimize additional burden through the utilization of existing data in the assessment instruments. We also noted that the patient and resident assessment instruments are considered part of the medical record and sought the inclusion of data elements relevant to patient care.

We also took into consideration the following factors for each data element: overall clinical relevance; ability to support clinical decisions, care planning, and interoperable exchange to facilitate care coordination during transitions in care; and the ability to capture medical complexity and risk factors that can inform both payment and quality. In addition, the data elements had to have strong scientific reliability and validity; be meaningful enough to inform longitudinal analysis by providers; had to have received general consensus agreement for its usability; and had to have the ability to collect such data once but support multiple uses. Further, to inform the final set of data elements for proposal, we took into account technical and clinical subject matter expert review, public comment, and consensus input in which such principles were applied.

We received several comments related to the reporting of the standardized patient assessment data.

Comment: Many commenters expressed significant concerns with respect to our standardized patient assessment data proposals. Several commenters stated that the new standardized patient assessment data reporting requirements will impose significant burden on providers, given the volume of new standardized patient assessment data elements that we proposed to add to the OASIS. Several commenters noted that the addition of the proposed standardized patient assessment data elements will require hiring more staff, retraining staff on revised questions or coding guidance, and reconfiguring internal databases and EHRs. Other commenters expressed concerns about the gradual but significant past and future expansion of the OASIS through the addition of standardized patient assessment data elements and quality measures, noting the challenge of coping with ongoing additions and changes.

Several commenters expressed concern related to the implementation timeline in the proposed rule. Several commenters noted that CMS had not yet provided sufficient specifications or educational materials to support implementation of the new patient assessments in the proposed timeline. A few commenters urged CMS to delay the reporting of new standardized patient assessment data elements and to carefully assess whether all of the proposed standardized patient assessment data elements are necessary under the IMPACT Act.

Response: We understand the concerns raised by commenters that finalizing our standardized patient assessment data proposals will require HHAs to spend a significant amount of resources preparing to report the data, including updating relevant protocols and systems and training appropriate staff. We also recognize that we can meet our obligation to require the reporting of standardized patient assessment data for the categories described in section 1899B(b)(1)(B) of the Act while simultaneously being responsive to these concerns. Therefore, after consideration of the public comments we received on these issues, we have decided that at this time, we will not finalize the standardized patient assessment data elements we proposed for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments.

Although we believe that the proposed standardized patient assessment data elements would promote transparency around quality of care and price as we continue to explore reforms to the PAC payment system, the data elements that we proposed for each of these categories would have imposed a new reporting burden on HHAs. We agree that it would be useful to evaluate further how to best identify the standardized patient assessment data that would satisfy each of these categories; would be most appropriate for our intended purposes including payment and measure standardization; and can be reported by HHAs in the least burdensome manner. As part of this effort, we intend to conduct a national field test that allows for stakeholder feedback and to consider how to maximize the time HHAs have to prepare for the reporting of standardized patient assessment data in these categories. We intend to make new proposals for the categories described in sections 1899B(b)(1)(B)(ii), (iii) and (v) of the Act no later than in the CY 2020 HH PPS proposed rule.

In this final rule, we are finalizing the standardized patient assessment data elements that we proposed to adopt for the IMPACT Act categories of Functional Status and Medical Conditions and Co-Morbidities. Unlike the standardized patient assessment data that we are not finalizing, the standardized patient assessment data that we proposed for Medical Conditions Co-Morbidities category is already required to calculate the Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (NQF #0678) quality measure, and the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury quality measure. We are finalizing the quality 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 the additional standardized patient assessment data elements in Section GG to satisfy the category of Functional Status.

Comment: Some commenters expressed support for the adoption of standardized patient assessment data elements. Several of these commenters expressed support for standardizing the definitions as well as the implementation of the data collection effort. A few commenters also supported CMS' goal of standardizing the

questions and responses across all PAC settings. Another commenter approved of the efforts CMS is making to engage the PAC community on the implementation of the IMPACT Act, including holding Special Open Door Forums and Medicare Learning Network (MLN) Calls to communicate with providers about expectations/timelines over five years. MedPAC recognized the value of and need for a unified patient assessment system for PAC as part of a potential unified payment system for PAC.

Response: We appreciate the support.

Comment: A few commenters stated that there is insufficient evidence demonstrating the reliability and validity of the proposed standardized patient assessment data elements. Several commenters stated that the expanded standardized patient assessment data reporting requirements have not yet been adequately tested to ensure they collect accurate and useful data in the HHA setting.

Response: Our standardized patient assessment data elements were selected based on a rigorous multistage process described in the CY 2018 HH PPS proposed rule (82 FR 35344). In addition, we believe that the PAC PRD testing of many of these data elements provides good evidence from a large, national sample of patients and residents in PAC settings to support the use of these standardized patient assessment data elements in and across PAC settings. However, as previously explained, we have decided at this time not to finalize the proposals for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments. Prior to making new proposals for these categories, we intend to conduct additional testing to ensure that the standardized patient assessment data elements we select are reliable, valid and appropriate for their intended use.

Comment: MedPAC suggested that CMS should be mindful that some data elements, when used for risk adjustment, may be susceptible to provider manipulation. MedPAC is concerned about the proposed elements such as oxygen therapy, intravenous medications, and nutritional approaches that may incentivize increased use of services. MedPAC supported the inclusion of these care items when they are tied to medical necessity, such as in previous MedPAC work, where patients were counted as using oxygen services only if they have diagnoses that typically require the use of oxygen. MedPAC encouraged CMS to take a similar approach in measuring use of services that are especially discretionary. For some data elements, MedPAC suggested that CMS consider requiring a physician to attest that the reported service was reasonable and necessary and include a statement adjacent to the signature line warning that filing a false claim is subject to treble damages under the False Claims Act.

Response: We thank MedPAC for their support of the standardized patient assessment data elements that are associated with medical necessity. We appreciate their suggestions to mitigate the potential for false data submission and the unintended consequence of use of services that are not medically indicated.

Comment: While supporting the overall concept of standardization across PAC settings, several commenters strongly believed that the home health setting is different than institutional settings and urged CMS to consider this. One of these commenters encouraged CMS to perform testing specifically in the home health setting. Another commenter was concerned about the use of some data elements because they were not designed for the home health setting and require specialized training to accurately administer. Several commenters emphasized the importance of risk adjustment, with some stating that effective risk adjustment will be an essential policy feature for home health agencies to distinguish how patients and data collection in non-standardized settings such as the beneficiary's home differ from institutional settings.

Response: We acknowledge that the four PAC provider types each have unique challenges and provide unique services and appreciate the commenters' concerns specific to the home health setting and the potential variation in services and populations. Because of this, we conducted a thorough process of phased testing and stakeholder consensus to ensure we considered items that are aligned across PAC settings and are relevant to and feasible in each setting. However, for the reasons previously explained, we have decided at this time not to finalize the standardized patient assessment data elements we proposed for three of the five categories under section 1899B(b)(1)(B) of the Act.

A full discussion of the standardized patient assessment data elements that we proposed to adopt for the categories described in sections 1899B(b)(1)(B)(ii), (iii) and (v) of the Act can be found in the CY 2018 HH PPS proposed rule (82 FR 35355 through 35371). In light of our decision not to finalize our proposals with respect to these categories, we are not going to address in this final rule the specific technical comments that we received on these proposed standardized patient assessment data elements. However, we appreciate the many technical comments we did receive specific to each of these data elements, and we will take them into consideration as we develop new proposals for these categories. In this section, we discuss the comments we received specific to the standardized patient assessment data we proposed to adopt and are finalizing in this final rule, for the categories of Functional Status and Medical Conditions and Co-Morbidities.

3. Standardized Patient Assessment Data by Category

a. Functional Status Data

We proposed that the data elements that will be reported by HHAs 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), as described in section V.F.2 of the proposed rule will also meet the definition of standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act. Details on the data used to calculate this measure is discussed in section V.F.2. of this final rule.

To further satisfy the requirements under section 1899B(b)(1)(B)(i) of the Act and specifically our efforts to achieve standardized patient assessment data pertaining to functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider, we also proposed to adopt the functional status data elements that specifically address mobility and self-care as provided in the Act. We noted that these data elements were also used to calculate the function outcome measures implemented and/or proposed for implementation in three other post-acute quality reporting programs to which the IMPACT Act applies (Application of NQF #2633—Change in Self-Care Score for Medical Rehabilitation Patients; Application of NQF #2634—Change in Mobility Score for Medical Rehabilitation Patients; Application of NQF #2635—Discharge Self-Care Score for Medical Rehabilitation Patients; and Application

of NQF #2636—Discharge Mobility Score for Medical Rehabilitation Patients).

To achieve standardization, we noted that we have implemented such data elements, or sub-sets of the items, into the other post-acute care patient/resident assessment instruments and we proposed that they also meet the definition of standardized patient assessment data for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of such data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act. These data elements currently are collected in the Section GG: Functional Abilities and Goals located in current versions of the MDS and the IRF–PAI assessment instruments.

As previously described, the patient assessment data that assess for functional status are from the CARE Item Set. They were specifically developed for cross-setting application and are the result of consensus building and public input. Further, we received public comment and input on these patient assessment data. Their reliability and validity testing were conducted as part of CMS' Post-Acute Care Payment Reform Demonstration, and we concluded that the functional status items have acceptable reliability and validity. We referred the reader to section V.F.2 of the proposed rule for a full description of the CARE Item Set and description of the testing methodology and results that are available in several reports. For more information about this quality measure and the data elements used to calculate it, we referred readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49739 through 49747), the FY 2016 IRF PPS final rule (80 FR 47100 through 47111), and the FY 2016 SNF PPS final rule (80 FR 46444 through 46453).

Therefore, we proposed to adopt the functional status data elements for the CY 2020 HH QRP, requiring HHAs to report these data starting on January 1, 2019. We noted that this proposal would align with the required reporting timeframe for the CY 2020 HH QRP. Following the initial 2 quarters of reporting for the CY 2020 HH QRP, we proposed that for subsequent years for the HH QRP, the reporting of standardized patient assessment data would be based on 12 months of data reporting beginning with July 1, 2019, through June 30, 2020 for the CY 2021 HH QRP.

Comment: Several commenters, including MedPAC, supported the collection of standardized patient assessment data across PAC settings. Some commenters specifically addressed support for CMS' proposal that data elements submitted to CMS 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), would also satisfy the requirement to report standardized patient assessment data elements under section 1899B(b)(1)(B)(i) of the Act addressing functional status, such as mobility and self-care at admission to a PAC provider and before discharge from a PAC provider.

Response: We appreciate the commenters' support.

Comment: A commenter suggested that CMS use the functional assessment item, GG0170C: Lying to sitting on the side of bed for purposes of standardization.

Response: We do not believe that collecting only GG170C would be sufficient for purposes of collecting standardized function data. We need a larger subset of Section GG items to calculate one of the measures that we are finalizing in this final rule, 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), which is already finalized for SNFs, LTCHs and IRFs. Section GG in its entirety also meets the definition of standardized patient assessment data with respect to function because it is standardized across the four PAC settings. If we did not collect Section GG in its entirety from HHAs, we would be collecting a different set of function items from HHAs than we collect from other PAC provider types.

Final Decision: After consideration of the public comments received, we are finalizing that the data elements in Section GG: Functional Abilities and Goals meet the definition of standardized patient assessment data elements for functional status under section 1899B(b)(1)(B)(i) of the Act, specifically those Section GG standardized patient assessment data elements that are used in the quality measure, ''Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631)'', and the additional standardized functional status data elements in Section GG. We note that Section GG includes item GG170Q, which we inadvertently omitted in the specifications that accompanied the CY 2018 HH PPS proposed rule. The Section GG data elements can be found in the Finalized Specifications for HH QRP Quality Measures and Standardized Patient Assessment Data Elements document available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.* We are also finalizing that the data elements needed 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), meet the definition of standardized patient assessment data elements for functional status under section 1899B(b)(1)(B)(i) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act will also satisfy the requirement to report standardized patient assessment data elements under section 1895(b)(3)(B)(v)(IV)(bb) of the Act.

b. Medical Condition and Comorbidity Data

We proposed that the data elements needed to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and that the proposed measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, meet the definition of standardized patient assessment data element with respect to medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act.

