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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–0889; Product Identifier 2009–NE–35–AD; Amendment 39–19305; AD 2018–12–01]

RIN 2120–AA64

Airworthiness Directives; Safran Helicopter Engines, S.A., Turboshaft Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2012–03–11 for all Safran Helicopter Engines, S.A., Arriel 2B and 2B1 turboshaft engines. AD 2012–03–11 required checking the transmissible torque between the low-pressure (LP) pump impeller and the high-pressure (HP) pump shaft on the HP/LP pump and metering valve assembly, hereafter referred to as the hydro-mechanical metering unit (HMU). Since we issued AD 2012–03–11, the manufacturer determined that incorporating Modification TU 178 is a more effective method to reduce the risk of uncoupling between the LP fuel pump impeller and the HP fuel pump shaft than the prior Modification TU 147. This AD requires inspection and possible replacement of the HMU. This AD was prompted by three cases of uncoupling of the HMU LP fuel pump impeller and the HP fuel pump shaft since AD 2012–03–11 was issued. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 12, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of March 11, 2010 (75 FR 5689, February 4, 2010).

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of March 20, 2012 (77 FR 8092, February 14, 2012).

ADDRESSES: For service information identified in this final rule, contact Safran Helicopter Engines, S.A., 40220 Tarnos, France; phone: (33) 05 59 74 40 00; fax: (33) 05 59 74 45 15. 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 781–238–7759. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2009–0889.

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–2009–0889; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information, regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is Document Operations, 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: John Frost, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7756; fax: 781–238–7199; email: *john.frost@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2012–03–11, Amendment 39–16953 (77 FR 8092, February 14, 2012), (''AD 2012–03–11''). AD 2012–03–11 applied to all Safran Helicopter Engines, S.A., Arriel 2B and 2B1 turboshaft engines. The NPRM published in the **Federal Register** on October 6, 2017 (82 FR 46727). The NPRM was prompted by instances of uncoupling between the LP fuel pump impeller and the HP fuel pump shaft. The NPRM proposed to require inspection and, depending on the results of the inspection, possible replacement of the HMU. The NPRM also proposed to require replacement of pre-Modification TU 178 HMUs with an HMU incorporating Modification TU 178 within 2,200 engine flight hours or 72 months, whichever occurs first, after the effective date of this AD. We are issuing this AD to address the unsafe condition on these products.

Comments

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

Request To Clarify Reason for AD

An individual commenter questioned how the new modification in this AD is better and different from the actions required by the previous AD 2012–03–11.

AD 2012–03–11 required a check of the transmissible torque between the LP fuel pump impeller and the HP fuel pump shaft and replacement of the HMU if it does not pass the torque check. Since we issued AD 2012–03–11, Safran Service Bulletin (SB) 292 73 2178, Version A, dated April 1, 2015 introduced Modification TU 178. This AD accepts Modification TU 178 as a more robust drive link between the LP fuel pump impeller and the HP fuel pump shaft that ensures the LP impeller pump is driven even if the link with the drive shaft loosens. This AD requires installation of a Modification TU 178 HMU for any HMU that fails the torque sensor check and as a mandatory terminating action for the inspections required by this AD, as well as purging the fleet of the pre- and post-TU 147 configuration parts. We did not change this AD.

Clarification to Service Information for Torque Check

We updated paragraphs (g)(1)(i) and (ii) of this AD to clarify that only paragraph 2.A, rather than paragraph 2, in Turbomeca Alert Mandatory SB (MSB) A292 73 2830, Version B, dated July 10, 2009, and Turbomeca Alert MSB A292 73 2836, Version A, dated August 17, 2010, is used to perform the torque check.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

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

Related Service Information Under 1 CFR Part 51

We reviewed Turbomeca, S.A., Alert MSB A292 73 2830, Version B, dated July 10, 2009, and Alert MSB A292 73 2836, Version A, dated August 17, 2010. Turbomeca Alert MSB A292 73 2830, Version B, describes procedures for inspecting pre-Modification TU 147 HMUs. Turbomeca Alert MSB A292 73 2836, Version A, dated August 17, 2010, describes procedures for inspecting HMUs that have incorporated Modification TU 147. 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.

Other Related Service Information

We reviewed Safran Helicopter Engines MSB 292 73 2178, Version B, dated March 23, 2017. Safran Helicopter Engines MSB 292 73 2178, Version B, describes HMU improvements that includes a reinforced drive link between the LP impeller and HP fuel pump shaft (Modification TU 178). Safran Helicopter Engines has also issued MSB A292 73 2830, Version C; and A292 73 2836, Version B, both dated April 5, 2017, which exempt HMUs incorporating Modification TU 178 from the inspections previously recommended by Safran Helicopter Engines.

Costs of Compliance

We estimate that this AD affects 417 engines installed on helicopters 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
Remove and replace the HP/LP fuel pump metering unit.	2 work-hours × $85 per hour = $170	$17,400	$17,570	$7,326,690

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

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

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

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

(3) Will not affect intrastate aviation in Alaska, 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 removing Airworthiness Directive (AD) 2012–03–11, Amendment 39–16953 (77 FR 8092, February 14, 2012), and adding the following new AD:

2018–12–01 Safran Helicopter Engines (Type Certificate previously held by Turbomeca, S.A.): Amendment 39–19305; Docket No. FAA–2009–0889; Product Identifier 2009–NE–35–AD.

(a) Effective Date

This AD is effective September 12, 2018.

(b) Affected ADs

This AD replaces AD 2012–03–11, Amendment 39–16953 (77 FR 8092, February 14, 2012).

(c) Applicability

This AD applies to Safran Helicopter Engines, S.A., Arriel 2B and 2B1 turboshaft engines, except those incorporating Modification TU 178.

(d) Subject

Joint Aircraft System Component (JASC) Code 7300, Engine Fuel and Control.

(e) Unsafe Condition

This AD was prompted by analysis that indicated the modification of an engine to incorporate Modification TU 178 provides a more effective method than Modification TU

147 to reduce the risk of uncoupling between the low-pressure (LP) fuel pump impeller and the high-pressure (HP) fuel pump shaft of the HP/LP pump and hydro-mechanical metering unit (HMU). We are issuing this AD to prevent failure of the HMU. The unsafe condition, if not corrected, could result in failure of the engine, in-flight shutdown, and loss of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Check the transmissible torque between the LP fuel pump impeller and the HP fuel pump shaft as follows:

(i) For pre-Modification TU 147 HMUs, check the torque before accumulating 500 engine flight hours (FHs) since March 11, 2010 or before the next flight after the effective date of this AD, whichever occurs later. Use Paragraph 2.A. of Turbomeca Alert Mandatory Service Bulletin (MSB) A292 73 2830, Version B, dated July 10, 2009 to do the check.

(ii) For HMUs that incorporated Modification TU 147 on or before March 31, 2010, and those HMUs not listed in Figure 2 or 3 of Turbomeca Alert MSB A292 73 2836, Version A, dated August 17, 2010, check the torque before the next flight after the effective date of this AD. Use Paragraph 2.A. of Turbomeca Alert MSB A292 73 2836, Version A, dated August 17, 2010, to do the check.

(2) If the HMU does not pass the torque check, replace the HMU with a post-Modification TU 178 HMU before the next flight after the effective date of this AD.

(h) Mandatory Terminating Action

Within 2,200 engine FHs or 72 months after the effective date of this AD, whichever occurs first, replace any pre-Modification TU 178 HMU with a post-Modification TU 178 configuration HMU.

(i) Installation Prohibition

After the effective date of this AD, do not install a pre-Modification TU 178 HMU on engines incorporating a post-Modification TU 178 HMU.

(j) 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 (k)(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.

(k) Related Information

(1) For more information about this AD, contact John Frost, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7756; fax: 781–238–7199; email: *john.frost@faa.gov.*

(2) Refer to European Aviation Safety Agency (EASA) AD 2017–0102, dated June 13, 2017, for more information. You may examine the EASA AD on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2009–0889.

(l) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on March 11, 2010 (75 FR 5689, February 4, 2010).

(i) Turbomeca Alert Mandatory Service Bulletin (MSB) No. A292 73 2830, Version B, dated July 10, 2009.

(ii) Reserved.

(4) The following service information was approved for IBR on March 20, 2012 (77 FR 8092, February 14, 2012).

(i) Turbomeca Alert MSB No. A292 73 2836, Version A, dated August 17, 2010.

(ii) Reserved.

(5) For Safran Helicopter Engines, S.A, service information identified in this AD, contact Safran Helicopter Engines, S.A., 40220 Tarnos, France; phone: (33) 05 59 74 40 00; fax: (33) 05 59 74 45 15.

(6) 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 781–238–7759.

(7) 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 July 31, 2018.

Robert J. Ganley,

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

[FR Doc. 2018–16652 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0640; Product Identifier 2018–NM–075–AD; Amendment 39–19343; AD 2018–16–03]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for all Airbus SAS Model A319–133 airplanes and Model A321–232 airplanes. This AD requires modification and re-identification, or replacement, of certain engine fan cowl doors (FCDs) and installation of a placard in the flight deck. This AD was prompted by reports of in-service engine FCD losses, and the development of a new FCD front latch and keeper assembly that addresses this unsafe condition. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD becomes effective August 23, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 3, 2017 (82 FR 29371, June 29, 2017).

We must receive comments on this AD by September 24, 2018.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email

account.airworth-eas@airbus.com; internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0640.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0640; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

SUPPLEMENTARY INFORMATION:

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2016–0053, dated March 14, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for all Airbus Model A319–131, –132, and –133 airplanes, Model A320–231, –232, and –233 airplanes, and Model A321–131, –231, and –232 airplanes. The MCAI states:

> Fan Cowl Door (FCD) losses during take-off were reported on aeroplanes equipped with IAE V2500 engines. Prompted by these occurrences, DGAC [Direction Générale de l'Aviation Civile] France issued AD 2000–444–156(B), mandating FCD latch improvements. This [DGAC] AD was later superseded by [DGAC] AD 2001–381(B) [which corresponds to FAA AD 2003–18–06, Amendment 39–13297 (68 FR 53501, September 11, 2003)], requiring installation of additional fan cowl latch improvement by installing a hold open device.
>
> Since that [DGAC] AD was issued, further FCD in flight losses were experienced in service. Investigations confirmed that in all cases, the fan cowls were opened prior to the flight and were not correctly re-secured. During the pre-flight inspection, it was then not detected that the FCD were not properly latched.
>
> This condition, if not corrected, could lead to in-flight loss of a FCD, possibly resulting in damage to the aeroplane and/or injury to persons on the ground.
>
> Prompted by these recent events, new FCD front latch and keeper assembly were developed, having a specific key necessary to un-latch the FCD. This key cannot be removed unless the FCD front latch is safely closed. The key, after removal, must be stowed in the flight deck at a specific location, as instructed in the applicable Aircraft Maintenance Manual. Applicable Flight Crew Operating Manual has been amended accordingly. After modification, the FCD is identified with a different Part Number (P/N).
>
> For the reasons described above, this [EASA] AD retains the requirements of DGAC AD 2001–381(B), which is superseded, and requires modification and re-identification of FCD.

You may examine the MCAI on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0640.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A320–71–1069, Revision 01, including Appendix 01, dated April 28, 2016. This service information describes procedures for modifying the engine FCDs, installing placards, and re-identifying the FCDs with new part numbers. 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 another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are issuing this AD because we evaluated all pertinent information and determined the unsafe condition exists and is likely to exist or develop on other products of these same type designs.