''Medical conditions and co-morbidities'' and the conditions addressed in the standardized assessment patient data elements used in the calculation and risk adjustment of these measures, that is, the presence of pressure ulcers, diabetes, incontinence, peripheral vascular disease or peripheral arterial disease, mobility, as well as low body mass index (BMI), are all health-related conditions that indicate medical complexity that can be indicative of underlying disease severity and other comorbidities.

Specifically, the data elements used in the measure are important for care planning and provide information pertaining to medical complexity. Pressure ulcers are serious wounds representing poor outcomes, and can

result in sepsis and death. Assessing skin condition, care planning for pressure ulcer prevention and healing, and informing providers about their presence in patient transitions of care are a customary and best practice. Venous and arterial disease and diabetes are associated with insufficient low blood flow, which may increase the risk of tissue damage. These diseases commonly are indicators of factors that may place individuals at risk for pressure ulcer development and are therefore important for care planning. Low BMI, which may be an indicator of underlying disease severity, may be associated with loss of fat and muscle, resulting in potential risk for pressure ulcers due to shearing. Bowel incontinence, and the possible maceration to the skin associated, can lead to higher risk for pressure ulcers. In addition, the bacteria associated with bowel incontinence can complicate current wounds and cause local infection. Mobility is an indicator of impairment or reduction in mobility and movement which is a major risk factor for the development of pressure ulcers. These data elements are important for care planning, transitions in services and identifying medical complexities.

Comment: Commenters supported our proposal to use data elements already implemented in the HH QRP to satisfy the requirement to report standardized patient assessment data.

Response: We appreciate the support.

Final decision: After consideration of the public comments received, we are finalizing as proposed that the data elements currently reported by HHAs to calculate the current measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), and the finalized measure, Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury, meet the definition of standardized patient assessment data for medical conditions and co-morbidities under section 1899B(b)(1)(B)(iv) of the Act, and that the successful reporting of that data under section 1895(b)(3)(B)(v)(IV)(aa) of the Act will also satisfy the requirement to report standardized patient assessment data under section 1895(b)(3)(B)(v)(IV)(bb) of the Act.

We note that for purposes of meeting the requirements of the CY 2020 HH QRP, HHAs will be required to report the data elements needed to calculate the current pressure ulcer measure for the last two quarters of CY 2018 (July–December) and the data elements needed to calculate the updated pressure ulcer measure for the first two quarters of CY 2019 (January–June).

I. Form, Manner, and Timing of Data Submission Under the HH QRP

1. Start Date for Reporting Standardized Patient Assessment Data by New HHAs

In the CY 2016 HH PPS final rule (80 FR 68703 through 68706), we adopted timing for new HHAs to begin reporting data on quality measures under the HH QRP. In the CY 2018 HH PPS proposed rule (82 FR 35371), we proposed that new HHAs would be required to begin reporting standardized patient assessment data on the same schedule.

Comment: One commenter supported our proposed policy to require that new HHAs begin reporting standardized patient assessment data on the same schedule that they are required to begin reporting data on quality measures.

Response: We thank the commenter for the support.

Final Decision: After consideration of the comments we received, we are finalizing our proposal that new HHAs will be required to begin reporting standardized patient assessment data on the same schedule that they are currently required to begin reporting other quality data under the HH QRP.

2. Mechanism for Reporting Standardized Patient Assessment Data Beginning With the CY 2019 HH QRP

Under our current policy, HHAs report data by completing applicable sections of the OASIS, and submitting the OASIS to CMS through the QIES, ASAP system. For more information on HH QRP reporting through the QIES ASAP system, we referred readers to *https://www.qtso.com/index.php.* In addition to the data currently submitted on quality measures as previously finalized and described in Table 18 of this rule, in the CY 2018 HH PPS proposed rule (82 FR 35372), we proposed that HHAs would be required to begin submitting the proposed standardized patient assessment data for HHA Medicare and Medicaid quality episodes that begin or end on or after January 1, 2019 using the OASIS.

Further, we proposed that all standardized patient assessment data elements would be collected at SOC/ROC using the OASIS item set, and all except the Brief Interview for Mental Status (BIMS), Hearing, and Vision data elements are or would be collected at discharge using the OASIS item set. Details on the modifications and assessment collection for the OASIS for the proposed standardized data are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

We invited public comment on these proposals.

Comment: We received a comment in support of the proposed mechanisms for reporting standardized patient assessment in the same manner as the quality measure data for assessment based data beginning with the CY 2019 HH QRP.

Response: We thank the commenter for its support.

Final Decision: After consideration of the public comment received, we are finalizing our policy as proposed to use the same data reporting mechanism for the submission of the standardized patient assessment data elements that is already used for reporting quality measure data used in the HH QRP beginning with the CY 2019 HH QRP.

3. Schedule for Reporting Standardized Patient Assessment Data Beginning With the CY 2019 HH QRP

In the CY 2018 HH PPS proposed rule (82 FR 35372) we proposed to apply our current schedule for the reporting of measure data to the reporting of standardized patient assessment data, beginning with the CY 2019 HH QRP. Under that policy, except for the first program year for which a measure is adopted, HHAs must report data on measures for HHA Medicare and Medicaid quality episodes that occur during the 12-month period (between July 1 and June 30) that applies to the program year. For the first program year for which a measure is adopted, HHAs are only required to report data on HHA Medicare and Medicaid quality episodes that begin on or after January 1 and end up to and including June 30 of the calendar year that applies to that program year. For example, for the CY 2019 HH QRP, data on measures adopted for earlier program years must be reported for all HHA Medicare and Medicaid quality episodes that begin on or after July 1, 2017, and end on or before June 30, 2018. However, data on new measures adopted for the first time for the CY 2019 HH QRP program year must only be reported for HHA Medicare and Medicaid quality episodes that begin or end during the first two quarters of CY 2018. Tables 20 and 21 illustrate this policy and its proposed application to the reporting of standardized patient assessment data, using CY 2019 and CY 2020 as examples.

TABLE 20—SUMMARY ILLUSTRATION OF INITIAL REPORTING FOR NEWLY ADOPTED MEASURES AND PROPOSED STANDARDIZED PATIENT ASSESSMENT DATA REPORTING USING CY Q1 AND Q2 DATA FOR THE HH QRP *

Proposed data collection/submission reporting period *	Proposed data submission deadlines beginning with CY 2019 HH QRP *
January 1, 2018–June 30, 2018.	July 31, 2018.

* We note that submission of the OASIS must also adhere to the HH PPS deadlines.
– The term "CY 2019 HH QRP" means the calendar year for which the HH QRP requirements applicable to that calendar year must be met in order for a HHA to avoid a two percentage point reduction to its market basket percentage when calculating the payment rates applicable to it for that calendar year.

TABLE 21—SUMMARY ILLUSTRATION OF OASIS 12 MONTH DATA REPORTING FOR MEASURES AND PROPOSED STANDARDIZED PATIENT ASSESSMENT DATA REPORTING FOR THE HH QRP *

Proposed data collection/submission reporting period *	Proposed data submission deadlines beginning with CY 2020 HH QRP * ^
July 1, 2018–June 30, 2019.	July 31, 2019.

* We note that submission of the OASIS must also adhere to the HH PPS deadlines.
^ The term "CY 2020 HH QRP" means the calendar year for which the HH QRP requirements applicable to that calendar year must be met in order for a HHA to avoid a two percentage point reduction to its market basket percentage when calculating the payment rates applicable to it for that calendar year.

We invited comment on our proposal to extend our current policy governing the schedule for reporting the quality measure data to the reporting of standardized patient assessment data for the HH QRP beginning with the CY 2019 HH QRP.

We did not receive any comments regarding this proposal.

Final Decision: We are finalizing our proposal as proposed to extend our current policy governing the schedule for reporting the quality measure data to the reporting of standardized patient assessment data for the HH QRP beginning with the CY 2019 HH QRP.

4. Schedule for Reporting Quality Measures Beginning With the CY 2020 HH QRP

As discussed in section V.I. of this final rule, we are finalizing the adoption of three quality measures beginning with the CY 2020 HH QRP: Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury; Application of The Percent of Residents Experiencing One or More Falls with Major Injury (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). In the CY 2018 HH PPS proposed rule (82 FR 35372), we proposed that HHAs would report data on these measures using OASIS reporting that is submitted through the QIES ASAP system. More information on OASIS reporting using the QIES ASAP system is located at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/DataSpecifications.html.*

For the CY 2020 HH QRP, under our current policy HHAs will be required to report these data for HHA Medicare and Medicaid quality episodes that begin or end during the period from January 1, 2019, to June 30, 2019. Beginning with the CY 2021 HH QRP, we proposed that HHAs would will be required to submit data for the entire 12-month period from July 1 to June 30. Further, for the purposes of measure calculation, our policy was established in the CY 2017 HH PPS final rule (81 FR76784) that data are utilized using calendar year timeframes with review and correction periods.

Comment: A commenter supported the proposed schedule for reporting the three new quality measures beginning with the CY 2020 QRP. However, the commenter also suggested that there is a disparity in how home health providers are reimbursed, which creates challenges for their submission of the required data.

Response: We interpret the comment to be suggesting that Medicare reimbursement rates for HH services, compared to Medicare rates for post-acute care services furnished by different provider-types, may affect the ability of HHAs to comply with the data reporting requirements under the HH QRP. We are cognizant of the challenges of data collection and we consider this when developing and adopting our measures.

Final Decision: After consideration of the public comment received, we are finalizing our policy as proposed for the Schedule for Reporting the Quality Measures beginning with the CY 2020 HH QRP.

5. Input Sought for Data Reporting Related to Assessment Based Measures

We have received input suggesting that we expand the population for quality measurement to include all patients regardless of payer. Approximately 75 percent of home health expenditures in 2014 were made by either Medicare or Medicaid and currently both Medicare and Medicaid collect and report data for OASIS. We believe that expanding the patient population for which OASIS collects data will allow us to ensure data that is representative of quality provided to all patients in the HHA setting, and therefore, allow us to better determine whether HH Medicare beneficiaries receive the same quality of care that other patients receive. We also appreciate that collecting quality data on all patients regardless of payer source may create additional burden. However, we have also received input that the effort to separate out Medicare and Medicaid beneficiaries, who are currently reported through OASIS, from other patients, creates clinical and work flow implications with an associated burden too, and noted that we further appreciate that it is common practice for HHAs to collect OASIS data on all patients, regardless of payer source. Thus, we sought input on whether we should require quality data reporting on all HH patients, regardless of payer, where feasible—noting that because Medicare Part A claims data are submitted only with respect to Medicare beneficiaries, claims-based measures would continue to be calculated only for Medicare beneficiaries. We would like to clarify that CMS sought comment on this all payor topic and therefore there

is no proposed policy to finalize. We appreciate the comments received and will take all recommendations into consideration.

Comment: Several commenters supported data collection on all patients regardless of payor. One commenter requested that CMS provide additional explanation of what the benefit would be to collecting OASIS data on all patients regardless of payor. Several commenters stated that the addition of OASIS reporting for all patients regardless of payor will impose significant burden on HHAs. Some commenters noted that they used separate assessment documents for patients who are insured by private payors and that they used these assessments, in part, to avoid the burden of OASIS. A few commenters suggested that the collection of OASIS data on all patients regardless of payor could result in healthcare professionals spending more time with documentation and less time providing patient care. Some commenters suggested that if CMS requires HHAs to submit OASIS assessments on all patients, they might need to increase their staff hours, hire additional staff and incur additional expenses.

Response: We continue to believe that the reporting of all-payor data under the HH QRP would add value to the program and provide a more accurate representation of the quality provided by HHAs. Although we acknowledge the concerns raised by commenters regarding the potential burden of reporting all-payer data and on the potential impact of such a requirement for the HH QRP, we wish to clarify that under the HH Conditions of Participation (42 CFR 484.55), each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment that accurately reflects the patient's current health status and includes information that may be used to demonstrate the patient's progress toward achievement of desired outcomes. The comprehensive assessment must also incorporate the use of the current version of the OASIS items, using the language and groupings of the OASIS items, as specified by the Secretary.

Comment: We received several comments pertaining to the submission requirements of the OASIS instrument. Some commenters suggested that OASIS data was required for submission on only Medicare fee-for-service beneficiaries, while other commenters stated that HHAs must complete the OASIS for all Medicare and Medicaid patients. Another commenter noted that the HH Conditions of Participation already apply to all patients in a Medicare-certified HHA. Other commenters stated that they did not know what patient populations must be given an OASIS assessment.

Response: As previously discussed, for the purposes HH QRP, data reporting on the OASIS includes all Medicare and Medicaid beneficiaries. However, the comprehensive assessment must also incorporate the collection of the current version of the OASIS items, using the language and groupings of the OASIS items.

Comment: Several commenters stated concerns about the potential impact of all-payor information on the HH QRP public reporting and on the HHVBP model because private payors differ from CMS with regard to care pathways, approval, and authorization processes. Some commenters stated that private payors had proprietary information and that CMS would exceed its authority if it required all-payor reporting. Commenters also stated that some private insurers had different requirements than CMS pertaining to the number of visits paid for by such insurers, which would inhibit the agency in comparing performance across HHAs.

Response: We acknowledge concerns raised for the HHVBP model and the potential downstream impacts. With regard to the commenter suggesting that private payors' patients would generate proprietary information, we want to clarify that the OASIS is not a proprietary instrument and therefore we do not believe that a requirement that HHAs use the OASIS in compliance with our CoPs raises proprietary issues.

J. Other Provisions for the CY 2019 HH QRP and Subsequent Years

1. Application of the HH QRP Data Completion Thresholds to the Submission of Standardized Patient Assessment Data Beginning With the CY 2019 HH QRP

In the CY 2016 HH PPS final rule (80 FR 68703 through 68704), we defined the pay-for-reporting performance system model that could accurately measure the level of an HHA's submission of OASIS data based on the principle that each HHA is expected to submit a minimum set of two matching assessments for each patient admitted to their agency. These matching assessments together create what is considered a quality episode of care, consisting ideally of a SOC or ROC assessment and a matching End of Care EOC assessment. EOC assessments comprise the Discharge from Agency, Death at Home and Transfer to an Inpatient Facility time points. For further information on successful submission of OASIS assessments, types of assessments submitted by an HHA that fit the definition of a quality assessment, defining the ''Quality Assessments Only'' (QAO) formula, and implementing a pay-for-reporting performance requirement over a 3-year period, please see the CY 2016 HH PPS final rule (80 FR 68704 to 68705).

Additionally, we finalized the pay-for-reporting threshold requirements in the CY 2016 HH PPS final rule. We finalized a policy through which HHAs must score at least 70 percent on the QAO metric of pay-for-reporting performance requirement for CY 2017 (reporting period July 1, 2015, to June 30, 2016), 80 percent for CY 2018 (reporting period July 1, 2016, to June 30, 2017) and 90 percent for CY 2019 (reporting period July 1, 2017, to June 30, 2018). An HHA that does not meet this requirement for a calendar year will be subject to a two percentage point reduction to the market basket percentage increase that will otherwise apply for that calendar year. In the CY 2018 HH PPS proposed rule (82 FR 35373), we proposed to apply the threshold requirements established in the CY 2016 HH PPS rule to the submission of standardized patient assessment data beginning with the CY 2019 HH QRP.

Comment: Commenter provided feedback on the QAO standard which requires that at least 90 percent of OASIS assessments be usable for calculating quality measures or be subject to a 2-percentage point reduction to the market basket update for CY 2019. One commenter agreed with our proposal to apply the HH QRP data completion thresholds to the submission of standardized patient assessment data beginning in the CY 2019 HH QRP. A commenter suggested that the proposed 90 percent threshold is very high and may be difficult for small or rural providers meet, and suggested changing this to 80 percent or higher.

Response: We disagree that the 90 percent threshold for CY 2019 is too high or difficult for HHAs to meet.

The home health CoPs as codified (42 CFR 484.55) mandate use of the OASIS data set. OASIS reporting was first implemented on July 19, 1999 and in 2007, we adopted mandatory OASIS reporting for quality reporting purposes under section 1895(b)(3)(B)(v)(I) of the Act. Furthermore, HHAs have been required to submit OASIS data as a condition of payment of their Medicare claims since 2010. Since, HHAs have been required to report OASIS data for

the last 18 years as a CoP in the Medicare program and as a condition of payment of their Medicare claims for the past 7 years, our establishment of a 90 percent threshold for OASIS reporting should not place any new or additional burden on HHAs.

Final Decision: After consideration of the comments received, we are finalizing our proposal as proposed to extend our current HH QRP data completion requirements to the submission of standardized patient assessment data.

2. HH QRP Submission Exception and Extension Requirements

Our experience with other QRPs has shown that there are times when providers are unable to submit quality data due to extraordinary circumstances outside their control (for example, natural, or man-made disasters). Other extenuating circumstances are reviewed on a case-by-case basis. In the CY 2018 HH QRP proposed rule (82 FR 35373), we proposed to define a ''disaster'' as any natural or man-made catastrophe which causes damages of sufficient severity and magnitude to partially or completely destroy or delay access to medical records and associated documentation. Natural disasters could include events such as hurricanes, tornadoes, earthquakes, volcanic eruptions, fires, mudslides, snowstorms, and tsunamis. Man-made disasters could include such events as terrorist attacks, bombings, floods caused by man-made actions, civil disorders, and explosions. A disaster may be widespread and impact multiple structures or be isolated and impact a single site only.

In certain instances of either natural or man-made disasters, an HHA may have the ability to conduct a full patient assessment and record and save the associated data either during or before the occurrence of the extraordinary event. In this case, the extraordinary event has not caused the agency's data files to be destroyed, but it could hinder the HHA's ability to meet the QRP's data submission deadlines. In this scenario, the HHA will potentially have the ability to report the data at a later date, after the emergency has passed. In such cases, a temporary extension of the deadlines for reporting might be appropriate.

In other circumstances of natural or man-made disaster, an HHA may not have had the ability to conduct a full patient assessment, or to record and save the associated data before the occurrence of the extraordinary event. In such a scenario, the agency may not have complete data to submit to CMS. We believe that it may be appropriate, in these situations, to grant a full exception to the reporting requirements for a specific period of time.

We do not wish to penalize HHAs in these circumstances or to unduly increase their burden during these times. Therefore, we proposed a process for HHAs to request and for us to grant exceptions and extensions for the reporting requirements of the HH QRP for one or more quarters, beginning with the CY 2019 HH QRP, when there are certain extraordinary circumstances outside the control of the HHA. When an exception or extension is granted, we would not reduce the HHA's PPS payment for failure to comply with the requirements of the HH QRP.

We proposed that if an HHA seeks to request an exception or extension for the HH QRP, the HHA must request an exception or extension within 90 days of the date that the extraordinary circumstances occurred. The HHA may request an exception or extension for one or more quarters by submitting a written request to CMS that contains the information noted below, via email to the HHA Exception and Extension mailbox at *HHAPureConsiderations@cms.hhs.gov*. Requests sent to CMS through any other channel would not be considered as valid requests for an exception or extension from the HH QRP's reporting requirements for any payment determination.

The subject of the email must read ''HH QRP Exception or Extension Request'' and the email must contain the all following information:

- HHA CCN.
- HHA name.
- CEO or CEO-designated personnel contact information including name, telephone number, email address, and mailing address (the address must be a physical address, not a post office box).
- HHA's reason for requesting an exception or extension.
- Evidence of the impact of extraordinary circumstances, including but not limited to photographs, newspaper and other media articles.
- A date when the HHA believes it will be able to again submit HH QRP data and a justification for the proposed date.

We proposed that exception and extension requests would need to be signed by the HHA's CEO or CEO-designated personnel, and that if the CEO designates an individual to sign the request, the CEO-designated individual would be able to submit such a request on behalf of the HHA. Following receipt of the email, we would provide a: (1) Written acknowledgement, using the contact information provided in the email, to the CEO or CEO-designated contact notifying them that the request has been received; and (2) a formal response to the CEO or any CEO-designated HHA personnel, using the contact information provided in the email, indicating our decision.

We stated that this proposal would not preclude us from granting exceptions or extensions to HHAs that have not requested them when we determine that an extraordinary circumstance, such as an act of nature, affects an entire region or locale. If we were to make the determination to grant an exception or extension to all HHAs in a region or locale, we proposed to communicate this decision through routine communication channels to HHAs and vendors, including, but not limited to, issuing memos, emails, and notices on our HH QRP Web site once it is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html.*

We also proposed that we may grant an exception or extension to HHAs if we determine that a systemic problem with one of our data collection systems directly affected the ability of the HHA to submit data. Because we do not anticipate that these types of systemic errors will happen often, we do not anticipate granting an exception or extension on this basis frequently.

If an HHA is granted an exception, we would not require that the HHA submit any measure data for the period of time specified in the exception request decision. If we grant an extension to the original submission deadline, the HHA would still remain responsible for submitting quality data collected during the timeframe in question, although we would specify a revised deadline by which the HHA must submit this quality data.

We also proposed that any exception or extension requests submitted for purposes of the HH QRP would apply to that program only, and not to any other program we administer for HHAs such as survey and certification. OASIS requirements, including electronic submission, during Declared Public Health Emergencies can be found at FAQs I–5, I–6, I–7, I–8 at *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/downloads/AllHazardsFAQs.pdf.*

We intend to provide additional information pertaining to exceptions and extensions for the HH QRP, including any additional guidance, on

the HH QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html.*

In the CY 2018 HH PPS proposed rule (82 FR 35374), we proposed to codify the HH QRP Submission Exception and Extension Requirements at § 484.250(d) of our regulations.

Comment: One commenter expressed support for the creation of an exception and extension request process for HHAs that experience disasters or other extraordinary circumstances.

Response: We thank the commenter for the comment and support.

Final Decision: After consideration of comments received, we are finalizing the adoption of the policy as proposed for HH QRP Submission Exception and Extension Requirements beginning with the CY 2019 HH QRP and our decision to codify the HH QRP Submission Exception and Extension Requirements at § 484.250(d) of our regulations.

3. HH QRP Submission Reconsideration and Appeals Procedures

The HH QRP reconsiderations and appeals process was finalized in the CY 2013 HH PPS final rule (77 FR 67096). At the conclusion of the required quality data reporting and submission period, we review the data received from each HHA during that reporting period to determine if the HHA met the HH QRP reporting requirements. HHAs that are found to be noncompliant with the HH QRP reporting requirements for the applicable calendar year will receive a 2 percentage point reduction to its market basket percentage update for that calendar year.

Similar to our other quality reporting programs, such as the SNF QRP, the LTCH QRP, and the IRF QRP, we include an opportunity for the providers to request a reconsideration of our initial noncompliance determination. To be consistent with other established quality reporting programs and to provide an opportunity for HHAs to seek reconsideration of our initial noncompliance decision, in the CY 2018 HH PPS proposed rule (82 FR 35374 through 35375) we proposed a process that enables an HHA to request reconsideration of our initial non-compliance decision in the event that it believes that it was incorrectly identified as being non-compliant with the HH QRP reporting requirements for a particular calendar year.

For the CY 2019 HH QRP, and subsequent years, we proposed a HHA would receive a notification of noncompliance if we determine that the HHA did not submit data in accordance with the HH QRP reporting requirements for the applicable CY. The purpose of this notification is to put the HHA on notice that the HHA: (1) Has been identified as being non-compliant with the HH QRP's reporting requirements for the applicable calendar year; (2) will be scheduled to receive a reduction in the amount of two percentage points to its market basket percentage update for the applicable calendar year; (3) may file a request for reconsideration if it believes that the finding of noncompliance is erroneous, has submitted a request for an extension or exception that has not yet been decided, or has been granted an extension or exception; and (4) must follow a defined process on how to file a request for reconsideration, which will be described in the notification.

We stated that we would only consider requests for reconsideration after an HHA has been found to be noncompliant.

Notifications of noncompliance and any subsequent notifications from CMS would be sent via a traceable delivery method, such as certified U.S. mail or registered U.S. mail, or through other practicable notification processes, such as a report from CMS to the provider as a Certification and Survey Provider Enhanced Reports (CASPER) report, that will provide information pertaining to their compliance with the reporting requirements for the given reporting cycle or from the Medicare Administrative Contractors assigned to process the provider's claims. To obtain the compliance reports, we stated that HHAs must access the CASPER Reporting Application. HHAs can access the CASPER Reporting application via their CMS OASIS System Welcome page by selecting the CASPER Reporting link. The ''CASPER Reports'' link will connect an HHA to the QIES National System Login page for CASPER Reporting.