Differences Between This AD and the MCAI or Service Information

The MCAI applies to Airbus SAS Model A319–131 and –132 airplanes; Model A320–231, –232, and –233 airplanes; and Model A321–131 and –231 airplanes, in addition to Model A319–133 airplanes and Model A321–232 airplanes. The unsafe condition on Model A319–131 and –132 airplanes; Model A320–231, –232, and –233 airplanes; and Model A321–131 and –231 airplanes is already addressed in AD 2017–13–10, Amendment 39–18940 (82 FR 29371, June 29, 2017); therefore this AD only applies to Model A319–133 airplanes and Model A321–232 airplanes.

FAA's Determination of the Effective Date

There are currently no domestic operators of 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.

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–2018–0640; Product Identifier 2018–NM–075–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 based on those comments.

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

Costs of Compliance

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

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product
6 work-hours × $85 per hour = $510	$4,813	$5,323

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 transport category airplanes to the Director of the System Oversight 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 that 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):

2018–16–03 Airbus SAS: Amendment 39–19343; Docket No. FAA–2018–0640; Product Identifier 2018–NM–075–AD.

(a) Effective Date

This AD becomes effective August 23, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A319–133 airplanes and Model A321–232 airplanes, certificated in any category, all manufacturer serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 71, Powerplant.

(e) Reason

This AD was prompted by reports of in-service engine fan cowl door (FCD) losses, and the development of a new FCD front latch and keeper assembly that addresses this unsafe condition. We are issuing this AD to address in-flight loss of an engine FCD and possible consequent damage to the airplane.

(f) Compliance

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

(g) Modification

Within 36 months after the effective date of this AD, do the actions specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–71–1069, Revision 01, including Appendix 01, dated April 28, 2016.

(1) Modify the left-hand and right-hand engine FCDs on engines 1 and 2.

(2) Install a placard that specifies the FCD keys stowage location in the flight deck on the box located at the bottom of panel 120VU or at the bottom of the coat stowage, as applicable to airplane configuration.

(3) Re-identify both engine FCDs with the new part numbers, as specified in figure 1 to paragraphs (g), (j), and (k) of this AD.

Figure 1 to paragraphs (g), (j), and (k) of this AD – *FCD Part Number Change*

Door Position	Old Part Number	New Part Number
Left-Hand Side	740-4000-501	740-4000-9501
	740-4000-503	740-4000-9503
	745-4000-501	745-4000-513
	745-4000-503	745-4000-515
	745-4000-505	745-4000-517
Right-Hand Side	740-4000-502	740-4000-9502
	740-4000-504	740-4000-9504
	740-4000-506	740-4000-9506
	740-4000-508	740-4000-9508
	745-4000-502	745-4000-9502
	745-4000-504	745-4000-9504
	745-4000-506	745-4000-9506
	745-4000-508	745-4000-514
	745-4000-510	745-4000-516
	745-4000-512	745-4000-518

(h) Missing FCD Keys or Placard

Flights with one or both FCD keys missing from the stowage location in the fight deck, or with the placard (that specifies the FCD keys stowage location) missing or damaged, are permitted for a period not to exceed 10 calendar days from the date of discovery.

(i) Alternative Location of FCD Keys and Placard

As an option to paragraph (g)(2) of this AD, an alternative location for the key stowage in the flight deck and installation of a placard for identification of that stowage location are permitted as specified in the operator's FAA-accepted maintenance or inspection program, provided the keys can be retrieved from that flight deck location when needed and the placard installation is done within 36 months after the effective date of this AD.

(j) Optional Compliance by Replacement or Installation

(1) Replacing an engine FCD having a part number listed as ''Old Part Number'' in figure 1 to paragraphs (g), (j), and (k) of this AD with an FCD having the corresponding part number listed as ''New Part Number'' in figure 1 to paragraphs (g), (j), and (k) of this AD is an acceptable method of compliance with the requirements of paragraphs (g)(1) and (g)(3) of this AD for that engine FCD only.

(2) An airplane on which Airbus Modification 157516 has been embodied in production is compliant with the requirements of paragraphs (g)(1) and (g)(3) of this AD, provided no engine FCD having a part number identified as ''Old Part Number'' in figure 1 to paragraphs (g), (j), and (k) of this AD is installed on that airplane.

(3) An airplane on which Airbus Modification 157718 has been embodied in production is compliant with the requirements of paragraph (g)(2) of this AD.

(4) Installation on an engine of a right-hand and left-hand engine FCD having a part number approved after the effective date of this AD is a method of compliance with the requirements of paragraphs (g)(1) and (g)(3) of this AD for that engine only, provided the part number is approved, and the installation is accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Parts Installation Limitations

(1) For an airplane with an engine FCD installed having a part number identified as ''Old Part Number'' in figure 1 to paragraphs (g), (j), and (k) of this AD: After modification of that airplane as required by paragraph (g) of this AD, do not install an engine FCD, having a part number identified as ''Old Part Number'' in figure 1 to paragraphs (g), (j), and (k) of this AD.

(2) For an airplane that does not have an engine FCD installed having a part number identified as ''Old Part Number'' in figure 1 to paragraphs (g), (j), and (k) of this AD: On or after the effective date of this AD, do not install an engine FCD having a part number identified as ''Old Part Number'' in figure 1 to paragraphs (g), (j), and (k) of this AD.

(l) Credit for Previous Actions

This paragraph provides credit for actions required by paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Airbus Service Bulletin A320–71–1069, dated December 18, 2015.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (n)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2016–0053, dated March 14, 2016, for related information. You may examine the MCAI on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0640.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards

Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

(3) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (o)(4) and (o)(5) of this AD.

(o) Material Incorporated by Reference

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

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

(3) The following service information was approved for IBR on August 3, 2017 (82 FR 29371, June 29, 2017).

(i) Airbus Service Bulletin A320–71–1069, Revision 01, including Appendix 01, dated April 28, 2016.

(ii) Reserved.

(4) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EIAS, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.*

(5) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

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

Issued in Des Moines, Washington, on July 23, 2018.

James Cashdollar,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–16576 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0276; Product Identifier 2017–NM–079–AD; Amendment 39–19346; AD 2018–16–06]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain The Boeing Company Model 747–100, –100B, –100B SUD, –200B, –200C, –200F, –300, –400, –400D, 747SP, and 747SR, and 747–8 series airplanes. This AD was prompted by reports indicating that additional areas of Boeing Material Specification (BMS) 8–39 flexible urethane foam were found during an inspection required by a related AD. This AD requires inspecting for BMS 8–39 flexible urethane foam insulation in the floor panel assemblies and the power drive unit (PDU) cover assemblies, doing applicable on-condition actions, modifying certain dripshields, and replacing BMS 8–39 foam strips on certain dripshields with BMS 8–371 foam strips. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 12, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of September 12, 2018.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0276.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0276; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is Docket Operations, 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: Scott Craig, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3566; email: *Michael.S.Craig@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 certain The Boeing Company Model 747–100, –100B, –100B SUD, –200B, –200C, –200F, –300, –400, –400D, 747SP, and 747SR, and 747–8 series airplanes. The NPRM published in the **Federal Register** on April 17, 2018 (83 FR 16796). The NPRM was prompted by reports indicating that additional areas of BMS 8–39 flexible urethane foam were found during an inspection required by a related AD. The NPRM proposed to require inspecting for BMS 8–39 flexible urethane foam insulation in the floor panel assemblies and the PDU cover assemblies, doing applicable on-condition actions, modifying certain dripshields, and replacing BMS 8–39 foam strips on certain dripshields with BMS 8–371 foam strips.

We are issuing this AD to address BMS 8–39 flexible urethane foam in certain areas, which, if exposed to an ignition source, could cause an uncontrolled fire leading to loss of control of the airplane.

Comments

We gave the public the opportunity to participate in developing this final rule. We have considered the comment received. Boeing stated that it had no objection to the NPRM.

Conclusion

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

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

Related Service Information Under 1 CFR Part 51

We reviewed the following Boeing service information.

- Boeing Special Attention Service Bulletin 747–53–2877, dated August 5, 2014, which describes procedures for performing a general visual inspection for BMS 8–39 flexible urethane foam insulation in the floor panel assemblies and the PDU cover assemblies, and applicable on-condition actions.
- Boeing Special Attention Service Bulletin 747–25–3646, Revision 1, dated

August 2, 2017, which describes procedures for replacing BMS 8–39 foam strips with BMS 8–371 foam strips on certain dripshields.

• Boeing Special Attention Service Bulletin 747–25–3692, dated June 22, 2016, which describes procedures for modifying and replacing BMS 8–39 foam strips with BMS 8–371 foam strips on certain dripshields.

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 87 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 and replacement	25 work-hour × $85 per hour = $2,125.	Up to $184,460	Up to $186,585	Up to $6,157,305 (33 airplanes affected).
Modification and installation of the dripshields.	10 work-hours × $85 per hour = $850.	Unavailable [1]	$850	$44,200 (52 airplanes affected).
Replacement of the foam on the dripshields.	8 work-hours × $85 per hour = $680.	Unavailable [1]	$680	$4,760 (7 airplanes affected).

[1] We have received no definitive data that would enable us to provide parts cost estimates as the parts and materials are to be supplied by the operator for the actions specified in this AD.

We have received no definitive data that would enable us to provide cost estimates for the on-condition actions specified in this AD.

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all available costs in our cost estimate.

Authority for This Rulemaking

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

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 transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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

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

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

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

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

2018–16–06 The Boeing Company: Amendment 39–19346; Docket No. FAA–2018–0276; Product Identifier 2017–NM–079–AD.

(a) Effective Date

This AD is effective September 12, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company airplanes, certificated in any category, as identified in paragraphs (c)(1), (c)(2), and (c)(3) of this AD.

(1) Model 747–100, –100B, –100B SUD, –200B, –200C, –200F, –300, –400, –400D, 747SP, and 747SR series airplanes, as identified in Boeing Special Attention Service Bulletin 747–53–2877, dated August 5, 2014.

(2) Model 747–400, –400D, and 747–8 series airplanes, as identified in Boeing Special Attention Service Bulletin 747–25–3646, Revision 1, dated August 2, 2017.

(3) Model 747–100, –100B, –100B SUD, –200B, –300, 747SP, and 747SR series airplanes, as identified in Boeing Special Attention Service Bulletin 747–25–3692, dated June 22, 2016.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings; 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports indicating that additional areas of Boeing Material Specification (BMS) 8–39 flexible urethane foam were found during an inspection required by a related AD. The degradation of the foam increases the

potential for an uncontrolled fire below the passenger compartment floor and other locations outside the areas covered by smoke detection and fire protection systems. We are issuing this AD to detect and replace BMS 8–39 flexible urethane foam in certain areas, which, if exposed to an ignition source, could cause an uncontrolled fire leading to loss of control of the airplane.

(f) Compliance

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

(g) Required Actions

Within 72 months after the effective date of this AD, do all actions identified as ''RC'' (required for compliance) in, and in accordance with, the Accomplishment Instructions of the applicable service information identified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD.

(1) For airplanes identified in paragraph (c)(1) of this AD: Boeing Special Attention Service Bulletin 747–53–2877, dated August 5, 2014.

(2) For airplanes identified in paragraph (c)(2) of this AD: Boeing Special Attention Service Bulletin 747–25–3646, Revision 1, dated August 2, 2017.

(3) For airplanes identified in paragraph (c)(3) of this AD: Boeing Special Attention Service Bulletin 747–25–3692, dated June 22, 2016.

(h) Credit for Previous Actions

This paragraph provides credit for the actions specified in paragraph (g)(2) of this AD, if those actions were performed before the effective date of this AD using Boeing Special Attention Service Bulletin 747–25–3646, dated June 19, 2015.