We proposed to disseminate communications regarding the availability of compliance reports through routine channels to HHAs and vendors, including, but not limited to issuing memos, emails, Medicare Learning Network (MLN) announcements, and notices on our HH QRP Web site once it is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html.*

We proposed that an HHA would have 30 days from the date of the letter of noncompliance to submit to us a request for reconsideration. This proposed time frame would allow us to balance our desire to ensure that HHA s have the opportunity to request reconsideration with our need to complete the process and provide HHAs with our reconsideration decision in a timely manner. We proposed that an HHA may withdraw its request at any time and may file an updated request within the proposed 30-day deadline. We also proposed that, in very limited circumstances, we may grant a request by an HHA to extend the proposed deadline for reconsideration requests. We stated that it would be the responsibility of an HHA to request an extension and demonstrate that extenuating circumstances existed that prevented the filing of the reconsideration request by the proposed deadline.

We also proposed that as part of the HHA's request for reconsideration, the HHA would be required to submit all supporting documentation and evidence demonstrating full compliance with all HH QRP reporting requirements for the applicable calendar year, that the HHA has requested an extension or exception for which a decision has not yet been made, that the HHA has been granted an extension or exception, or has experienced an extenuating circumstance as defined in section V.I.2. of this final rule, but failed to file a timely request of exception. We proposed that we would not review any reconsideration request that fails to provide the necessary documentation and evidence along with the request.

We proposed that the documentation and evidence may include copies of any communications that demonstrate the HHA's compliance with the HH QRP, as well as any other records that support the HHA's rationale for seeking reconsideration, but must not include any protected health information (PHI). We stated that we intended to provide a sample list of acceptable supporting documentation and evidence, as well as instructions for HHAs on how to retrieve copies of the data submitted to CMS for the appropriate program year in the future on our HH QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html.*

We proposed that an HHA wishing to request a reconsideration of our initial noncompliance determination would be required to do so by submitting an email to the following email address: *HHAPureConsiderations@cms.hhs.gov.*

Any request for reconsideration submitted to us by an HHA would be required to follow the guidelines outlined on our HH QRP Web site once it is available once it is available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html.*

All emails must contain a subject line that reads ''HH QRP Reconsideration Request.'' Electronic email submission is the only form of reconsideration request submission that will be accepted by us. We proposed that any reconsideration requests communicated through another channel including, but not limited to, U.S. Postal Service or phone, would not be considered as a valid reconsideration request.

We proposed that a reconsideration request include the all of the following information:

- HHA CMS Certification Number (CCN).
- HHA Business Name.
- HHA Business Address.
- The CEO contact information including name, email address, telephone number, and physical mailing address; or the CEO-designated representative contact information including name, title, email address, telephone number and physical mailing address.
- CMS identified reason(s) for noncompliance from the non-compliance notification.
- The reason(s) for requesting reconsideration.

We proposed that the request for reconsideration must be accompanied by supporting documentation demonstrating compliance. Following receipt of a request for reconsideration, we would provide an email acknowledgment, using the contact information provided in the reconsideration request, to the CEO or CEO-designated representative that the request has been received. Once we have reached a decision regarding the reconsideration request, an email would be sent to the HHA CEO or CEO designated representative, using the contact information provided in the reconsideration request, notifying the HHA of our decision.

We also proposed that the notifications of our decision regarding reconsideration requests may be made available through a traceable delivery method, such as certified U.S. mail or registered U.S. mail or through the use of CASPER reports. If the HHA is dissatisfied with the decision rendered at the reconsideration level, the HHA may appeal the decision to the PRRB under 42 CFR 405.1835. We believe the proposed process is more efficient and less costly for CMS and for HHAs because it decreases the number of PRRB appeals by resolving issues earlier in the process. Additional information about the reconsideration process including details for submitting a reconsideration request will be posted in the future to our HH QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HomeHealthQualityReporting-Reconsideration-and-Exception-and-Extension.html.*

In the CY 2018 HH PPS proposed rule (82 FR 35375), we proposed to add the HH QRP Submission Reconsideration and Appeals Procedures at §§ 484.250(e) and (f) of our regulations.

Comment: One commenter expressed support for the submission reconsideration and appeals procedures for HHAs.

Response: We thank the commenter for the comment and support.

Final Decision: After consideration of the public comments received, we are finalizing as proposed the adoption of the policy for HH QRP Submission Reconsideration and Appeals Procedures for the CY 2019 HH QRP and subsequent years, which will be codified at § 484.250(e) and (f) of our regulations.

K. Policies Regarding Public Display of Quality Measure Data for the HH QRP

Our home health regulations, at § 484.250(a), require HHAs to submit OASIS assessments and Home Health Care Consumer Assessment of Healthcare Providers and Systems Survey® (HHCAHPS) data to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act. Section 1899B(g) of the Act requires that data and information of provider performance on quality measures and resource use and other measures be made publicly available beginning not later than 2 years after the applicable specified ''application date''. In addition, section 1895(b)(3)(B)(v)(III) of the Act requires the Secretary to establish procedures for making data submitted under section 1895(b)(3)(B)(v)(II) of the Act available to the public, and section 1899B(g)(1) of the Act requires the Secretary to do the same with respect to HHA performance on measures specified under sections 1899B(c)(1) and (d)(1) of the Act. Section 1895(b)(3)(B)(v)(III) of the Act requires that the public reporting procedures for data submitted under subclause (II) ensure that a HHA has the opportunity to review the data that is to be made public with respect to it prior to such data being made public. Under section 1899B(g)(2) of the Act, the public reporting procedures for performance on measures under sections 1899B(c)(1) and (d)(1) of the Act must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, (which refers to public display and review requirements in the Hospital Inpatient Quality Reporting (Hospital IQR) Program), that a HHA has the opportunity to review and submit corrections to its data and information that are to be made public for the agency prior to such data being made public. We recognize that public reporting of quality data is a vital component of a robust quality reporting program and are fully committed to ensuring that the data made available to the public are meaningful. Further, we agree that measures for comparing performance across home health agencies must be constructed from data collected in a standardized and uniform manner.

In the CY 2017 HH PPS final rule (81 FR 76785 through 76786), we finalized procedures that allow individual HHAs to review and correct their data and information on IMPACT Act measures that are to be made public before those measure data are made public. Information on how to review and correct data on IMPACT Act measures that are to be made public before those measure data are made public can be found on the HH QRP Web site at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html.* We did not propose any changes to these policies in the CY 2018 HH PPS proposed rule.

However, in the CY 2018 HH PPS proposed rule (82 FR 35375 and 35376), pending the availability of data, we proposed to publicly report data beginning in CY 2019 for the following two assessment-based measures: (1) Percent of Patients or Residents with Pressure Ulcers that are New or Worsened (NQF #0678); and (2) Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP. Data collection for these two assessment-based measures began on OASIS on January 1, 2017. We proposed to publicly report data beginning in CY 2019 for these assessment-based measures based on four rolling quarters of data, beginning with data collected for discharges in 2017.

We proposed to publicly report data beginning in CY 2019 for the following

3 claims-based measures: (1) Medicare Spending Per Beneficiary—PAC HH QRP; (2) Discharge to Community-PAC HH QRP; and (3) Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP. As adopted in the CY 2017 HH PPS final rule (81 FR 43773), for the MSPB–PAC HH QRP measure, we will use 1 year of claims data beginning with CY 2016 claims data to inform confidential feedback reports for HHAs, and CY 2017 claims data for public reporting for the HH QRP. For the Discharge to Community—PAC HH QRP measure we will use 2 years of claims data, beginning with CYs 2015 and 2016 claims data to inform confidential feedback and CYs 2016 and 2017 claims data for public reporting. For the Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP, we will use 3 years of claims data, beginning with CY 2014, 2015 and 2016 claims data to inform confidential feedback reports for HHAs, and CY 2015, 2016 and 2017 claims data for public reporting.

Finally, we proposed to assign HHAs with fewer than 20 eligible cases during a performance period to a separate category: ''The number of patient episodes for this measure is too small to report,'' [102] to ensure the statistical reliability of the measures. If a HHA had fewer than 20 eligible cases, the HHA's performance would not be publicly reported for the measure for that performance period.

TABLE 22—NEW HH QRP MEASURES PROPOSED FOR CY 2019 PUBLIC DISPLAY

Proposed measures:
Percent of Residents or Patients with Pressure Ulcers that Are New or Worsened (Short Stay) (NQF #0678).
Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP.
Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH QRP.
Discharge to Community—(PAC) HH QRP.
Medicare Spending Per Beneficiary (PAC) HH QRP.

We invited public comments on these proposals for the public display of quality data.

Comment: Commenters provide feedback regarding the public display of quality measures beginning CY 2019 for data collected beginning CY 2017. One commenter questioned if the Medicare Spending Per Beneficiary—PAC HH QRP measure includes spending data that is specific to HH services or the total amount of Medicare spending for beneficiaries specific to a defined timeframe. One commenter did not support public reporting for the Discharge to Community—PAC HH QRP measure based on the potential for providers to have incentives against the appropriate use of hospice services in a patient-centered continuum of care. Another commenter did not support publicly reporting the Drug Regimen Review Conducted with Follow-Up for Identified Issues—PAC HH QRP measure, stating that this measure is dependent on physician response and is not a measure of HHA quality or performance. Finally, a commenter suggested a dashboard of measures aligned across home health quality initiatives, including star ratings, Home Health Compare and the HH VBP demonstration.

Response: We appreciate the commenters' suggestions regarding the public display of quality measures. As finalized in the CY 2017 rule, the MSPB–PAC HH QRP measure episode is comprised of a treatment period and an associated services period. The treatment period includes those services that are provided directly by the HHA. The associated services period is the time during which Medicare Part A and Part B services that are not treatment services are counted towards the episode, subject to certain exclusions, such as planned admissions and organ transplants. More detailed specifications for the MSPB–PAC measures, including the MSPB–PAC HH QRP measure, are available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/HHQIQualityMeasures.html.*

The Discharge to Community measure excludes patients discharged to home or facility-based hospice care. Thus, discharges to hospice are not considered discharges to community, but rather are excluded from the measure calculation. We wish to also note that including 31-day post-discharge mortality outcomes is intended to identify successful discharges to community, and to avoid the potential unintended consequence of inappropriate community discharges that bypass hospice care. With respect to the public reporting of Drug Regimen Review Conducted with Follow-Up for Identified Issues, the intent of the measure is to capture timely follow up for all potential clinically significant issues. We believe the timely review and follow up of potentially clinically significant medication issues at every assessment time period and across the patient's episode of care is essential for providing the best quality care for patients, and that this measure helps to ensure that high quality care services are furnished and that patient harm is avoided.

With regard to the commenter's suggestion that we provide a dashboard that communicates alignment across the measures, we will take the commenter's suggestion under consideration.

Comment: We received several comments about the Quality of Patient Care star ratings. One commenter noted increased administrative and clinical costs HHAs incur to maintain or improve the number of stars instead of focusing on improving the scores on individual quality measures. Another commenter stated that poor performing home health agencies could rate higher than their actual performance while good or excellent agencies could rate lower than their actual performance due to the way the data is calculated.

Response: We thank the commenters, but note that these comments relate to issues for which we made no proposals in the CY 2018 HH proposed rule. Therefore, we believe these comments to be outside the scope of the proposed rule and will not address them here.

Final Decision: After considering the comments received, we are finalizing our proposals regarding public display of quality measure data in the HH QRP.

L. Mechanism for Providing Confidential Feedback Reports to HHAs

Section 1899B(f) of the Act requires the Secretary to provide confidential feedback reports to post-acute care (PAC) providers on their performance on the measures specified under subsections (c)(1) and (d)(1) of section 1899B of the Act, beginning one year after the specified application date that applies to such measures and PAC

[102] This language is currently available as Footnote #4 on Home Health Compare (*https://www.medicare.gov/HomeHealthCompare/Data/Footnotes.html*).

providers. In the CY 2017 HH PPS final rule (81 FR 76702), we finalized processes to allow HH providers the opportunity to review their data and information using confidential feedback reports that will enable HHAs to review their performance on the measures required under the HH QRP. Information on how to obtain these and other reports available to the HH QRP can be found at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Home-Health-Quality-Reporting-Requirements.html.* We did not propose any changes to this policy.

M. Home Health Care CAHPS® Survey (HHCAHPS)

In the CY 2017 HH PPS final rule (81 FR 76787), we stated that the home health quality measures reporting requirements for Medicare-certified agencies includes the Home Health Care CAHPS® (HHCAHPS) Survey for the Home Health Quality Reporting Program and along with OASIS measures, HHCAHPS participation is required for the Annual Payment Update (APU). In the CY 2017 HH PPS final rule, we finalized the reporting requirements and the data submission dates for the CY 2017–CY 2020 APU periods. We proposed to continue the HHCAHPS requirements in future years for the continuous monthly data collection and quarterly data submission of HHCAHPS data.

1. Background and Description of HHCAHPS

The HHCAHPS survey is part of a family of CAHPS® surveys that asks patients to report on and rate their experiences with health care. For more details about the HHCAHPS Survey please see 81 FR 76787 through 76788.

We stated in previous rules that Medicare-certified HHAs are required to contract with an approved HHCAHPS survey vendor. This requirement continues, and Medicare-certified agencies are required to provide a monthly list of their HHCAHPS-eligible patients to their respective HHCAHPS survey vendors. Home health agencies are not allowed to influence their patients about how the HHCAHPS survey.

As previously required, new HHCAHPS survey vendors are required to attend Introduction training, and current HHCAHPS vendors are required to attend Update training conducted by CMS and the HHCAHPS Survey Coordination Team. New HHCAHPS vendors need to pass a post-training certification test. We have approximately 25 approved HHCAHPS survey vendors. The list of approved HHCAHPS survey vendors is available at *https://homehealthcahps.org.*

2. HHCAHPS Oversight Activities

We stated in prior final rules that all approved HHCAHPS survey vendors are required to participate in HHCAHPS oversight activities to ensure compliance with HHCAHPS protocols, guidelines, and survey requirements. The purpose of the oversight activities is to ensure that approved HHCAHPS survey vendors follow the HHCAHPS Protocols and Guidelines Manual.

In the CY 2013 HH PPS final rule (77 FR 67095 through 67097, 67164), we codified at § 484.250(c)(3) that all approved HHCAHPS survey vendors are required to fully comply with all HHCAHPS oversight activities.

In the CY 2018 HH PPS proposed rule (82 FR 35377), we restated the HHCAHPS requirements for CY 2019, because participation occurs in the period of the publication of the proposed and final rules for CY 2018. We additionally presented the HHCAHPS requirements for CY 2020 for the sake of continuity. We proposed the HHCAHPS requirements for the CY 2021 Annual Payment Update.

3. HHCAHPS Requirements for the CY 2019 HH QRP

In the CY 2017 HH PPS final rule (81 FR 76789), we finalized the requirements for the CY 2019 HH QRP. For the CY 2019 HH QRP, we require continuous monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2018 HH QRP includes the second quarter 2017 through the first quarter 2018 (the months of April 2017 through March 2018). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2017 by 11:59 p.m., eastern daylight time (e.d.t.) on October 19, 2017; for the third quarter 2017 by 11:59 p.m., eastern standard time (e.s.t.) on January 18, 2018; for the fourth quarter 2017 by 11:59 p.m., e.d.t. on April 19, 2018; and for the first quarter 2018 by 11:59 p.m., e.d.t. on July 19, 2018. These deadlines are firm; no exceptions will be permitted.

For more details on the CY 2019 HH QRP, we refer readers to 81 FR 76789.

4. HHCAHPS Requirements for the CY 2020 HH QRP

In the CY 2017 HH PPS final rule (81 FR 76789), we finalized the requirements for the CY 2020 HH QRP. For the CY 2020 HH QRP, we require continued monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2020 HH QRP includes the second quarter 2018 through the first quarter 2019 (the months of April 2018 through March 2019). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2018 by 11:59 p.m., e.d.t. on October 18, 2018; for the third quarter 2018 by 11:59 p.m., e.s.t. on January 17, 2019; for the fourth quarter 2018 by 11:59 p.m., e.d.t. on April 18, 2019; and for the first quarter 2019 by 11:59 p.m., e.d.t. on July 18, 2019. These deadlines are firm; no exceptions will be permitted.

For more details about the CY 2020 HH QRP, we refer readers to 81 FR 76789.

5. HHCAHPS Requirements for the CY 2021 HH QRP

For the CY 2021 HH QRP, we proposed to require the continued monthly HHCAHPS data collection and reporting for four quarters. The data collection period for the CY 2021 HH QRP includes the second quarter 2019 through the first quarter 2020 (the months of April 2019 through March 2020). HHAs will be required to submit their HHCAHPS data files to the HHCAHPS Data Center for the second quarter 2019 by 11:59 p.m., e.d.t. on October 17, 2019; for the third quarter 2019 by 11:59 p.m., e.s.t. on January 16, 2020; for the fourth quarter 2019 by 11:59 p.m., e.d.t. on April 16, 2020; and for the first quarter 2020 by 11:59 p.m., e.d.t. on July 16, 2020. These deadlines are firm; no exceptions will be permitted.

For the CY 2021 HH QRP, we proposed to require that all HHAs with fewer than 60 HHCAHPS-eligible unduplicated or unique patients in the period of April 1, 2018 through March 31, 2019 are exempt from the HHCAHPS data collection and submission requirements for the CY 2021 HH QRP, upon completion of the CY 2021 HHCAHPS Participation Exemption Request form, and upon CMS verification of the HHA patient counts. Agencies with fewer than 60 HHCAHPS-eligible, unduplicated or unique patients in the period of April 1, 2018 through March 31, 2019 were proposed to be required to submit their patient counts on the CY 2021 HHCAHPS Participation Exemption Request form posted on *https://homehealthcahps.org* from April 1, 2019 to 11:59 p.m., e.d.t. to March 31, 2020. This deadline is firm, as are all of the quarterly data submission deadlines for the HHAs that participate in HHCAHPS.

We proposed to automatically exempt HHAs receiving Medicare certification on or after the start of the period in which HHAs do their patient count for a particular year's HHCAHPS data submission from the HHCAHPS reporting requirement for the year. We proposed that HHAs receiving Medicare-certification on or after April 1, 2019 would be exempt from the HHCAHPS reporting requirement for the CY 2021 HH QRP. As we have finalized in previous years, we proposed that these newly-certified HHAs do not need to complete the HHCAHPS Participation Exemption Request Form for the CY 2021 HH QRP.

6. HHCAHPS Reconsiderations and Appeals Process

As finalized in previous rules, we proposed that HHAs must monitor their respective HHCAHPS survey vendors to ensure that vendors submit their HHCAHPS data on time, by accessing their HHCAHPS Data Submission Reports on *https://homehealthcahps.org.* This helps HHAs ensure that their data are submitted in the proper format for data processing to the HHCAHPS Data Center.

We proposed to continue HHCAHPS oversight activities as finalized in the previous rules. In the CY 2013 HH PPS final rule (77 FR 67068, 67164), we codified the current guideline that all approved HHCAHPS survey vendors must fully comply with all HHCAHPS oversight activities. We included this survey requirement at § 484.250(c)(3).

For further information on the HH QRP reconsiderations and appeals process, please see section V.J.3. of this final rule.

7. Summary

We did not propose any changes to the participation requirements, or to the requirements pertaining to the implementation of the Home Health CAHPS® Survey (HHCAHPS). We only proposed updates to the information to reflect the dates for future HH QRP years. We encouraged HHAs to keep up-to-date about the HHCAHPS by regularly viewing the official Web site for the HHCAHPS at *https://homehealthcahps.org.* We noted that HHAs can also send an email to the HHCAHPS Survey Coordination Team at *hhcahps@rti.org* or to CMS at *homehealthcahps@cms.hhs.gov*, or telephone toll-free (1–866–354–0985) for more information about the HHCAHPS Survey.

Final Decision: We did not receive any comments on our proposals. Accordingly, we are finalizing the proposals. We again strongly encourage HHAs to keep up-to-date about the HHCAHPS by regularly viewing the official Web site for the HHCAHPS at *https://homehealthcahps.org.* HHAs can also send an email to the HHCAHPS Survey Coordination Team at hhcahps@rti.org or to CMS at *homehealthcahps@cms.hhs.gov*, or telephone toll-free (1–866–354–0985) for more information about the HHCAHPS Survey.

VI. 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. We note that we will submit a revised information collection request (OMB control number 0938–1279) to OMB for review. This will also extend the information collection request which expires December 30, 2019. 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 the HH QRP

We believe that the burden associated with the HH QRP is the time and effort associated with data collection and reporting. As of April 1, 2017, there are approximately 12,149 HHAs 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 2016 National Occupational Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). To account for overhead and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in Table 23.

TABLE 23—U.S. BUREAU OF LABOR STATISTICS' MAY 2016 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit (100%) ($/hr)	Adjusted hourly wage ($/hr)
Registered Nurse (RN)	29–1141	$34.70	$34.70	$69.40
Physical therapists HHAs	29–1123	46.42	46.42	92.84
Speech-Language Pathologists (SLP)	29–1127	37.60	37.60	75.20
Occupational Therapists (OT)	29–1122	40.25	40.25	80.50

The OASIS changes that we are finalizing in section V.D of this final rule will result in the removal of 70 data elements from the OASIS at the time point of Start of Care (SOC), 70 data elements at the time point of Resumption of Care (ROC), 18 data elements at the time point of Follow-up (FU), 42 data elements at the time point of Transfer to an Inpatient Facility (TOC), 1 data element at the time point of Death at Home (Death), and 34 data elements at the time point of Discharge from Agency (Discharge). These data items will not be used in the calculation of quality measures adopted in the HH QRP, or for other purposes that are not related to the HH QRP.

Section V.F.1. of this final rule adopts a new pressure ulcer measure to replace the current pressure ulcer measure that

we previously specified under section 1899B(c)(1)(B) of the Act, beginning with the CY 2020 HH QRP. The replacement measure is entitled, ''Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.'' The new measure will be calculated using data elements that are currently collected and reported using the OASIS–C2 (version effective January 1, 2017). Adoption of the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure will result in the removal of item M1313, which has 6 data elements that cover the same issues that are addressed in the pressure ulcer assessment that will be required under the new pressure ulcer measure, making it duplicative and no longer necessary to separately collect.

In sections V.F.2. of this final rule, we are adopting a new quality measure under section 1899B(c)(1)(A) of the Act beginning with the CY 2020 HH QRP entitled ''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).'' In the CY 2018 HH PPS proposed rule (82 FR 35379), we stated that if we finalized the adoption of this measure, we would add 13 standardized patient assessment data elements at SOC, 13 data elements at ROC, 15 standardized patient assessment data elements at FU, and 13 standardized patient assessment data elements at Discharge. We inadvertently did not include in our original burden estimate two OASIS items (GG0170Q and GG0170RR) that are needed to calculate this measure.[103] We have updated our burden estimate to include these items, and note that as a result of finalizing this measure, we will be adding 15 standardized patient assessment data elements at SOC, 15 standardized patient assessment data elements at ROC, 16 standardized patient assessment data elements at FU, and 15 standardized patient assessment data elements at Discharge.

In sections V.F.3. of this final rule, we are adopting a new quality measure under section 1899B(c)(1)(D) of the Act beginning with the CY 2020 HH QRP entitled ''Application of Percent of Residents Experiencing One or More Falls with Major Injury (NQF# 0674).'' The new measure will be calculated using new standardized data elements added to the OASIS. Specifically, we are adding 4 data elements at TOC, 4 data elements at Death, and 4 data elements at Discharge.

In sections V.H.2 and V.H.3 of this final rule, we are finalizing our proposal to collect standardized patient assessment data with respect to the Medical Condition and Comorbidity category beginning with the CY 2019 HH QRP and Functional Status beginning with the CY 2020 HH QRP. As a result, we are adding to the OASIS the standardized patient assessment data elements associated with these categories, which include 17 standardized patient assessment data elements at SOC, 17 standardized patient assessment data elements at ROC, and 12 standardized patient assessment data elements at Discharge.

We are not finalizing our proposals to require HHAs to report standardized patient assessment data elements for three of the five categories under section 1899B(b)(1)(B) of the Act: Cognitive Function and Mental Status; Special Services, Treatments, and Interventions; and Impairments. As a result, we will not be adding to the OASIS the data elements associated with these proposals, which included 36 data elements at SOC, 36 data elements at ROC, or 24 data elements at discharge.

The OASIS instrument is used for both the HH QRP and the HH PPS. In sections III.E. of this final rule, after receiving detailed comments from the public we are not finalizing the implementation of the HHGM. Therefore, we are not finalizing the proposal to add two current OASIS–C2 items, M1033 and M1800, at the FU time point or to remove collection of eight current OASIS–C2 integumentary status items at the FU time point.