(i) Alternative Methods of Compliance (AMOCs)

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

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

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

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

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

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(j) Related Information

(1) For more information about this AD, contact Scott Craig, Aerospace Engineer, Cabin Safety and Environmental Systems Section, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3566; email: *Michael.S.Craig@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (k)(3) and (k)(4) of this AD.

(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) Boeing Special Attention Service Bulletin 747–25–3646, Revision 1, dated August 2, 2017.

(ii) Boeing Special Attention Service Bulletin 747–25–3692, dated June 22, 2016.

(iii) Boeing Special Attention Service Bulletin 747–53–2877, dated August 5, 2014.

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

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

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

Issued in Des Moines, Washington, on July 23, 2018.

James Cashdollar,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–16509 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0077; Product Identifier 2017–NM–126–AD; Amendment 39–19352; AD 2018–16–12]

RIN 2120–AA64

Airworthiness Directives; Airbus Airplanes

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

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for certain Airbus Model A319 and A320 series airplanes; and A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. This AD was prompted by reports of battery retaining rod failures due to quality defects of the material used during parts manufacturing. This AD requires a detailed inspection of the battery support assemblies to identify the battery retaining rod manufacturer, replacement of the battery retaining rods with serviceable battery retaining rods if necessary, and the addition of the applicable service information label on each battery retaining rod if necessary. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 12, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of September 12, 2018.

ADDRESSES: For service information identified in this final rule, contact Airbus, Airworthiness Office—EIAS, 2 Rond Point Emile Dewoitine, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.* You may view this referenced service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for

and locating Docket No. FAA–2018–0077.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0077; 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 regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone 800–647–5527) is Docket 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: Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Airbus Model A319 and A320 series airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The NPRM published in the **Federal Register** on February 12, 2018 (83 FR 5960) (''the NPRM'').

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2017–0161R1, dated September 19, 2017; corrected September 20, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus Model A319 and A320 series airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The MCAI states:

> Several occurrences have been reported of battery rod failures on certain Airbus aeroplanes. Subsequent examination of broken rod parts determined that these failures were due to quality defects of the material used during parts manufacturing. Each battery is secured on an aeroplane by two rods. Failure of one rod, in case of severe turbulence during flight or hard landing, could lead to battery displacement, or roll on the remaining rod side, up to a point where the remaining rod could be disengaged. The battery could ultimately detach from its housing and damage relays, connectors, contactor boxes, air ducts and surrounding structure.
>
> This condition, if not detected and corrected, could lead to the loss of the normal electrical generation not followed by an automatic recovery of essential network.
>
> To address this potential unsafe condition, Airbus issued Alert Operators Transmission (AOT) A92N001–16 (later revised) and EASA issued AD 2016–0204 [which corresponds to FAA AD 2016–25–24 (81 FR 90958, December 16, 2016) (''AD 2016–25–24'')] requiring repetitive general visual inspections (GVI) of the four battery rods (two per battery), and, in case of findings, replacement of battery rods.
>
> Since that [EASA] AD was issued, the manufacturer of the broken battery retaining rods has been identified, which allows proper identification of the affected parts and their withdrawal from service. Consequently, Airbus issued [service bulletin] SB A320–92–1116 and SB A320–92–1118 to provide the necessary instructions to the affected operators. No rods delivered as spare parts are affected by the manufacturing issue.
>
> For the reason described above, this [EASA] AD retains the requirements of EASA AD 2016–0204, which is superseded, and requires replacement of battery retaining rods depending on manufacturer identification. This [EASA] AD also provides a terminating action for the repetitive inspections.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0077.

Comments

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

Request To Revise the Compliance Time

Air Line Pilots Association, International (ALPA) requested that we revise the compliance time. ALPA stated that the proposed AD specifies a compliance time of within 24 months after the AD effective date. ALPA commented that because the proposed AD is related to quality, it believes this compliance time is insufficient. ALPA also commented that since the issuance of the manufacturer's service information, operators have had over 12 months to comply with the required corrective actions. ALPA stated that, additionally, the time estimated to complete the inspections and replacement of the affected parts is minimal. ALPA recommended that we consider a compliance time of within 12 months after the AD effective date.

We disagree with the commenter. While some U.S. operators have had time to plan and schedule the work contained in the Airbus service information, there is no obligation for any U.S. operator to perform those actions without a regulatory requirement. Therefore, we agree with EASA's decision to allow a 24-month compliance time to plan, schedule, and accomplish the actions necessary to remove the unsafe condition. If additional data are presented that would justify a shorter compliance time, we may consider further rulemaking on this issue. We have not changed this AD in this regard.

Request To Revise the Definition of Serviceable Rod

Delta Airlines (DAL) requested that we revise the definition of a serviceable rod in paragraph (g) of the proposed AD. DAL stated to add an additional paragraph that specifies:

> A battery retaining rod with an ISB [inspection service bulletin] label installed in accordance with the accomplishment instructions of Airbus Service Bulletin A320–92–1116, Revision 00, dated January 31, 2017 (for Airbus Model A319 and A320 series airplanes; and A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes); or Airbus Service Bulletin A320–92–1118, Revision 00, dated January 31, 2017 (for Airbus Model A320–251N and –271N airplanes).

We partially agree with revising the definition of a serviceable rod in paragraph (g) of this AD. We have determined that the installation of the ISB label does not affect the unsafe condition and have removed the requirement from this AD. We have coordinated this changed with EASA. Furthermore, we have revised paragraph (g) of this AD to clarify that the battery retaining rod used for replacement must be positively identified as a serviceable battery retaining rod.

Request for Clarification Regarding Manufacturer Serial Numbers

United Airlines (UAL) requested clarification regarding manufacturer serial numbers in the proposed AD. UAL stated that the manufacturer serial numbers are not applicable to the proposed AD as identified in Airbus Service Bulletin A320–92–1116, Revision 00, dated January 31, 2017, and Airbus Service Bulletin A320–92–1118, Revision 00, dated January 31, 2017. UAL stated that, although the machining that caused the failure mode is identified in the service information, the same battery retaining rod part number used in pre- and post-service information remains unchanged. UAL commented that it is unclear whether a serial number, batch number, or date exists for those battery retaining rods. UAL also asked how were the battery

retaining rod spares deemed to be serviceable in paragraph (g)(1) of the proposed AD?

We agree to provide clarification for the commenter. According to EASA AD 2017–0161R1, dated September 19, 2017; corrected September 20, 2017; no spares with manufacturing defects were delivered by Airbus. Only a certain batch of defective parts were installed in production on certain manufacturer serial numbers as specified in Airbus Service Bulletin A320–92–1116, Revision 00, dated January 31, 2017; and Airbus Service Bulletin A320–92–1118, Revision 00, dated January 31, 2017. If an operator does not have an airplane affected as specified in the service information, then there is no concern relative to defective spare parts. We have not changed this AD in this regard.

Request To Clarify the Identification of Affected Parts

DAL requested that we clarify the identification of the affected parts in paragraph (h) of the proposed AD. DAL stated that the detailed inspection to identify the battery retaining rod manufacturer should be of the battery support assemblies and not the battery retaining rods.

We agree with the commenter's request. We have revised paragraph (h) of this AD to require a detailed inspection of the battery support assemblies to identify the manufacturer of the battery retaining rods.

Request To Include an Additional Method of Compliance to the AD Requirements

DAL requested that we add an additional method of compliance for paragraphs (h), (i), and (j) of the proposed AD. DAL stated that the language, ''or using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or EASA; or Airbus's EASA Design Organization Approval (DOA),'' should be included as an option to using the service information. DAL also stated that this language should be considered standard wording for future ADs as applicable.

We disagree with the commenter's request. We have already provided a method of compliance (MOC) for paragraphs (h), (i), and (j) of this AD in accordance with the applicable service information. Any deviations from the required MOC would need an evaluation in form of an AMOC. DAL's proposed option is generally utilized in cases where no MOC has been established or we have known information that the MOC may not be applicable for all airplanes in the U.S fleet. We have not changed the AD in this regard.

Request To Not Require Certain Service Information Labels on the Battery Rod

DAL and American Airlines (AA) requested that we not mandate that a service information label be attached to each battery retaining rod as required by the Airbus service information specified in paragraphs (j) and (l) of the proposed AD. AA also requested that we not mandate attachments of a service information label as part of the replacement required by paragraph (i) of the proposed AD. DAL stated that it has 7 affected airplanes that would have a different final configuration than the current and future fleet of 348 airplanes in its A320FAM fleet.

AA stated that all battery retaining rods provided by Airbus post August 2016 are marked and stamped with manufactures part number (MPN) D8241023700000. AA commented that this marking of the new battery retaining rods can be used in lieu of the information service bulletin (ISB) label. AA also commented that it plans to replace all existing battery retaining rods with the new battery retaining rods that are marked with MPN D8241023700000.

In addition, AA stated that installing the ISB label on the battery retaining rods on 128 of its A319/A320 airplanes does not add a safety value, but will put a burden on AA to maintain two different configurations of battery retaining rod installation between 128 airplanes that are effected by the service information in the proposed AD and 265 airplanes that are not affected by the service information in the proposed AD.

We agree with the commenters' request. We agree that the ISB label is not necessary to mitigate the risk addressed in this AD. Therefore, we have determined that the installation of ISB label should be optional and not a required for compliance (RC) step.

However, 14 CFR 39.9, specifies that operators have a continuing obligation to maintain compliance with an AD, and the installation of the ISB label or an equivalent method to identify a serviceable battery retaining rod provides the operators with a simplified way to demonstrate compliance with the AD requirements. We have removed paragraph (j) of the proposed AD and revised paragraph (l) of this AD to revise the terminating action requirements. We have also added paragraph (j) of this AD to provide an exception to paragraph (i) of this AD, which specifies that installing the ISB label is not a requirement in this AD.

Request To Revise the Terminating Action Paragraph

DAL requested that paragraph (l) of the proposed AD, ''Terminating Action,'' be revised to read, ''Replacement of all battery retaining rods,'' and not, ''Replacement of all battery retaining rods marked 'SA. . . .'" DAL stated that the battery retaining rods are not marked with ''SA,'' only the battery support assemblies.

We agree with the commenter's request and have revised the AD accordingly.

Request To Use Alternate Part Numbers

Spirit Airlines requested that either the service information or the proposed AD be revised to provide the use of alternate materials to label part number (P/N) ASNE0248A1–4H9. Spirit Airlines stated that P/N ASNE0248A1–4H9 is no longer available, and that alternate P/N E0248A1–4H9P and P/N ASNE0248A1–4H9T may be obtained from Airbus. Spirit Airlines believes that use of these alternate part numbers would provide an equivalent level of safety as referenced in Airbus Dossier Reference 80403684/003, dated January 8, 2018, and Airbus Retrofit Information Letter SA92M16012714 R00, dated February 1, 2017.

DAL requested that a previously approved AMOC be used in the proposed AD. DAL stated that in paragraph (h) and (j) of the proposed AD, Airbus Service Bulletin A320–92–1116, Revision 00, dated January 31, 2017, calls out a non-procurable part number for the identification label. Therefore, DAL proposed that recognition of AMOC AIR–676–18–152, issued against AD 2016–25–24, which allows an alternate label part number, be added to paragraph (m) of the proposed AD as an acceptable method of compliance to the proposed AD.

We partially agree with the commenters request. As we stated previously, we have determined that installation of an ISB label is not an RC step. Therefore, a previously issued AMOC for allowing alternate label part numbers is unnecessary. However, we would like to remind operators that 14 CFR 39.9 specifies an operator's continuing obligation to maintain compliance with an AD, and installation of an ISB label or an equivalent method provides operators with a method to demonstrate the affected battery retaining rods have been removed and replaced with serviceable retaining rods in compliance with the AD requirements.