In summary, as a net result of the policies we are finalizing in this final rule, we will be removing 38 data elements at SOC, 38 data elements at ROC, 2 data elements at FU, 38 data elements at TOC and 9 data elements at Discharge. We will be adding 3 data elements at Death.

Under section 1899B(m) of the Act, the Paperwork Reduction Act does not apply to section 1899B, or to the sections of the OASIS that require modification to achieve the standardization of patient assessment data. We are, however, setting out the burden as a courtesy to advise interested parties of the actions' time and costs and for reference in the regulatory impact analysis (RIA) section VII. of this final rule. The requirement and burden will be submitted to OMB for review and approval when the modifications to the OASIS have achieved standardization and are no longer exempt from the requirements under section 1899B(m) of the Act.

We assume that each data element requires 0.3 minutes of clinician time to complete. Therefore, there is a reduction in clinician burden per OASIS assessment of 11.4 minutes at SOC, 11.4 minutes at ROC, 0.6 minutes at FU, 11.4 minutes at TOC 2.7 minutes at Discharge. There is an increase in clinician burden per assessment of 0.9 minutes at Death.

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2016 show that the SOC/ROC OASIS is completed by RNs (approximately 87 percent of the time), PTs (approximately 12.7 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.3 percent of the time). Based on this analysis, we estimated a weighted clinician average hourly wage of $72.40, inclusive of fringe benefits, using the hourly wage data in Table 23. Individual providers determine the staffing resources necessary.

Table 24 shows the total number of assessments submitted in CY 2016 and estimated burden at each time point.

TABLE 24—CY 2016 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT

Time point	CY 2016 assessments completed	Estimated burden ($)
Start of Care	6,261,934	−$86,139,164.10
Resumption of Care	1,049,247	−14,443,441.73
Follow-up	3,797,410	−2,749,324.84
Transfer to an inpatient facility	1,892,099	−26,027,713.84
Death at Home	41,128	44,665.01
Discharge from agency	5,120,124	−16,681,363.99

TABLE 24—CY 2016 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT—Continued

Time point	CY 2016 assessments completed	Estimated burden ($)
Total	18,161,942	−145,986,343.50

*Estimated Burden ($) at each Time-Point = (# CY 2016 Assessments Completed) x (clinician burden [min]/60) x ($72.40 [weighted clinician average hourly wage]).

Based on the data in Table 24, for the 12,149 active Medicare-certified HHAs in April 2017, we estimate the total average decrease in cost associated with changes to the HH QRP at $12,016.33 per HHA annually, or $145,986,343.50 for all HHAs annually. This corresponds to an estimated reduction in clinician burden associated with changes to the HH QRP of 166 hours per HHA annually, or 2,016,386 hours for all HHAs annually. This decrease in burden will be accounted for in the information collection under OMB control number 0938–1279.

C. Submission of PRA-Related Comments

We have submitted a copy of this final rule to OMB for its review of the rule's information collection and recordkeeping requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*
3. Call the Reports Clearance Office at (410) 786–1326.

See this final rule's **DATES** and **ADDRESSES** sections for the comment due date and for additional instructions.

VII. Regulatory Impact Analysis

A. Statement of Need

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) The computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that was the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase.

The HHVBP Model will apply a payment adjustment based on an HHA's performance on quality measures to test the effects on quality and expenditures.

B. Overall Impact

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), 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 (UMRA, 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). We included a detailed alternatives considered section in the CY 2018 HH PPS proposed rule, which outlined alternatives considered for the CY 2018 HH PPS payment update, the proposed HHGM, and HH VBP model (82 FR 35388 and 35389).

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). The savings impacts related to the HHVBP Model as a whole are estimated at a total projected 5-year gross savings of $378 million assuming a savings estimate of a 6 percent annual reduction in hospitalizations and a 1.0 percent annual reduction in SNF admissions; the portion attributable to this final rule is negligible. In section VII. of this final rule, we identified a reduction in our regulatory reporting burden of $ 145,986,343.50. 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. Accordingly, we have prepared a Regulatory Impact Analysis that, to the best of our ability, presents the costs and benefits of the rulemaking.

In addition, section 1102(b) of the Act requires us to prepare a RIA 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 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. This rule is applicable exclusively to HHAs. Therefore, the Secretary has determined this final rule will not have a significant economic impact on the operations of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2017, that threshold is approximately $148 million. This final rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $148 million or more.

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we must 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 this year's 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 this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of commenters will 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 proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this final rule is $105.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/2016/may/naics4_621100.htm*). Assuming an average reading speed, we estimate that it will take approximately 2.6 hours for the staff to review half of this final rule. For each HHA that reviews the rule, the estimated cost is $273.42 (2.6 hours x $105.16). Therefore, we estimate that the total cost of reviewing this regulation is $368,023.32 ($273.42 x 1,346 reviewers).

1. HH PPS for CY 2018

The update set forth in this final rule applies to Medicare payments under HH PPS in CY 2018. Accordingly, the following analysis describes the impact in CY 2018 only. We estimate that the net impact of the policies in this final rule is approximately $80 million in decreased payments to HHAs in CY 2018. We applied a wage index budget neutrality factor and a case-mix weights budget neutrality factor to the rates as discussed in section III.C.3. of this final rule. Therefore, the estimated impact of the 2018 wage index and the recalibration of the case-mix weights for 2018 is zero. The −$80 million impact reflects the distributional effects of a 0.5 percent reduction in payments due to the sunset of the rural add-on provision ($100 million decrease), a 1 percent home health payment update percentage ($190 million increase), and a −0.97 percent adjustment to the national, standardized 60-day episode payment rate to account for nominal case-mix growth for an impact of −0.9 percent ($170 million decrease). The $80 million in decreased payments is reflected in the last column of the first row in Table 25 as a 0.4 percent decrease in expenditures when comparing CY 2017 payments to estimated CY 2018 payments.

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 hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. For the purposes of the RFA, we estimate that almost all HHAs are small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare-paid visits, and therefore, the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies in this final rule will result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS rule will have a significant economic impact on a substantial number of small entities. Further detail is presented in Table 25, by HHA type and location.

With regards to options for regulatory relief, the sunset of rural add-on payments for CY 2018 is statutory and we do not have the authority to authorize rural add-on payments past December 31, 2017. We believe it is appropriate to reduce the national, standardized 60-day episode payment amount by 0.97 percent in CY 2018 to account for the estimated increase in nominal case-mix in order to move towards more accurate payment for the delivery of home health services where payments better align with the costs of providing such services.

2. HHVBP Model

Under the HHVBP Model, the first payment adjustment will apply in CY 2018 based on PY1 (2016) data and the final payment adjustment will apply in CY 2022 based on PY5 (2020) data. In the CY 2016 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately $380 million (80 FR 68716). In the CY 2017 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction

of approximately $378 million (81 FR 76795). We do not believe the changes finalized in this final rule will affect the prior estimates.

C. Detailed Economic Analysis

This final rule updates for CY 2018 the HH PPS rates contained in the CY 2017 HH PPS final rule (81 FR 76702 through 76797). The impact analysis of this final rule presents the estimated expenditure effects of policy changes that are be finalized. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based primarily on Medicare claims data from 2016. 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 errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH 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 HHAs.

1. HH PPS for CY 2018

Table 25 represents how HHA revenues are likely to be affected by the policy changes in this final rule for CY 2018. For this analysis, we used an analytic file with linked CY 2016 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2016. The first column of Table 25 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the CY 2018 wage index. The fourth column shows the payment effects of the CY 2018 case-mix weights. The fifth column shows the effects the 0.97 percent reduction to the national, standardized 60-day episode payment amount to account for nominal case-mix growth. The sixth column shows the payment effects from the sunset of the rural add-on payment provision in statute. The seventh column shows the effects of the CY 2018 home health payment update percentage.

The last column shows the combined effects of all the policies in this final rule. Overall, it is projected that aggregate payments in CY 2018 will decrease by 0.4 percent. As illustrated in Table 25, the combined effects of all of the changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2018 wage index, the extent to which HHAs had episodes in case-mix groups where the case-mix weight decreased for CY 2018 relative to CY 2017, the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization. In addition, we clarify that there are negative estimated impacts attributed to the sunset of the rural add-on provision for HHAs located in urban areas as well as rural areas. This is due to the fact that HHAs located in urban areas provide services to patients located in rural areas and payments are based on the location of the beneficiary.

TABLE 25—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2018

	Number of agencies	CY 2018 wage index [1] %	CY 2018 case-mix weights [2] %	60-Day episode rate nominal case-mix reduction [3] %	Sunset of rural add-on	HH payment update percentage [4] %	Total %
All Agencies	11,056	0.0	0.0	−0.9	−0.5	1.0	−0.4
Facility Type and Control							
Free-Standing/Other Vol/NP	1,110	0.0	0.1	−0.8	−0.4	1.0	−0.1
Free-Standing/Other Proprietary	8,724	0.0	0.0	−0.9	−0.4	1.0	−0.3
Free-Standing/Other Government	318	−0.3	0.1	−0.9	−1.3	1.0	−1.4
Facility-Based Vol/NP	634	0.0	0.2	−0.8	−0.7	1.0	−0.3
Facility-Based Proprietary	81	−0.3	0.2	−0.9	−1.3	1.0	−1.3
Facility-Based Government	189	0.0	0.2	−0.9	−1.5	1.0	−1.2
Subtotal: Freestanding	10,152	0.0	0.0	−0.9	−0.4	1.0	−0.3
Subtotal: Facility-based	904	0.0	0.2	−0.8	−0.8	1.0	−0.4
Subtotal: Vol/NP	1,744	0.0	0.1	−0.8	−0.5	1.0	−0.2
Subtotal: Proprietary	8,805	0.0	0.0	−0.9	−0.5	1.0	−0.4
Subtotal: Government	507	−0.2	0.2	−0.9	−1.4	1.0	−1.3
Facility Type and Control: Rural							
Free-Standing/Other Vol/NP	265	0.2	0.1	−0.9	−2.5	1.0	−2.1
Free-Standing/Other Proprietary	832	−0.1	−0.2	−0.9	−2.3	1.0	−2.5
Free-Standing/Other Government	224	−0.4	0.0	−0.9	−2.6	1.0	−2.9
Facility-Based Vol/NP	285	−0.4	0.1	−0.8	−2.7	1.0	−2.8
Facility-Based Proprietary	42	−0.1	0.1	−0.9	−2.7	1.0	−2.6
Facility-Based Government	142	−0.2	0.1	−0.8	−2.6	1.0	−2.5
Facility Type and Control: Urban							
Free-Standing/Other Vol/NP	845	−0.9	0.1	−0.8	−0.1	1.0	−0.7
Free-Standing/Other Proprietary	7,892	0.0	0.0	−0.9	−0.2	1.0	−0.1
Free-Standing/Other Government	94	−0.3	0.2	−0.9	−0.1	1.0	−0.1
Facility-Based Vol/NP	349	0.1	0.2	−0.8	−0.1	1.0	0.4
Facility-Based Proprietary	39	−0.5	0.2	−0.9	−0.2	1.0	−0.4

TABLE 25—ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2018—Continued

	Number of agencies	CY 2018 wage index [1] %	CY 2018 case-mix weights [2] %	60-Day episode rate nominal case-mix reduction [3] %	Sunset of rural add-on	HH payment update percentage [4] %	Total %
Facility-Based Government	47	0.3	0.2	−0.9	−0.3	1.0	0.3
Facility Location: Urban or Rural							
Rural	1,790	−0.1	−0.1	−0.9	−2.4	1.0	−2.5
Urban	9,266	0.0	0.0	−0.9	−0.2	1.0	−0.1
Facility Location: Region of the Country (Census Region)							
New England	359	0.0	0.1	−0.8	−0.3	1.0	0.0
Mid Atlantic	495	0.0	−0.1	−0.8	−0.2	1.0	−0.1
East North Central	2,235	0.0	0.2	−0.9	−0.4	1.0	−0.1
West North Central	711	0.2	0.1	−0.9	−0.8	1.0	−0.4
South Atlantic	1,736	−0.2	−0.1	−0.9	−0.3	1.0	−0.5
East South Central	426	−0.2	−0.2	−0.9	−1.3	1.0	−1.6
West South Central	2,987	0.2	−0.3	−0.9	−0.7	1.0	−0.7
Mountain	683	−0.2	0.1	−0.9	−0.4	1.0	−0.4
Pacific	1,377	0.1	0.5	−0.9	−0.1	1.0	0.6
Other	47	0.1	−1.0	−0.8	−0.6	1.0	−1.3
Facility Size (Number of 1st Episodes)							
<100 episodes	3,092	0.0	0.1	−0.9	−0.4	1.0	−0.2
100 to 249	2,467	0.1	0.2	−0.9	−0.5	1.0	−0.1
250 to 499	2,225	0.1	0.2	−0.9	−0.5	1.0	−0.1
500 to 999	1,710	0.0	0.0	−0.9	−0.5	1.0	−0.4
1,000 or More	1,562	−0.1	−0.1	−0.9	−0.5	1.0	−0.6

Source: CY 2016 Medicare claims data for episodes ending on or before December 31, 2016 for which we had a linked OASIS assessment.