Differences Between This AD and the MCAI

The MCAI includes a requirement to install an ISB label. This AD does not include that requirement. We have determined that the ISB label is not necessary to mitigate the risk addressed in this AD. However, 14 CFR 39.9, specifies that operators have a continuing obligation to maintain compliance with an AD, and the installation of the ISB label or an equivalent method to identify a serviceable battery retaining rod provides the operators with a simplified way to demonstrate compliance with the AD requirements.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

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

We also determined that these changes will not increase the economic burden on any operator or increase the scope of this AD.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A320–92–1116, Revision 00, dated January 31, 2017; and Service Bulletin A320–92–1118, Revision 00, dated January 31, 2017. This service information describes a detailed inspection of the battery support assemblies to identify the battery retaining rod manufacturer, replacement of the battery retaining rods with serviceable battery retaining rods if necessary, and adding the applicable service information label on each battery retaining rod if necessary. These documents are distinct since they apply to different airplane models. 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 330 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	1 work-hour × $85 per hour = $85	$0	$85	$28,050

We estimate the following costs to do any necessary replacement that would be required based on the results of the inspection. We have no way of determining the number of aircraft that might need this replacement:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replacement	1 work-hour × $85 per hour = $85	$0	$85

Authority for This Rulemaking

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

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 transport category airplanes to the Director of the System Oversight 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 that 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):

2018–16–12 Airbus: Amendment 39–19352; Docket No. FAA–2018–0077; Product Identifier 2017–NM–126–AD.

(a) Effective Date

This AD is effective September 12, 2018.

(b) Affected ADs

This AD affects AD 2016–25–24, Amendment 39–18750 (81 FR 90958, December 16, 2016) (''AD 2016–25–24'').

(c) Applicability

This AD applies to Airbus Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes; Model A320–211, –212, –214, –216, –231, –232, –233, –251N, and –271N airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes, certificated in any category, as identified in Airbus Service Bulletin A320–92–1116, Revision 00, dated January 31, 2017; or Airbus Service Bulletin A320–92–1118, Revision 00, dated January 31, 2017.

(d) Subject

Air Transport Association (ATA) of America Code 92, Electrical system installation.

(e) Reason

This AD was prompted by reports of battery retaining rod failures due to quality defects of the material used during parts manufacturing. We are issuing this AD to detect and correct broken battery retaining rods, which, in the event of a hard landing or severe turbulence, could cause the battery to detach from its housing, resulting in damage to other electrical equipment and surrounding structure. This condition could lead to loss of normal electrical power generation and subsequent inability to restore electrical power to essential airplane systems.

(f) Compliance

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

(g) Definition of a Serviceable Rod

For the purpose of this AD, a serviceable battery retaining rod is defined in paragraphs (g)(1) or (g)(2) of this AD.

(1) A battery retaining rod provided as a spare part by Airbus.

(2) A battery retaining rod previously fitted on a battery support assembly installed on an airplane manufacturer serial number that is not specified in Airbus Service Bulletin A320–92–1116, Revision 00, dated January 31, 2017 (for Airbus Model A319 and A320 series airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes); or Airbus Service Bulletin A320–92–1118, Revision 00, dated January 31, 2017 (for Airbus Model A320–251N and –271N airplanes), provided the battery retaining rod used for replacement can be positively identified as a serviceable battery retaining rod.

(h) Identification of Affected Parts

Within 24 months after the effective date of this AD: Accomplish a detailed inspection of the battery support assemblies to identify the battery retaining rod manufacturer, in accordance with the Accomplishment Instructions of the Airbus Service Bulletin A320–92–1116, Revision 00, dated January 31, 2017 (for Airbus Model A319 and A320 series airplanes, and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes); or Airbus Service Bulletin A320–92–1118, Revision 00, dated January 31, 2017 (for Airbus Model A320–251N and –271N airplanes).

(i) Replacement of Affected Parts if Marking Is Found on Battery Support Assembly

If, during the inspection specified in paragraph (h) of this AD, the quality stamp on any battery support assemblies are found marked with an ''SA'' manufacturer identification, before further flight, replace the battery retaining rods with serviceable battery retaining rods, in accordance with the Accomplishment Instructions of the Airbus Service Bulletin A320–92–1116, Revision 00, dated January 31, 2017 (for Airbus Model A319 and A320 series airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes); or Airbus Service Bulletin A320–92–1118, Revision 00, dated January 31, 2017 (for Airbus Model A320–251N and –271N airplanes); except as provided by paragraph (j) of this AD.

(j) Exception to the Service Information

Although Airbus Service Bulletin A320–92–1116, Revision 00, dated January 31, 2017; and Airbus Service Bulletin A320–92–1118, Revision 00, dated January 31, 2017; specify to install inspection service bulletin (ISB) labels, this AD does not include that requirement.

(k) Parts Installation Prohibition

As of the effective date of this AD, no person may install, on any airplane, a non-serviceable battery retaining rod.

(l) Terminating Action

Replacement of all battery retaining rods with a serviceable battery retaining rod as required by paragraph (i) of this AD constitutes terminating action for all requirements of AD 2016–25–24 for that airplane.

(m) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (n)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* If any service information contains procedures or tests that are identified as RC, those procedures and tests must be done to comply with this AD; any procedures or tests that are not identified as RC are recommended. Those procedures and tests that are not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the procedures and tests identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to procedures or tests identified as RC require approval of an AMOC.

(n) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2017–0161R1, dated September 19, 2017; corrected September 20, 2017; for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0077.

(2) For more information about this AD, contact Sanjay Ralhan, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3223.

(o) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A320–92–1116, Revision 00, dated January 31, 2017.

(ii) Airbus Service Bulletin A320–92–1118, Revision 00, dated January 31, 2017.

(3) For service information identified in this AD, contact Airbus, Airworthiness Office—EIAS, 2 Rond Point Emile Dewoitine, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 44 51; email *account.airworth-eas@airbus.com;* internet *http://www.airbus.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the

National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on July 27, 2018.

James Cashdollar,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–16736 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 154, 260, and 284

[Docket Nos. RM18–11–000, RP18–415–000; Order No. 849]

Interstate and Intrastate Natural Gas Pipelines; Rate Changes Relating to Federal Income Tax Rate; American Forest & Paper Association

Correction

In rule document 2018–15786 appearing on pages 36672–36717 in the issue of July 30, 2018, make the following correction:

§ 260.402 [Corrected]

■ On page 36715, in § 260.402, in the second column, under Amendatory Instruction 4, in the first line, ''§ 60.402'' should read ''§ 260.402''.

[FR Doc. C1–2018–15786 Filed 8–7–18; 8:45 am]

BILLING CODE 1301–00–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2017–0699; FRL–9981–41—Region 6]

Air Plan Approval; Arkansas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is approving portions of the revisions to the Arkansas State Implementation Plan (SIP) submitted by the Arkansas Department of Environmental Quality (ADEQ) on March 24, 2017. Most of the revisions are administrative in nature and make the SIP current with Federal rules. The EPA is also making ministerial changes to the Code of Federal Register (CFR) to reflect SIP actions pertaining to the Arkansas Prevention of Significant Deterioration (PSD) program.

DATES: This rule is effective on November 6, 2018 without further notice, unless the EPA receives relevant adverse comment by September 7, 2018. If the EPA receives such comment, the EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2017–0699, at *http://www.regulations.gov* or via email to *paige.carrie@epa.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact Carrie Paige, 214–665–6521, *paige.carrie@epa.gov.* For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Docket: The index to the docket for this action is available electronically at *www.regulations.gov* and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Carrie Paige, 214–665–6521, *paige.carrie@epa.gov.* To inspect the hard copy materials, please schedule an appointment with Ms. Paige or Mr. Bill Deese at 214–665–7253.

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

I. Background

The SIP is a set of air pollution regulations, control strategies, and technical analyses developed by the state to ensure that the state meets the National Ambient Air Quality Standards (NAAQS). These ambient standards are established under section 109 of the Act and they currently address six criteria pollutants: Carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter, and sulfur dioxide. The SIP is required by Section 110 of the Act and can be extensive, containing state regulations or other enforceable documents and supporting information such as emission inventories, monitoring networks, and modeling demonstrations.

On March 24, 2017, the Governor of Arkansas submitted to the EPA revisions to the Arkansas SIP. The submittal includes revisions to the Regulations of the Arkansas Plan of Implementation for Air Pollution Control enacted at Arkansas Annotated Code (''Ark. Code Ann.'') Regulation 19 (''Reg. 19''), Chapters 1–5, 7, 9, 11, 13–15, Appendix A, and Appendix B, and the Infrastructure and NAAQS SIPs. EPA has taken separate action on the following portions of this submittal: (1) On December 21, 2017, EPA approved the revisions to Reg. 19, Chapter 2, that address the definition of ''Volatile Organic Compounds'' (see 82 FR 60517); (2) On February 14, 2018, EPA approved the Infrastructure portion (see 83 FR 6470); (3) On June 29, 2018, EPA approved the revisions to Reg. 19, Chapter 4, that address Minor New Source Review (see 83 FR 30553); And, (4) on June 29, 2018, EPA proposed to approve the revisions that address interstate transport requirements for the 2012 $PM_{2.5}$ NAAQS and the revisions to Reg. 19, Chapter 2 and Appendix B, that address the definition of 2012 $PM_{2.5}$ in the definition of ''NAAQS'' and the table for ''Particle Pollution, $PM_{2.5}$'' (see 83 FR 30622). Because these prior EPA actions did not address all the submitted revisions to Reg. 19, Chapter 2 and Appendix B, today's action addresses the remaining submitted revisions to Reg. 19, Chapter 2 and Appendix B, and the submitted revisions to Reg. 19, Chapters 1, 3, 5, 13, 14, and 15. For a detailed list of each revision with our evaluation, please see our Technical Support Document (TSD) in the docket for this rulemaking.

II. Summary of Revisions to the Arkansas SIP and EPA Evaluation

A. Non-Substantive Changes

Non-substantive changes were made to Regulation 19, Chapter 1, Sections

101 and 103; Chapter 2 definitions; Chapter 3, Sections 301 and 304; Chapter 5, Sections 502–504; Chapter 13, Sections 1303 and 1308; Chapter 14, Section 1401; and Chapter 15, Sections 1502 and 1504 such as edits to acronyms, punctuation and section symbols. A complete listing of the non-substantive changes is in the TSD for this action. These changes are being approved here to maintain consistency between State rules and the approved SIP.

B. Regulation 19, Chapter 2—Definitions

Two definitions, ''NAAQS state implementation plan or NAAQS SIP'' and ''State implementation plan or SIP'' are new—these definitions are applicable to revised provisions in this SIP submittal. Several other revisions provide current references and publication dates for the specified Federal regulations within the definition. These revisions are necessary because Arkansas does not incorporate changes to the Federal regulations by reference prospectively and thus, must update its rules as Federal regulations are revised. For example, when the EPA revises test methods to allow the use of newly approved alternative procedures, the State must revise their state rules to incorporate the date of that Federal action. We find these revisions approvable.

In addition, the revisions to the definition for ''CO2 equivalent emissions'' delete a sentence commonly referred to as EPA's Biomass Deferral language, which EPA disapproved as a revision to the Arkansas SIP on May 23, 2016 (see 81 FR 32239 and 40 CFR 52.172). Because of our disapproval (see 81 FR 32239), the Biomass Deferral language was never in the Arkansas approved SIP and thus, the State's removal of this language from its State rules is a non-substantive change. Because the submitted revisions delete previously disapproved language, we are removing the prior disapproval listed in 40 CFR 52.172(c) as described in paragraph *D* of this action.

C. Regulation 19, Appendix B—National Ambient Air Quality Standards List

The revisions to the tables for Lead, $PM_{2.5}$, and PM_{10} are non-substantive because the revisions remove unnecessary punctuation. The revisions to the tables for Nitrogen Dioxide, Ozone, and Sulfur Dioxide expand the applicability of these NAAQS from Chapter 9, which addresses Administrative Permit Amendments, to include all chapters in Reg. 19. We find these revisions approvable.

D. Ministerial Changes to the CFR

We are making ministerial changes to the CFR to reflect that (1) our March 4, 2015 approval of revisions to the Arkansas PSD regulations for the $PM_{2.5}$ NAAQS (80 FR 11573) addressed our August 20, 2012 disapproval of Arkansas infrastructure SIP elements pertaining to these NAAQS (77 FR 50033) and (2) our approval of the revised definition for ''CO2 equivalent emissions'' submitted on March 24, 2017 addresses our May 23, 2016 disapproval of the definition (81 FR 32239), as described in paragraph *B* of this action and the TSD.

E. Section 110(l) Analysis

Section 110(l) of the Act precludes EPA from approving a revision of a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171 of the CAA), or any other applicable requirement of the Act. The submitted revisions in this action expand the applicability of the NAAQS in Appendix B to all chapters in Reg. 19. In addition, the submitted revisions evaluated in this action do not relax or otherwise weaken existing rules in the Arkansas SIP. Therefore, these revisions would not contribute to future violations of the NAAQS or interfere with reasonable further progress or any applicable CAA requirements. The non-substantive revisions also would not contribute to future violations of the NAAQS or interfere with reasonable further progress or any applicable CAA requirements.

III. Final Action

Pursuant to section 110 of the CAA, EPA is approving revisions to the Arkansas SIP submitted on March 24, 2017. Specifically, we are approving revisions to Regulation 19, Chapter 1, Sections 101 and 103; Chapter 2 definitions; Chapter 3, Sections 301 and 304; Chapter 5, Sections 502–504; Chapter 13, Sections 1303 and 1308; Chapter 14, Section 1401; Chapter 15, Sections 1502 and 1504; and Appendix B tables addressing Lead, Nitrogen Dioxide, Ozone, PM_{10}, and Sulfur Dioxide. The EPA is also removing the disapproval of the Greenhouse Gas (GHG) Biomass Deferral listed at 40 CFR 52.172(c).

The EPA is publishing this rule without prior proposal because we view this as a non-controversial 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 SIP revision if relevant adverse comments are received. This rule will be effective on November 6, 2018 without further notice unless we receive relevant adverse comment by September 7, 2018. If we receive relevant adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect. We will address all public comments in a subsequent final rule based on the proposed rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so now. Please note that if we receive relevant adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, we may adopt as final those provisions of the rule that are not the subject of an adverse comment.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the revisions to the Arkansas regulations as described in the Final Action section above. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 6 Office (please contact Carrie Paige, 214–665–6521, *paige.carrie@epa.gov* for more information). Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely 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. The EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 9, 2018. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: July 31, 2018.

Anne Idsal,

Regional Administrator, Region 6.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart E—Arkansas

■ 2. In § 52.170:

■ a. In paragraph (c), the table titled ''EPA-Approved Regulations in the Arkansas SIP'' is amended by revising the entries under Regulation 19 for ''Reg. 19.101'', ''Reg. 19.103'', ''Chapter 2'', ''Reg. 19.301'', ''Reg. 19.304'', ''Reg. 19.502–504'', ''Reg. 19.1303'', ''Reg. 19.1308'', ''Reg. 19.1401'', ''Reg. 19.1502'', ''Reg. 19.1504'', and ''Appendix B''; and

■ b. In paragraph (e), the third table titled ''EPA-Approved Non-Regulatory Provisions and Quasi-Regulatory Measures in the Arkansas SIP'' is amended by revising the entry for ''Infrastructure for the 1997 and 2006 $PM_{2.5}$ NAAQS''.

The revisions read as follows:

§ 52.170 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED REGULATIONS IN THE ARKANSAS SIP

State citation	Title/subject	State submittal/ effective date	EPA approval date	Explanation
Regulation No. 19: Regulations of the Arkansas Plan of Implementation for Air Pollution Control				
Chapter 1: Title, Intent and Purpose				
Reg. 19.101	Title	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	
*	* *		* *	* *
Reg. 19.103	Intent and Construction	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	

EPA-APPROVED REGULATIONS IN THE ARKANSAS SIP—Continued

State citation	Title/subject	State submittal/ effective date	EPA approval date	Explanation
*	*	*	*	*
Chapter 2: Definitions				
Chapter 2	Definitions	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	The definition of VOC submitted on 3/24/2017 was approved on 12/21/2017 (82 FR 60517). Revisions to the definition of National Ambient Air Quality Standard submitted on 3/24/2017 are addressed in a separate action.
Chapter 3: Protection of the National Ambient Air Quality Standards				
Reg. 19.301	Purpose	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	
*	*	*	*	*
Reg. 19.304	Delegated Federal Programs.	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	
*	*	*	*	*
Chapter 5: General Emission Limitations Applicability to Equipment				
*	*	*	*	*
Reg. 19.502	General Regulations	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	
*	*	*	*	*
Reg. 19.504	Stack Height/Dispersion Regulations.	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	
*	*	*	*	*
Chapter 13: Stage I Vapor Recovery				
*	*	*	*	*
Reg. 19.1303	Definitions	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	
*	*	*	*	*
Reg. 19.1308	Vapor Recovery Systems.	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	
*	*	*	*	*
Chapter 14: CAIR NO_X Ozone Season Trading Program General Provisions				
Reg. 19.1401	Adoption of Regulations	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	
*	*	*	*	*
Chapter 15: Regional Haze				
*	*	*	*	*
Reg. 19.1502	Definitions	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	

EPA-APPROVED REGULATIONS IN THE ARKANSAS SIP—Continued

State citation	Title/subject	State submittal/ effective date	EPA approval date	Explanation
*	*	*	*	*
Reg. 19.1504	Facilities Subject-to-BART.	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	
*	*	*	*	*
Appendix B: National Ambient Air Quality Standards List				
Appendix B	National Ambient Air Quality Standards List.	3/24/2017	8/8/2018, [Insert **Federal Register** citation].	
*	*	*	*	*

* * * * * (e) * * *

EPA-APPROVED NONREGULATORY PROVISIONS AND QUASI-REGULATORY MEASURES IN THE ARKANSAS SIP

Name of SIP provision	Applicable geographic or nonattainment area	State submittal/ effective date	EPA approval date	Explanation
*	*	*	*	*
Infrastructure for the 1997 and 2006 $PM_{2.5}$ NAAQS.	Statewide	3/28/2008, 9/16/2009, 12/1/2014	3/4/2015 (80 FR 11573)	Approval for CAA elements 110(a)(2)(A), (B), (E), (F), (G), (H), (K), (L), and (M) on 8/20/2012 (77 FR 50033). Approval for PSD elements (C), (D)(i)(II) (interfere with measures in any other state to prevent significant deterioration of air quality), D(ii) and (J) on March 4, 2015 (80 FR 11573).
*	*	*	*	*

§ 52.172 [Amended]

■ 3. Section 52.172 is amended by removing paragraphs (a), (b), and (c).

[FR Doc. 2018–16904 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2017–0152; FRL–9981–05—Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Delaware; Interstate Transport Requirements for the 2012 Fine Particulate Matter Standard; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: This document corrects an error in the amendatory language of a final rule pertaining to EPA's approval of a state implementation plan (SIP) revision submitted by Delaware to address the infrastructure requirements for interstate transport of pollution with respect to the 2012 fine particulate ($PM_{2.5}$) national ambient air quality standards (NAAQS).

DATES: Effective August 13, 2018.

FOR FURTHER INFORMATION CONTACT: Joseph Schulingkamp, (215) 814–2021 or by email at *schulingkamp.joseph@epa.gov.*

SUPPLEMENTARY INFORMATION: On July 12, 2018 (83 FR 32209), EPA published a final rulemaking action approving Delaware's December 14, 2015 SIP revision addressing the interstate transport requirements for the 2012 $PM_{2.5}$ NAAQS. In the published document appearing on page 32211, EPA inadvertently directed amendments to be published to 40 CFR 52.470. The correct section for the state of Delaware is 40 CFR 52.420.

EPA does not expect adverse comments on this action.

In FR Doc. 2018–14838 appearing on page 32209 in the **Federal Register** of Thursday, July 12, 2018, the following correction is made:

§ 52.420 [Corrected]

■ On page 32211, third column, under the heading ''Subpart I—Delaware'', the section heading ''§ 52.470 Identification of plan.'' is corrected to read ''§ 52.420 Identification of plan.''.

Dated: July 26, 2018.

Cecil Rodrigues,

Acting Regional Administrator, Region III.

[FR Doc. 2018–16878 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[EPA–HQ–OAR–2017–0472; FRL–9981–89–OAR]

RIN 2060–AT53

Protection of Stratospheric Ozone: Revision to References for Refrigeration and Air Conditioning Sector To Incorporate Latest Edition of Certain Industry, Consensus-Based Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: On December 11, 2017, the U.S. Environmental Protection Agency (EPA) published a direct final rule and an accompanying notice of proposed rulemaking entitled ''Protection of Stratospheric Ozone: Revision to References for Refrigeration and Air Conditioning Sector To Incorporate Latest Edition of Certain Industry, Consensus-based Standards.'' EPA proposed to modify the use conditions required for use of three flammable refrigerants—isobutane (R-600a), propane (R-290), and R-441A—in new household refrigerators, freezers, and combination refrigerators and freezers under the Significant New Alternatives Policy (SNAP) program to reflect an updated standard from Underwriters Laboratories. Because EPA received adverse comment, EPA withdrew the direct final rule through a separate notice. In this action, EPA is addressing relevant comments and finalizing the proposed use conditions with no changes.

DATES: This rule is effective on September 7, 2018. The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of September 7, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2017–0472. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov* or in hard copy at the Air and Radiation Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Avenue NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Air and Radiation Docket is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: Chenise Farquharson, Stratospheric Protection Division, Office of Atmospheric Programs (Mail Code 6205T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–564–7768; email address: *farquharson.chenise@epa.gov.* Notices and rulemakings under EPA's SNAP program are available on EPA's Stratospheric Ozone website at *https://www.epa.gov/snap/snap-regulations.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. General Information

A. What action is EPA taking?

On December 11, 2017, EPA published a direct final rule (82 FR 58122) to modify the use conditions for three flammable hydrocarbon refrigerants—isobutane (R-600a), propane (R-290), and R-441A—used in new household refrigerators, freezers, and combination refrigerators and freezers (hereafter ''household refrigerators and freezers'') by replacing four of the five use conditions in previous hydrocarbon refrigerants rules under EPA's Significant New Alternatives Policy (SNAP) program (76 FR 78832, December 20, 2011; 80 FR 19454, April 10, 2015) with the revised Underwriters Laboratories (UL) Standard 60335–2–24, ''Household and Similar Electrical Appliances—Safety—Part 2–24: Particular Requirements for Refrigerating Appliances, Ice-Cream Appliances and Ice-Makers'' (2nd edition, April 28, 2017). We stated in that direct final rule that if we received adverse comment by January 25, 2018, we would publish a timely withdrawal in the **Federal Register** so that the direct final rule would not take effect. EPA received adverse comment on the direct final rule and published a separate notice withdrawing the direct final rule on March 7, 2018 (83 FR 9703).