[1] The impact of the CY 2018 home health wage index is offset by the wage index budget neutrality factor described in section III.C.3 of this final rule.

[2] The impact of the CY 2018 home health case-mix weights reflects the recalibration of the case-mix weights offset by the case-mix weights budget neutrality factor described in section III.B of this final rule.

[3] The 0.97 percent reduction to the national, standardized 60-day episode payment amount in CY 2018 is estimated to have a 0.9 percent impact on overall HH PPS expenditures.

[4] The CY 2018 home health payment update percentage reflects the home health payment update of 1 percent as described in section III.C.1 of this final rule.

REGION KEY:
New England = Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont.
Middle Atlantic = Pennsylvania, New Jersey, New York.
South Atlantic = Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia.
East North Central = Illinois, Indiana, Michigan, Ohio, Wisconsin.
East South Central = Alabama, Kentucky, Mississippi, Tennessee.
West North Central = Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota.
West South Central = Arkansas, Louisiana, Oklahoma, Texas.
Mountain = Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming.
Pacific = Alaska, California, Hawaii, Oregon, Washington.
Other = Guam, Puerto Rico, Virgin Islands.

The following is a summary of the public comments received on the ''Regulatory Impact Analysis'' and our responses:

Comment: A commenter requested that CMS provide the impact analyses of the case-mix weight changes that are annually proposed.

Response: The analyses of the annual case-mix weight changes are included in Table 25 in the fourth column titled, ''CY 2018 Case-Mix Weights''.

Comment: A commenter stated that when isolating the case mix changes from CY2017 to the CY2018 proposed rule, they are seeing an average impact of −0.58% which differs from the CMS projected 0.0 percent in Table 54 of the proposed rule. This analysis is for the case-mix components only (weights and budget neutrality factor), and excludes all other components such as wage index, nominal CM reduction, sunset of rural add-on, and the payment update percentage. The commenter requested an explanation of the apparent discrepancy.

Response: We estimate that all HHAs nationwide will see a decrease in average case-mix between CY 2017 and CY 2018 of 1.6 percent due to recalibration of the case-mix weights (hence the BN factor of 1.6 percent). In increasing the base rate by 1.6 percent to offset the decrease in average case-mix, those HHAs that have a decrease in average case-mix of less than 1.6 percent between CY 2017 and CY 2018 will see a small increase in payment for CY 2018 due to the case-mix weights budget neutrality factor. Those HHAs that have a decrease in average case-mix of more than 1.6 percent due to the case-mix weight recalibration between CY 2017 and CY 2018 will see a small decrease in payment for CY 2018 (generally proportional to the decrease in average case-mix above and beyond −1.6 percent). The adjustment for case-mix normalization is budget neutral in the aggregate but not so for individual HHAs.

2. HHVBP Model

Table 26 displays our analysis of the distribution for possible payment adjustments at the 3-percent, 5-percent, 6-percent, 7-percent, and 8-percent rates that are being used in the Model using CY 2015 baseline data and CY 2016 PY 1 data for OASIS-based measures, claims-based hospitalization and Emergency Department (ED) measures, and HHCAHPS data. The estimated impacts account for the minimum 40 HHCAHPS completed surveys policy, beginning with PY 1, as finalized in this rule. For PY 1 and 2, we show the impacts based on ten OASIS quality measures (9 OASIS quality measures were used for PY 3 through 5 to represent the removal of the Drug Education measure), two claims-based measures in QIES, five HHCAHPS measures, and the three new measures

(using the October 2016 and January 2017 submission data), using the QIES Roll Up File data in the same manner as they will be in the Model. HHAs were classified as being in the smaller or larger volume cohort using the 2015 Quality Episode File, as updated for this final rule, which is created using OASIS assessments. The basis of the payment adjustment was derived from complete 2015 claims data. We note that this impact analysis is based on the aggregate value of all nine states.

Table 27 displays our analysis of the distribution of possible payment adjustments based on the same CY 2015 baseline data and 2016 PY 1 data used to calculate Table 26, providing information on the estimated impact of the finalized policies in this final rule. Note that all Medicare-certified HHAs that provide services in Massachusetts, Maryland, North Carolina, Florida, Washington, Arizona, Iowa, Nebraska, and Tennessee are required to compete in this Model. This analysis reflects that only HHAs that have data for at least five measures that meet the requirements of § 484.305, as amended by this final rule, will be included in the LEF and will have a payment adjustment calculated. Value-based incentive payment adjustments for the estimated 1,600 plus HHAs in the selected states that will compete in the HHVBP Model are stratified by size as described in section IV.B. of the CY 2017 HH PPS final rule. As finalized in section IV.B. of the CY 2017 HH PPS final rule, there must be a minimum of eight HHAs in any cohort.

Those HHAs that are in states that do not have at least eight smaller-volume HHAs do not have a separate smaller-volume cohort and thus there will only be one cohort that will include all the HHAs in that state. As indicated in Table 27, Arizona, Maryland, North Carolina, Tennessee and Washington will only have one cohort while Florida, Iowa, Massachusetts, and Nebraska will have both a smaller-volume cohort and a larger-volume cohort. For example, Iowa has 26 HHAs exempt from the requirement that their beneficiaries complete HHCAHPS surveys because they provided HHA services to fewer than 60 beneficiaries in CY 2015. Therefore, 26 HHAs competed in Iowa's smaller-volume cohort for the 2016 performance year under the Model.

Using CY 2015 baseline year data and CY 2016 PY 1 data and the maximum payment adjustment for PY 1 of 3-percent (as applied in CY 2018), based on the ten OASIS quality measures, two claims-based measures in QIES, the five HHCAHPS measures, and the three new measures, the smaller-volume HHAs in Iowa have a mean payment adjustment of −0.1 percent (Table 27). Ten percent of HHAs in the smaller-volume cohort will be subject to payment adjustments of more than minus 1.1 percent (−1.1 percent), the lowest 10th percentile. The next columns provide the distribution of scores by percentile; we see that the cohort payment adjustment distribution for HHAs in Iowa in the smaller-volume cohort ranges from −1.1 percent at the 10th percentile to +1.5 percent at the 90th percentile, while the cohort payment adjustment distribution median is −0.3 percent.

Table 28 provides the payment adjustment distribution based on agency size, proportion of dually-eligible beneficiaries, average case mix (using the average case-mix for non-LUPA episodes), the proportion of the HHA's beneficiaries that reside in rural areas and HHA organizational status. HHAs with a higher proportion of dually-eligible beneficiaries and HHAs whose beneficiaries have higher acuity tend to have better performance.

The payment adjustment percentages are calculated at the state and size cohort level. Hence, the values of each separate analysis in the tables reflect the baseline year of 2015 and the performance year of 2016. There are 1,622 Medicare-certified HHAs in the nine selected states that have a sufficient number of measures to receive a payment adjustment in the Model. We note in Table 28, that at the time of our analysis, seven of the 1,622 Medicare-certified HHAs were missing information needed for the stratifications in the table. Not all Medicare-certified HHAs in the nine states have a payment adjustment because some HHAs are servicing too small of a population to report an adequate number of measures to calculate a TPS. However, as noted previously, our updated analysis found that the number of such HHAs was not affected by the proposed minimum 40 HHCAHPS survey policy, which we are finalizing.

Additional analysis (see Table 29) was conducted to illustrate the effect of the finalized policy to require 40 or more completed HHCAHPS surveys versus 20 or more completed HHCAHPS surveys. We include information on average statewide TPS by size of the HHA. The percentage difference in the average TPS across all larger-volume HHAs for each state ranges from −0.3 percent through 1.8 percent and the majority of states are close to zero.

TABLE 26—ADJUSTMENT DISTRIBUTION BY PERCENTILE LEVEL OF QUALITY TOTAL PERFORMANCE SCORE AT DIFFERENT MODEL PAYMENT ADJUSTMENT RATES

[Percentage]*

Payment adjustment distribution	Range (%)	10%	20%	30%	40%	Median	60%	70%	80%	90%
3% Payment Adjustment For Performance Year 1 of the Model	2.8	−1.3	−0.9	−0.6	−0.4	−0.1	0.2	0.5	0.8	1.4
5% Payment Adjustment For Performance Year 2 of the Model	4.6	−2.2	−1.6	−1.0	−0.6	−0.1	0.3	0.8	1.4	2.4
6% Payment Adjustment For Performance Year 3 of the Model** ..	5.8	−2.8	−1.9	−1.3	−0.7	−0.2	0.4	1.0	1.7	3.0
7% Payment Adjustment For Performance Year 4 of the Model** ..	6.7	−3.2	−2.2	−1.5	−0.9	−0.2	0.5	1.2	1.9	3.5
8% Payment Adjustment For Performance Year 5 of the Model** ..	7.7	−3.7	−2.5	−1.7	−1.0	−0.2	0.5	1.4	2.2	4.0

* Based on measure performance data from Performance Year 1 (January 1, 2016 to December 31, 2016), the baseline year (January 1, 2015 to December 31, 2015), and home health Medicare claims data from 2015.

** For Performance Years 3, 4, and 5, the payment adjustment rate simulation incorporated the removal of the Drug Education measure.

TABLE 27—HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT

[Based on a 3-percent payment adjustment]

State	Number of HHAs	Average payment adj. %	10%	20%	30%	40%	50%	60%	70%	80%	90%
HHA Cohort in States with no small cohorts (percent)											
AZ	114	−0.1	−1.3	−0.9	−0.7	−0.4	−0.2	0.1	0.5	0.7	1.1
MD	51	0.1	−0.8	−0.8	−0.6	−0.4	0.1	0.4	0.5	0.8	1.0

TABLE 27—HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT—Continued

[Based on a 3-percent payment adjustment]

State	Number of HHAs	Average payment adj. %	10%	20%	30%	40%	50%	60%	70%	80%	90%
NC	163	−0.1	−1.3	−0.9	−0.5	−0.2	0.0	0.2	0.4	0.7	0.9
TN	123	−0.1	−1.3	−1.0	−0.7	−0.4	−0.1	0.2	0.3	0.6	1.0
WA	57	−0.1	−1.0	−0.8	−0.6	−0.2	−0.2	0.0	0.3	0.3	0.8
Smaller-volume HHA Cohort in states with small cohort (percent)											
FL	82	0.1	−1.6	−1.3	−1.0	−0.6	−0.2	0.6	0.9	1.5	2.2
IA	26	−0.1	−1.1	−1.0	−0.9	−0.6	−0.3	0.0	0.4	0.8	1.5
MA	16	−0.4	−1.7	−1.5	−1.5	−1.1	−0.8	−0.4	0.3	0.8	2.3
NE	16	0.2	−1.6	−1.5	−1.0	−0.1	0.2	0.6	1.1	1.2	2.7
Large-volume HHA Cohort in states with small cohort (percent)											
FL	706	0.1	−1.2	−0.8	−0.5	−0.3	0.0	0.2	0.6	1.0	1.7
IA	99	−0.2	−1.4	−1.1	−0.8	−0.5	−0.3	0.0	0.3	0.7	1.2
MA	124	−0.2	−1.5	−1.1	−0.8	−0.6	−0.3	0.0	0.3	0.6	1.1
NE	45	0.0	−1.4	−0.7	−0.6	−0.2	0.1	0.3	0.7	0.9	1.2

Notes: Based on measure performance data from Performance Year 1 (January 1, 2016 to December 31, 2016), the baseline year (January 1, 2015 to December 31, 2015), and home health Medicare claims data from 2015.