EPA also published a Notice of Proposed Rulemaking on December 11, 2017 accompanying the direct final rule, entitled ''Protection of Stratospheric Ozone: Revision to References for Refrigeration and Air Conditioning Sector To Incorporate Latest Edition of Certain Industry, Consensus-based Standards'' (82 FR 58154). That notice proposed to make the same changes to the relevant listing decisions as in the direct final rule. This action addresses the comments received and finalizes the revisions to the relevant listing decisions, as proposed.

B. Does this action apply to me?

This action regulates the use of three flammable hydrocarbon refrigerants—isobutane, propane, and the hydrocarbon blend R-441A—in new household refrigerators and freezers. Table 1 identifies entities potentially affected by this action. Regulated entities may include:

TABLE 1—POTENTIALLY REGULATED ENTITIES BY NORTH AMERICAN INDUSTRIAL CLASSIFICATION SYSTEM (NAICS) CODE

Category	NAICS code	Description of regulated entities
Industry	333415	Manufacturers of Refrigerators, Freezers, and Other Refrigerating or Freezing Equipment, Electric or Other (NESOI); Heat Pumps Not Elsewhere Specified or Included; and Parts Thereof.
Industry	335222	Household Refrigerator and Home Freezer Manufacturing.
Industry	811412	Appliance Repair and Maintenance.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table lists the types of entities that EPA is currently aware could potentially be regulated by this action. Other types of entities not listed in the table could also be regulated. To determine whether your entity is regulated by this action, you should carefully examine the applicability criteria found in 40 CFR part 82. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

II. Background

A. What is the affected end-use?

Household refrigerators and freezers are intended primarily for residential use, although they may be used outside the home (*e.g.,* workplace kitchen pantries). The designs and refrigeration capacities of equipment vary widely. This equipment is composed of three main categories: Household freezers only offer storage space at freezing temperatures, household refrigerators only offer storage space at non-freezing temperatures, and products with both a refrigerator and freezer in a single unit are referred to as combination refrigerators and freezers. The combination products are the most common. Certain small refrigerated household appliances (*e.g.,* chilled kitchen drawers, wine coolers, and mini-fridges) are also within this end-use. Household refrigerators and freezers have all refrigeration components integrated, and for the smallest types, the refrigeration circuit is entirely brazed or welded. These systems are charged with refrigerant at the factory and typically require only an electricity supply to begin operation.

The 2014 American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Handbook of Refrigeration provides an overview of food preservation in regard to household refrigerators and freezers. Generally, a storage temperature between 32 and 39 °F (0 to 3.9 °C) is desirable for preserving fresh food. Humidity and higher or lower temperatures are more suitable for certain foods and beverages. Wine chillers, for example, are frequently used for storing wine, and have slightly higher optimal temperatures from 45 to 65 °F (7.2 to 18.3 °C). In single-door refrigerators, the optimum conditions for food preservation are also slightly higher since food storage is not intended for long-term storage. Freezers and combination refrigerators and freezers that are designed to store food for long durations are generally designed to hold temperatures near 0 to 5 °F (−17.7 to −15 °C).

Refrigerant Flammability

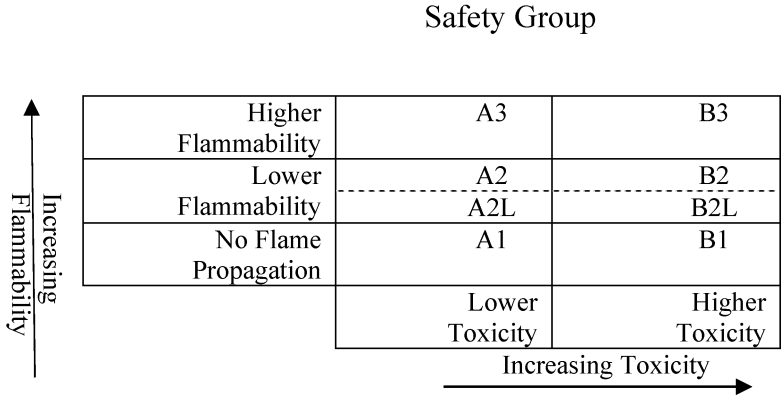
American National Standards Institute (ANSI)/ASHRAE Standard 34—2016 assigns a safety group classification for each refrigerant which consists of two alphanumeric characters (*e.g.,* A2 or B1). The capital letter indicates the toxicity and the numeral denotes the flammability. ASHRAE classifies Class A refrigerants as refrigerants for which toxicity has not been identified at concentrations less than or equal to 400 parts per million (ppm) by volume, based on data used to determine threshold limit values (TLV)–time weighted average (TWA) or consistent indices. Class B signifies refrigerants for which there is evidence of toxicity at concentrations below 400 ppm by volume, based on data used to determine TLV–TWA or consistent indices.

The refrigerants are also assigned a flammability classification of 1, 2, or 3. Tests are conducted in accordance with American Society for Testing and Materials (ASTM) E681 using a spark ignition source at 60 °C and 101.3 kPa.[1] The flammability classification ''1'' is given to refrigerants that, when tested, show no flame propagation. The flammability classification ''2'' is given to refrigerants that, when tested, exhibit flame propagation, have a heat of combustion less than 19,000 kJ/kg (8,174 British thermal units (BTU)/lb), and have a lower flammability limit (LFL) greater than 0.10 kg/m^3. Refrigerants within flammability classification ''2'' may optionally be designated in the subclass ''2L'' if they have a maximum burning velocity of 10 cm/s or lower when tested at 23.0 °C and 101.3 kPa. The flammability classification ''3'' is given to refrigerants that, when tested, exhibit flame propagation and that either have a heat of combustion of 19,000 kJ/kg (8,174 BTU/lb) or greater or an LFL of 0.10 kg/m^3 or lower. Thus, refrigerants with flammability classification ''3'' are highly flammable while those with flammability classification ''2'' are less flammable and those with flammability classification ''2L'' are mildly flammable.

For both toxicity and flammability classifications, refrigerant blends are designated based on the worst-case estimate of fractionation determined for the blend. Figure 1 illustrates these safety group classifications.

[1] ASHRAE, 2016. ANSI/ASHRAE Standard 34—2016: Designation and Safety Classification of Refrigerants.

Figure 1. Refrigerant Safety Group Classification



B. Use Conditions

EPA previously found isobutane, propane, and R-441A acceptable, subject to use conditions, in new household refrigerators and freezers (76 FR 78832, December 20, 2011; 80 FR 19454, April 10, 2015). In the proposed and final rules, EPA provided information on the environmental and health properties of the three refrigerants and the various other substitutes available for use in household refrigerators and freezers. EPA's risk screens for the three refrigerants are available in the docket for these rulemakings (EPA–HQ–OAR–2009–0286 and EPA–HQ–OAR–2013–0748).[2] [3]

Isobutane, propane, and R-441A have an ASHRAE classification of A3, indicating that they have low toxicity and high flammability. The flammability risks are of concern because household refrigerators and freezers have traditionally used refrigerants that are not flammable. In the presence of an ignition source (*e.g.,* static electricity, a spark resulting from a closing door, or a cigarette), an explosion or a fire could occur if the concentration of isobutane, propane, and R-441A were to exceed the LFL of 18,000 ppm, 21,000 ppm, and 20,500 ppm, respectively.

To address the flammability risk, which is not posed by other available refrigerants in this end-use, EPA listed the refrigerants as acceptable, subject to use conditions, in new household refrigerators and freezers. The use conditions ensure minimization of flammability risk by incorporating by reference Supplement SA to the 10th edition of UL Standard 250, and by including refrigerant charge size limits and requirements for markings on equipment using the refrigerants to inform consumers and technicians of potential flammability hazards. Without appropriate use conditions, the flammability risk posed by the refrigerants could be higher than non-flammable refrigerants because individuals may not be aware that their actions could potentially cause a fire, and because the refrigerants could be used in existing equipment that has not been designed specifically to minimize flammability risks. Our assessment and listing decisions (76 FR 78832; December 20, 2011 and 80 FR 19454; April 10, 2015) found that with the use conditions, the overall risk of these substitutes, including the risk due to flammability, does not present significantly greater risk in the end-use than other substitutes that are currently or potentially available for that same end-use.

The use conditions required the following:

1. *New equipment only; not intended for use as a retrofit alternative:* ''These refrigerants may be used only in new equipment designed specifically and clearly identified for the refrigerant (*i.e.,* none of these substitutes may be used as a conversion or 'retrofit' [4] refrigerant for existing equipment designed for a different refrigerant);''

2. *UL standard:* ''These refrigerants may be used only in a refrigerator or freezer, or combination refrigerator and freezer, that meets all requirements listed in Supplement SA to the 10th edition of the UL Standard for Household Refrigerators and Freezers, UL 250, dated August 25, 2000). In cases where the final rule includes requirements more stringent than those of the 10th edition of UL Standard 250, the appliance must meet the requirements of the final rule in place of the requirements in the UL standard;''

3. *Charge size:* ''The charge size must not exceed 57 grams (2.01 ounces) in any refrigerator, freezer, or combination refrigerator and freezer in each circuit;''

4. *Labeling:* ''As provided in clauses SA6.1.1 and SA6.1.2 of UL Standard 250, 10th edition, the following markings must be attached at the locations provided and must be permanent:

a. On or near any evaporators that can be contacted by the consumer: 'DANGER—Risk of Fire or Explosion. Flammable Refrigerant Used. Do Not Use Mechanical Devices To Defrost Refrigerator. Do Not Puncture Refrigerant Tubing.'

b. Near the machine compartment: 'DANGER—Risk of Fire or Explosion. Flammable Refrigerant Used. To Be Repaired Only By Trained Service Personnel. Do Not Puncture Refrigerant Tubing.'

c. Near the machine compartment: 'CAUTION—Risk of Fire or Explosion. Flammable Refrigerant Used. Consult Repair Manual/Owner's Guide Before Attempting To Service This Product. All Safety Precautions Must be Followed.'

d. On the exterior of the refrigerator: 'CAUTION—Risk of Fire or Explosion. Dispose of Properly In Accordance With Federal Or Local Regulations. Flammable Refrigerant Used.'

e. Near any and all exposed refrigerant tubing: 'CAUTION—Risk of Fire or Explosion Due To Puncture Of Refrigerant Tubing; Follow Handling Instructions Carefully. Flammable Refrigerant Used.'

All of these markings must be in letters no less than 6.4 mm (¼ inch) high.''

5. *Color-coded hoses and piping:* ''The refrigerator, freezer, or combination refrigerator and freezer

[2] Isobutane and R-441A: 75 FR 25799, May 10, 2010 (proposed rule); 76 FR 78832, December 20, 2011 (final rule).

[3] Propane: 79 FR 38811, July 9, 2014 (proposed rule); 80 FR 19454, April 10, 2015 (final rule).

[4] Sometimes conversion refrigerant substitutes are inaccurately referred to as ''drop in'' replacements.

must have red Pantone Matching System (PMS) #185 marked pipes, hoses, or other devices through which the refrigerant is serviced (typically known as the service port), to indicate the use of a flammable refrigerant. This color must be present at all service ports and where service puncturing or otherwise creating an opening from the refrigerant circuit to the atmosphere might be expected (*e.g.,* process tubes). The color mark must extend at least 2.5 centimeters (1 inch) from the compressor and must be replaced if removed.''

C. UL Standard 60335–2–24

In 2011, UL formed a Joint Task Group (JTG) comprised of members of its Standards Technical Panel (STP) to develop recommendations for addressing the use and safety of refrigerants classified as A2, A2L, and A3 in refrigeration and air conditioning (AC) equipment. One of the outcomes is the 2017 UL Standard 60335–2–24, which is based on International Electrotechnical Commission (IEC) Standard 60335–2–24 ''Household and Similar Electrical Appliances—Safety—Part 2–24: Particular Requirements for Refrigerating Appliances, Ice-Cream Appliances and Ice-Makers'' (edition 7.1, May 2012). The 2017 UL Standard 60335–2–24 was developed in an open and consensus-based approach, with the assistance of experts in the refrigeration and AC industry as well as experts involved in assessing the safety of products. The revision cycle, including final recirculation, concluded on February 6, 2017, and UL published the standard on April 28, 2017. The 2017 UL Standard replaces the previously published version of this same standard as well as UL Standard 250 Supplement SA, ''Requirements for Refrigerators and Freezers Employing a Flammable Refrigerant in the Refrigerating System'' (Edition 10, August 25, 2000).

The 2017 UL Standard 60335–2–24 limits the charge size for each separate refrigerant circuit (*i.e.,* compressor, condenser, evaporator, and refrigerant piping) to 150 grams (5.3 ounces). Additionally, the 2017 standard requires testing of refrigeration appliances containing flammable refrigerants, including leakage tests, temperature and scratch tests, and heat testing requirements to address the hazards due to ignition of leaked refrigerant by potential ignition sources associated with the appliance (see sections 22.107–22.110 and the relevant annexes of the standard for specific testing requirements). These tests are intended, among other things, to ensure that any leaks will result in concentrations well below the LFL, and that potential ignition sources will not be able to create temperatures high enough to start a fire. Appliances that are in compliance with the 2017 UL Standard 60335–2–24 have passed appropriate ignition or leakage tests as stipulated in the standard. Passing the leakage test ensures that refrigerant concentrations in the event of a leak do not reach or exceed 75 percent of the LFL inside any internal or external electrical component compartments.

III. What is EPA finalizing in this action?

As proposed, EPA is revising the use conditions for propane, isobutane and R-441 in the household refrigerators and freezers end-use. We are finalizing the use conditions for each substitute as follows:

A. Use Conditions

EPA is replacing the reference to Supplement SA to the 10th edition of UL Standard 250 in use condition ''2'' with ''UL Standard 60335–2–24, Safety Requirements for Household and Similar Electrical Appliances, Part 2: Particular Requirements for Refrigerating Appliances, Ice-Cream Appliances and Ice-Makers (2nd Edition, April 28, 2017).'' In addition, EPA is removing use conditions ''3,'' ''4,'' and ''5'' because the conditions specified in those use conditions are specified in 2017 UL standard 60335–2–24; the incorporation of 2017 UL standard 60335–2–24 in condition 2 includes the requirements in previous conditions 3, 4, and 5. The use conditions provide the same level of assurance that the three substitutes can be used as safely as other available alternatives. The revised use conditions apply to new household refrigerators and freezers manufactured after the effective date of this regulation. The new use conditions are as follows:

1. *New equipment only; not intended for use as a retrofit alternative:* Propane, isobutane, and R-441A may be used only in new equipment designed specifically and clearly identified for the refrigerant (*i.e.,* none of these substitutes may be used as a conversion or ''retrofit'' [5] refrigerant for existing equipment designed for a different refrigerant); and

2. *UL standard:* These refrigerants may be used only in equipment that meets all requirements in the 2017 UL Standard 60335–2–24.

[5] Sometimes conversion refrigerant substitutes are inaccurately referred to as ''drop in'' replacements.

B. Rationale for Changed Use Conditions

1. Charge Size

EPA previously required a charge size limit of 57 grams (2.01 ounces) for each separate refrigerant circuit in a refrigerator or freezer. The 2017 UL Standard 60335–2–24 specifies that the maximum charge size for each separate refrigerant circuit in a refrigerator or freezer must be no greater than 150 grams (5.29 ounces).

As discussed in the December 2017 direct final rule, EPA evaluated reasonable worst-case and more typical, yet conservative, scenarios to model the effects of the sudden release of each refrigerant from a household refrigerator or freezer containing the maximum charge size of 150 grams (5.29 ounces). This was done to determine whether the refrigerants would present flammability or toxicity concerns for consumers or workers, including those servicing or disposing of appliances. To represent a reasonable worst-case scenario, it was assumed that a catastrophic leak of each refrigerant would occur while the refrigerator or freezer unit is in a residential kitchen with a height of approximately 2.4 meters (*i.e.,* a standard 8-foot ceiling) and a minimum effective volume of 18 m^3 (640 ft^3) or an effective volume of 53 m^3 (1,870 ft^3) (*i.e.,* excluding the space filled by cabinets, other kitchen equipment) (Murray 1997; NKBA 2016). The minimum kitchen volume of 18 m^3 (640 ft^3) does not consider residential kitchen spaces that are often connected to breakfast nooks or other rooms (*e.g.,* living room, dining room) through open pathways or swinging doors, which would also increase the effective volume of the space into which a refrigerant would be released, thereby reducing the likelihood that the instantaneous concentration of the refrigerants would exceed the LFL. Conversely, the larger kitchen volume used in the analysis (*i.e.,* 53 m^3) considers air-mixing that is likely to occur within the spaces that are adjacent to the kitchen (Murray 1997; NKBA 2016). The minimum effective kitchen volume modeled in this analysis is conservative, as it is approximately half the size of the average kitchen in a new single-family home in the United States (*i.e.,* 36 m^3) (NKBA 2016). The larger kitchen volume of 53 m^3 includes adjacent areas to the kitchen, such as a breakfast nook, and is more conservative than the average estimated volume of a kitchen with a breakfast nook in a U.S. household (*i.e.,* 65 m^3) (NKBA 2016).

EPA's analysis for each of the refrigerants revealed that even if the

unit's full charge were emitted within one minute, the concentration would not reach the LFL for that refrigerant in the less conservative 53 m^3 (1,870 ft^3) kitchen, showing a lack of flammability risk. The threshold analyses demonstrated that a flammability concern could exist in the minimum modeled kitchen volume (*i.e.,* 18 m^3 (640 ft^3)) if the charge size of the household refrigerator or freezer exceeded 120 grams, which is slightly smaller than the maximum modeled charge size (*i.e.,* 150 grams). However, the estimated exposures were derived using conservative assumptions (*e.g.,* small room size, no ventilation). A 150-gram household refrigeration unit would have to be installed in a kitchen at least 2.3 times smaller than the less conservative kitchen size modeled, in the worst-case conditions at end-use, for flammability to be of concern. As a result, EPA determined that a release of a 150-gram unit does not present a significant flammability risk in the reasonable worst-case scenario for the three refrigerants in household refrigerators and freezers.

Concerning toxicity of the refrigerants, our risk screens found that the 30-minute acute exposure guideline level (AEGL) (*i.e.,* 6,900 ppm) is exceeded only in the worst-case scenario for the minimum kitchen volume (*i.e.,* 18 m^3). Based upon our analysis, the minimum room sizes in which installed equipment could cause a toxicity concern would have to be approximately 0.8 times smaller than the larger modeled room size of 53 m^3 (1,870 ft^3), which is a conservative kitchen volume in the United States (Murray 1997; NKBA 2016). Thus, we have determined that isobutane, propane, and R–441A do not pose significantly greater flammability and toxicity risks than other acceptable refrigerants in the household refrigerators and freezers end-use. The higher charge size included in the revised use condition will provide greater flexibility to appliance manufacturers in the design of equipment while also ensuring that such equipment will not pose greater risk than similar equipment using other acceptable alternatives. For more information about EPA's risk assessments, see the docket for this rulemaking (EPA–HQ–OAR–2017–0472).

EPA is not retaining a separate charge size limit as a use condition because it would be redundant of the updated UL standard. Therefore, we are replacing the use condition in ''3'' with the 2017 UL Standard 60335–2–24.

2. Color-Coded Hoses and Piping, and Labeling

The 2017 UL Standard 60335–2–24 includes requirements for red PMS #185 marked pipes, hoses, and other devices through which the refrigerant passes, and requirements for markings in letters no less than 6.4 mm (¼ inch) high to inform consumers and technicians of potential flammability hazards are addressed in (see sections 7.1 and 22.106 of the standard for additional information on the required marking and warning labels). Retaining the use conditions in ''4'' and ''5'' in EPA's previous hydrocarbon refrigerants rules would be redundant of the updated standard. Therefore, we are replacing the use conditions in ''4'' and ''5'' with the 2017 UL Standard 60335–2–24.

C. Incorporation by Reference

Through this action EPA is incorporating by reference the 2017 UL Standard 60335–2–24, which establishes requirements for the evaluation of household and similar electrical appliances, and safe use of flammable refrigerants. The standard is discussed in greater detail elsewhere in this preamble. This approach is the same as that used to incorporate Supplement SA to the 10th edition of UL Standard 250 in our previous rules on flammable refrigerants (76 FR 78832, December 20, 2011; 80 FR 19454, April 10, 2015).

The 2017 UL Standard 60335–2–24 is available for purchase by mail at: COMM 2000, 151 Eastern Avenue, Bensenville, IL 60106; Email: *orders@shopulstandards.com;* Telephone: 1–888–853–3503 in the U.S. or Canada (other countries dial 1–415–352–2178); internet address: *http://www.shopulstandards.com/ProductDetail.aspx?productId=UL60335-2-24_2_B_20170428(ULStandards2).* The cost of the 2017 UL Standard 60335–2–24 is $454 for an electronic copy and $567 for hardcopy. UL also offers a subscription service to the Standards Certification Customer Library (SCCL) that allows unlimited access to their standards and related documents. The cost of obtaining this standard is not a significant financial burden for equipment manufacturers and purchase is not required for those selling, installing, and servicing the equipment. Therefore, EPA concludes that the UL standard being incorporated by reference is reasonably available.

D. Equipment Manufactured Prior to Effective Date of This Rule

The use conditions in this action apply to new household refrigerators and freezers manufactured after the effective date of this regulation. This final rule does not apply to or affect equipment manufactured before the effective date of this action and manufactured in compliance with the SNAP requirements applicable at the time of manufacture.

IV. Response to Comments

EPA received 17 comments on the December 11, 2017, notice of proposed rulemaking. Below EPA is responding to six of those comments, which were either relevant to this rulemaking or raised issues that were addressed in related rulemakings. The other eleven comments raised issues that are outside the scope of this rulemaking or are not relevant to any related rulemaking, so EPA is not providing a specific response to those comments.

A. Compliance With the 2017 UL Standard 60335–2–24

Comment: Three commenters expressed support for the proposed changes to the use conditions to reflect the 2017 UL Standard 60335–2–24. The commenters noted that the revised use conditions would not place any significant burden on the regulated community, would ensure consistency with consensus-based standards, and would encourage manufacturers of home refrigeration appliances and suppliers of refrigerants to transition to more environmentally friendly refrigerants.

Response: EPA acknowledges the support and is finalizing the revised use conditions for use of isobutane, propane, and R-441A in household refrigerators and freezers as proposed.

B. Flammability

Comment: Three commenters raised concerns about flammability risks and firefighter safety in homes and other buildings due to the 150-gram maximum allowable charge size. The commenters asserted that there would be negative impacts and implications related to the higher charge size, particularly for propane, and encouraged EPA to consult with firefighter organizations, such as the National Volunteer Fire Council or the Fire Department Safety Officers of America.