TABLE 28—PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS

[Based on a 3-percent payment adjustment][1]

Cohort	Number of HHAs	Average payment adj. %	10%	20%	30%	40%	50%	60%	70%	80%	90%
Small HHA (<60 patients in CY 2015)	150	0.0	−1.6	−1.4	−1.0	−0.6	−0.3	0.2	0.7	1.2	2.2
Large HHA (≥60 patients in CY 2015)	1,465	0.0	−1.2	−0.9	−0.6	−0.3	−0.1	0.2	0.5	0.8	1.4
Low % Dually-Eligible	403	0.1	−1.1	−0.8	−0.5	−0.2	0.1	0.3	0.6	0.9	1.4
Medium % Dually-Eligible	809	−0.1	−1.3	−0.9	−0.6	−0.4	−0.1	0.1	0.4	0.6	1.0
High % Dually-Eligible	403	0.1	−1.5	−1.1	−0.8	−0.5	−0.1	0.3	0.7	1.3	2.1
Low Acuity	403	−0.3	−1.6	−1.2	−1.0	−0.7	−0.4	−0.1	0.2	0.6	1.1
Mid Acuity	809	0.0	−1.2	−0.9	−0.6	−0.4	−0.1	0.1	0.4	0.7	1.2
High Acuity	403	0.4	−1.1	−0.6	−0.3	0.0	0.3	0.6	0.9	1.4	2.1
All non-rural beneficiaries	956	0.1	−1.3	−0.9	−0.6	−0.3	0.0	0.3	0.6	1.0	1.7
Up to 35% rural beneficiaries	384	−0.1	−1.3	−0.9	−0.6	−0.3	−0.1	0.1	0.4	0.7	1.0
Over 35% rural beneficiaries	275	−0.1	−1.3	−1.0	−0.7	−0.4	−0.2	0.0	0.2	0.7	1.2
Non-Profit HHAs	295	0.1	−1.1	−0.8	−0.5	−0.2	0.0	0.3	0.6	0.9	1.3
For-Profit HHAs	1,211	0.0	−1.4	−1.0	−0.6	−0.4	−0.1	0.2	0.5	0.8	1.5
Government HHAs	109	−0.2	−1.1	−0.9	−0.8	−0.5	−0.3	0.0	0.1	0.4	1.0
Freestanding	1,460	0.0	−1.3	−0.9	−0.6	−0.4	−0.1	0.2	0.5	0.8	1.5
Facility-based	155	−0.1	−1.3	−0.9	−0.6	−0.3	−0.1	0.1	0.3	0.7	1.0

Notes:

[1] Rural beneficiaries identified based on the CBSA code reported on the claim. Acuity is based on the average case-mix weight for non-LUPA episodes. Low acuity is defined as the bottom 25 percent (among HHVBP Model participants); mid-acuity is the middle 50 percent and high acuity is the highest 25 percent. Note that at the time of the analysis, seven HHAs were missing information needed for the stratifications in this table.

TABLE 29—IMPACT OF CHANGING MINIMUM REQUIRED SAMPLE SIZE FOR HHCAHPS PERFORMANCE MEASURES ON AVERAGE TPS AND PAYMENT ADJUSTMENT RANGE*

State	HHA count	Average TPS				Minimum payment adjustment		Maximum payment adjustment	
		20 Minimum	40 Minimum	Difference	% Difference	20 Minimum (%)	40 Minimum (%)	20 Minimum (%)	40 Minimum (%)
Larger-volume HHAS									
AZ	107	42.160	42.924	0.765	1.8	−2.3	−2.3	2.8	2.7
FL	706	39.110	39.731	0.621	1.6	−2.5	−2.5	3.0	3.0
IA	99	43.191	43.186	−0.005	0.0	−2.1	−2.1	2.0	2.4
MA	124	41.380	41.256	−0.125	−0.3	−2.6	−2.5	2.4	2.5
MD	50	49.179	49.549	0.370	0.7	−1.3	−1.3	2.0	2.0
NC	163	45.798	46.187	0.390	0.8	−2.1	−2.1	2.9	2.9
NE	45	42.252	43.028	0.776	1.8	−2.1	−2.1	2.6	2.4
TN	119	47.462	47.540	0.078	0.2	−2.5	−2.3	1.6	2.1
WA	57	51.840	51.712	−0.128	−0.2	−1.5	−1.6	1.1	1.1
Total	1,470								
Smaller-volume HHAS									
AZ	7	36.706	36.706	0.000	0.0	−1.8	−1.9	1.0	1.0
FL	82	42.810	42.810	0.000	0.0	−2.3	−2.3	2.9	2.9
IA	26	38.663	38.663	0.000	0.0	−1.8	−1.8	2.2	2.2
MA	16	25.004	25.004	0.000	0.0	−1.7	−1.7	2.3	2.3

TABLE 29—IMPACT OF CHANGING MINIMUM REQUIRED SAMPLE SIZE FOR HHCAHPS PERFORMANCE MEASURES ON AVERAGE TPS AND PAYMENT ADJUSTMENT RANGE*—Continued

State	HHA count	Average TPS				Minimum payment adjustment		Maximum payment adjustment	
		20 Minimum	40 Minimum	Difference	% Difference	20 Minimum (%)	40 Minimum (%)	20 Minimum (%)	40 Minimum (%)
MD	1	61.135	61.135	0.000	0.0	0.8	0.8	0.8	0.8
NE	16	37.485	37.485	0.000	0.0	−2.6	−2.6	3.0	3.0
TN	4	39.983	39.983	0.000	0.0	−1.8	−1.8	1.9	1.9
Total	152								
Total	1,622								

*OASIS, claims and HHCAHPS measures run from January 1, 2016 to December 31, 2016 for Performance Year 1. The baseline year is January 1, 2015 to December 31, 2015. Payment based on 2015 Medicare home health claims data. North Carolina and Washington did not have any smaller-volume HHAs.

3. HH QRP

Failure to submit data required under section 1895(b)(3)(B)(v) of the Act will result in the reduction of the annual update to the standard federal rate for discharges occurring during such fiscal year by 2 percentage points for any HHA that does not comply with the requirements established by the Secretary. At the time that this analysis was prepared, 1,206, or approximately 9.9 percent, of the 12,149 active Medicare-certified HHAs, did not receive the full annual percentage increase for CY 2017 because they did not meet the requirements of the HH QRP. Information is not available to determine the precise number of HHAs that will not meet the requirements to receive the full annual percentage increase for the CY 2018 payment determination.

As noted in section VII.B. of this final rule, the net effect of our provisions is an estimated decrease in cost associated with changes to the HH QRP on average of $12,016.33 per HHA annually, or $145,986,343.50 for all HHAs annually.

Comment: A commenter stated that CMS had underestimated the cost of changes to the OASIS, adding that CMS had not considered training and opportunity costs related to data set changes.

Response: Our burden estimates reflect the burden on data submission. We intend to provide educational resources on the OASIS changes, including training and guidance, to providers at no cost.

D. Accounting Statements and Tables

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 30, we have prepared an accounting statement showing the classification of the transfers and costs associated with the HH PPS provisions of this final rule. Table 30 provides our best estimate of the decrease in Medicare payments under the HH PPS as a result of the changes presented in this final rule for the HH PPS provisions in CY 2018. Table 31 provides our best estimates of the changes associated with the HH QRP provisions.

TABLE 30—ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2017 TO 2018

Category	Transfers
Annualized Monetized Transfers.	−$80 million.
From Whom to Whom?	Federal Government to HHAs.

TABLE 31—ACCOUNTING STATEMENT: HH QRP CLASSIFICATION OF ESTIMATED COSTS, FROM CY 2018 TO 2019

Category	Costs
Annualized Monetized Net Burden for HHAs Submission of the OASIS	−$146.0 million.

E. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, entitled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), was issued on January 30, 2017. This final rule is considered an E.O. 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in the rule's PRA and economic analysis.

F. Conclusion

1. HH PPS

In conclusion, we estimate that the net impact of the HH PPS policies in this final rule is a decrease of 0.4 percent, or $80 million, in Medicare payments to HHAs for CY 2018. The −$80 million impact reflects the effects of a 0.5 percent reduction in payments due to the sunset of the rural add-on provision ($100 million decrease), a 1 percent CY 2018 HH payment update percentage ($190 million increase), and a 0.9 percent decrease in payments due to the 0.97 percent reduction to the national, standardized 60-day episode payment rate in CY 2017 to account for nominal case-mix growth ($170 million decrease).

2. HHVBP Model

In conclusion, we estimate there will be no net impact (to include either a net increase or reduction in payments) in this final rule in Medicare payments to HHAs competing in the HHVBP Model for CY 2018. However, the overall economic impact of the HHVBP Model is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the home health industry over the life of the HHVBP Model.

3. HH QRP

In conclusion, for CY 2019 we estimate that there will be a total decrease in costs of $145,986,343.50 associated with the changes to the HH QRP.

This analysis, together with the remainder of this preamble, provides afinal Regulatory Flexibility Analysis.

VIII. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of states, local or tribal governments.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

List of Subjects for 42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR part 484 as set forth below:

PART 484—HOME HEALTH SERVICES

■ 1. The authority citation for part 484 continues to read as follows:

Authority: Secs 1102 and 1871 of the Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

■ 2. Section 484.250 is amended by revising paragraph (a)(1) and adding paragraphs (d) through (f) to read as follows:

§ 484.250 Patient assessment data.

(a) * * *

(1) The OASIS data described at § 484.55(b) and (d) for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484. 230, 484.235, and 484.240; and to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

* * * * *

(d) *Exceptions and extension requirements.* (1) A HHA may request and CMS may grant exceptions or extensions to the reporting requirements under section 1895(b)(3)(B)(v) of the Act for one or more quarters, when there are certain extraordinary circumstances beyond the control of the HHA.

(2) A HHA may request an exception or extension within 90 days of the date that the extraordinary circumstances occurred by sending an email to CMS HHAPU reconsiderations at *HHAPUReconsiderations@cms.hhs.gov* that contains all of the following information:

(i) HHA CMS Certification Number (CCN).

(ii) HHA Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address (the address must be a physical address, not a post office box).

(v) HHA's reason for requesting the exception or extension.

(vi) Evidence of the impact of extraordinary circumstances, including, but not limited to, photographs, newspaper, and other media articles.

(vii) Date when the HHA believes it will be able to again submit data under section 1895(b)(3)(B)(v) of the Act and a justification for the proposed date.

(3) Except as provided in paragraph (d)(4) of this section, CMS will not consider an exception or extension request unless the HHA requesting such exception or extension has complied fully with the requirements in this paragraph (d).

(4) CMS may grant exceptions or extensions to HHAs without a request if it determines that one or more of the following has occurred:

(i) An extraordinary circumstance affects an entire region or locale.

(ii) A systemic problem with one of CMS's data collection systems directly affected the ability of a HHA to submit data under section 1895(b)(3)(B)(v) of the Act.

(e) *Reconsideration.* (1) HHAs that do not meet the quality reporting requirements under section 1895(b)(3)(B)(v) of the Act for a program year will receive a letter of non-compliance via the United States Postal Service and notification in CASPER. An HHA may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

(2) Reconsideration requests may be submitted to CMS by sending an email to CMS HHAPU reconsiderations at *HHAPureConsiderations@cms.hhs.gov* containing all of the following information:

(i) HHA CCN.

(ii) HHA Business Name.

(iii) HHA Business Address.

(iv) CEO or CEO-designated personnel contact information including name, telephone number, title, email address, and mailing address (the address must be a physical address, not a post office box).

(v) CMS identified reason(s) for non-compliance from the non-compliance letter.

(vi) Reason(s) for requesting reconsideration, including all supporting documentation.

(3) CMS will not consider an exception or extension request unless the HHA has complied fully with the requirements in paragraph (e)(2) of this section.

(4) CMS will make a decision on the request for reconsideration and provide notice of the decision to the HHA through CASPER and via letter sent via the United States Postal Service.

(f) *Appeals.* (1) A HHA that is dissatisfied with CMS' decision on a request for reconsideration submitted under paragraph (e) of this section may file an appeal with the Provider Reimbursement Review Board (PRRB) under 42 CFR part 405, subpart R.

(2) [Reserved]

■ 3. Section 484.305 is amended by revising the definition of ''Applicable measure'' to read as follows:

§ 484.305 Definitions.

* * * * *

Applicable measure means a measure for which a competing HHA has provided a minimum of—

(1) Twenty home health episodes of care per year for the OASIS-based measures;

(2) Twenty home health episodes of care per year for the claims-based measures; or

(3) Forty completed surveys for the HHCAHPS measures.

* * * * *

Dated: October 23, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 24, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017–23935 Filed 11–1–17; 4:15 pm]

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