Response: EPA recognizes that flammability is an important consideration with regard to the 150-gram charge size. As discussed above in section III.2.a, EPA evaluated flammability and toxicity risks for isobutane, propane, and R-441A at the maximum charge size as provided in the risk screens included in the docket for

this rulemaking (Docket ID EPA–HQ–OAR–2017–0472–0006, –0007, and –0008). EPA evaluated toxicity risk by considering exposure to workers (including those servicing or disposing of appliances), consumers, and the general public. EPA evaluated flammability risk by evaluating reasonable worst-case and more typical, yet conservative, scenarios to model the effects of the sudden release of each refrigerant from a household refrigerator or freezer containing the maximum charge. Our risk screens found that equipment that met the 150-gram charge limit did not exceed the LFL for each of the three refrigerants in household refrigerators and freezers in a conservatively sized 53 m^3 (1,870 ft^3) kitchen (see section III.B.1 above for the minimum and average kitchen zone volumes). The commenters did not provide any technical support for their statements or information demonstrating that use of any of the three refrigerants in household refrigerators and freezers at a charge of 150 grams (5.3 ounces) would pose significantly greater risk than other available alternatives in this end-use. We note that the use conditions required by this final rule include specific safety testing requirements in the 2017 UL Standard 60335–2–24, which are intended, among other things, to ensure that any leaks will result in concentrations well below the LFL, and that potential ignition sources will not be able to create temperatures high enough to start a fire. The use conditions also provide additional safety measures and labeling requirements (*e.g.,* visible warning statement and red coloring on the pipes, hoses, and devices which contain refrigerant) that make equipment owners, consumers, fire marshals, and emergency first responders aware of the presence of a flammability risk. Moreover, EPA is aware of the longstanding widespread use on a global basis of household refrigerators and freezers using this charge limit. EPA agrees that greater awareness of the presence, risks, and benefits of flammable refrigerants among fire marshals and first responders would be beneficial.

C. Recovery and Recycling Equipment

Comment: One commenter voiced concerns that isobutane, propane, and R-441A were exempted from the venting prohibition because machines for the recovery of flammable refrigerants are not currently available in the United States. The commenter stated that hydrocarbon refrigerants are odorless, require a procedure for proper handling and storing, and ''undermine our whole premise of not knowingly venting an ODS refrigerant or its alternate.'' In contrast, two commenters provided supporting information regarding the safe servicing of household appliances with flammable refrigerants and the availability of equipment and technologies to safely recover and reclaim flammable refrigerants.

Response: These comments are outside the scope of this rulemaking. EPA did not propose and is not today finalizing any changes to its previous determinations that venting, releasing, or disposing of these refrigerants used in this end-use does not pose a threat to the environment under CAA section 608(c)(2). EPA made these determinations under section 608(c)(2) in final rules issued in 2014 and 2015 (79 FR 29682, May 23, 2014; 80 FR 19454, April 10, 2015) and did not reopen those determinations in this rulemaking. EPA directs the commenters to those rules for additional information. EPA appreciates the information provided by commenters with regard to the availability of recovery and recycling equipment.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This action is not an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. OMB has previously approved the information collection requirements contained in the existing regulations and has assigned OMB control number 2060–0226. This rule contains no new requirements for reporting or recordkeeping.

D. Regulatory Flexibility Act

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden or otherwise has a positive economic effect on the small entities subject to the rule.

The use conditions of this rule apply to manufacturers of new household refrigerators and freezers that choose to use flammable refrigerants. Today's action allows equipment manufacturers to use flammable refrigerants at a higher charge size than previously allowed in new household refrigerators and freezers but does not mandate such use; the change to the use conditions allows more flexibility for manufacturers in the design of equipment and thus reduces the regulatory burden to the regulated community. In some cases, it may reduce costs by allowing manufacturers to design equipment with a single, larger refrigerant circuit instead of multiple, smaller refrigerant circuits for the same piece of equipment.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. This action's health and risk assessments are contained in risk screens for the various substitutes.[6] [7] [8] The risk screens are available in the docket for this rulemaking.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action involves a technical standard. EPA is revising the use conditions for the household refrigerators and freezers end-use by incorporating by reference UL Standard 60335–2–24, ''Safety Requirements for Household and Similar Electrical Appliances, Part 2: Particular Requirements for Refrigerating Appliances, Ice-Cream Appliances and Ice-Makers'' (2nd edition, April 2017), which establishes requirements for the evaluation of household and similar electrical appliances, and safe use of flammable refrigerants. The 2017 UL Standard 60335–2–24 supersedes the current edition of Supplement SA the 10th edition of UL Standard 250, ''Requirements for Refrigerators and Freezers Employing a Flammable Refrigerant in the Refrigerating System'' (August 2000). EPA's revision to the use conditions will replace Supplement SA to the 10th edition of UL Standard 250 with the 2017 UL standard 60335–2–24. This standard is available at *https://standardscatalog.ul.com/standards/en/standard_60335-2-24_2,* and may be purchased by mail at: COMM 2000, 151 Eastern Avenue, Bensenville, IL 60106; Email: *orders@shopulstandards.com;* Telephone: 1–888–853–3503 in the U.S. or Canada (other countries dial 1–415–352–2178); internet address: *http://www.shopulstandards.com/ProductDetail.aspx?productId=UL60335-2-24_2_B_20170428(UL Standards2).* The cost of UL 60335–2–24 is $454 for an electronic copy and $567 for hardcopy. UL also offers a subscription service to the Standards Certification Customer Library (SCCL) that allows unlimited access to their standards and related documents. The cost of obtaining this standard is not a significant financial burden for equipment manufacturers and purchase is not required for those selling, installing and servicing the equipment. Therefore, EPA concludes that the UL standard being incorporated by reference is reasonably available.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. This action's health and environmental risk assessments are contained in the risk screens for the various substitutes. The risk screens are available in the docket for this rulemaking.

L. Congressional Review Act (CRA)

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

VI. References

Unless specified otherwise, all documents are available electronically through the Federal Docket Management System, Docket #EPA–HQ–OAR–2017–0472.

ASHRAE, 2016. ANSI/ASHRAE Standard 34–2016: Designation and Safety Classification of Refrigerants.

ICF, 2018a. Risk Screen on Substitutes in Household Refrigerators and Freezers; Substitute: Propane (R-290).

ICF, 2018b. Risk Screen on Substitutes in Household Refrigerators and Freezers; Substitute: Isobutane (R-600a).

ICF, 2018c. Risk Screen on Substitutes in Household Refrigerators and Freezers; Substitute: R-441A.

Murray, D.M., 1997. Residential house and zone volumes in the United States: Empirical and Estimated Parametric Distributions. *Risk Anal* 17: 439–446. Available online at: *http://onlinelibrary.wiley.com/doi/10.1111/j.1539-6924.1997.tb00884.x/full.*

National Kitchen and Bath Association (NKBA), 2016. Size of Kitchens in New U.S. Single Family Homes. August 2016. Available online at: *https://nkba.myshopify.com/collections/research/products/size-of-kitchens-in-new-u-s-single-family-homes.*

UL 250. Household Refrigerators and Freezers. 10th edition. Supplement SA: Requirements for Refrigerators and Freezers Employing a Flammable Refrigerant in the Refrigerating System. August 2000.

UL 60335–2–24. Safety Requirements for Household and Similar Electrical Appliances, Part 2: Particular Requirements for Refrigerating Appliances, Ice-Cream Appliances and Ice-Makers. 2nd edition. April 2017.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Recycling, Reporting and recordkeeping requirements, Stratospheric ozone layer.

Dated: July 30, 2018.

Andrew R. Wheeler,

Acting Administrator.

For the reasons set out in the preamble, 40 CFR part 82 is amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

■ 1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart G—Significant New Alternatives Policy Program

■ 2. Amend Appendix R to subpart G of part 82 by:

■ a. Revising the appendix heading.

■ b. Removing the two entries for ''Household refrigerators, freezers, and combination refrigerators and freezers (New equipment only)'' and adding a new entry in their place; and

■ c. Revising the NOTE to Appendix R.

The revisions and additions to read as follows:

Appendix R to Subpart G of Part 82—Substitutes Subject to Use Restrictions Listed in the December 20, 2011, Final Rule, Effective February 21, 2012, in the April 10, 2015 Final Rule, Effective May 11, 2015, and in the August 8, 2018 Final Rule, Effective September 7, 2018

[6] ICF, 2018a. Risk Screen on Substitutes in Household Refrigerators and Freezers; Substitute: Propane (R-290).

[7] ICF, 2018b. Risk Screen on Substitutes in Household Refrigerators and Freezers; Substitute: Isobutane (R-600a).

[8] ICF, 2018c. Risk Screen on Substitutes in Household Refrigerators and Freezers; Substitute: R-441A.

SUBSTITUTES THAT ARE ACCEPTABLE SUBJECT TO USE CONDITIONS

End-use	Substitute	Decision	Use conditions	Further information
Household refrigerators, freezers, and combination refrigerators and freezers (New equipment only).	Isobutane (R-600a). Propane (R-290). R-441A	Acceptable subject to use conditions.	As of September 7, 2018: ..... These refrigerants may be used only in new equipment designed specifically and clearly identified for the refrigerant (*i.e.,* none of these substitutes may be used as a conversion or ''retrofit'' refrigerant for existing equipment designed for a different refrigerant). These refrigerants may be used only in a refrigerator or freezer, or combination refrigerator and freezer, that meets all requirements listed in the 2nd edition of the Underwriters Laboratories (UL) Standard for Safety: Household and Similar Electrical Appliances—Safety—Part 2–24: Particular Requirements for Refrigerating Appliances, Ice-Cream Appliances and Ice-Makers, UL 60335–2–24, dated April 28, 2017.	Applicable OSHA requirements at 29 CFR part 1910 must be followed, including those at 29 CFR 1910.106 (flammable and combustible liquids), 1910.110 (storage and handling of liquefied petroleum gases), 1910.157 (portable fire extinguishers), and 1910.1000 (toxic and hazardous substances). Proper ventilation should be maintained at all times during the manufacture and storage of equipment containing hydrocarbon refrigerants through adherence to good manufacturing practices as per 29 CFR 1910.106. If refrigerant levels in the air surrounding the equipment rise above one-fourth of the lower flammability limit, the space should be evacuated and reentry should occur only after the space has been properly ventilated. Technicians and equipment manufacturers should wear appropriate personal protective equipment, including chemical goggles and protective gloves, when handling these refrigerants. Special care should be taken to avoid contact with the skin since these refrigerants, like many refrigerants, can cause freeze burns on the skin. A Class B dry powder type fire extinguisher should be kept nearby. Technicians should only use spark-proof tools when working on refrigerators and freezers with these refrigerants. Any recovery equipment used should be designed for flammable refrigerants. Any refrigerant releases should be in a well-ventilated area, such as outside of a building. Only technicians specifically trained in handling flammable refrigerants should service refrigerators and freezers containing these refrigerants. Technicians should gain an understanding of minimizing the risk of fire and the steps to use flammable refrigerants safely.
*	*	*	*	*	*	*

Note: The use conditions in this appendix contain references to certain standards from Underwriters Laboratories Inc. (UL). The standards are incorporated by reference, and the referenced sections are made part of the regulations in part 82:

1. UL 471. Commercial Refrigerators and Freezers. 10th edition. Supplement SB: Requirements for Refrigerators and Freezers Employing a Flammable Refrigerant in the Refrigerating System. Underwriters Laboratories, Inc. November 24, 2010.
2. UL 484. Room Air Conditioners. 8th edition. Supplement SA: Requirements for Room Air Conditioners Employing a Flammable Refrigerant in the Refrigerating System and Appendices B through F. December 21, 2007, with changes through August 3, 2012.
3. UL 541. Refrigerated Vending Machines. 7th edition. Supplement SA: Requirements for Refrigerated Venders Employing a Flammable Refrigerant in the Refrigerating System. December 30, 2011.
4. UL Standard 60335–2–24. Standard for Safety: Requirements for Household and Similar Electrical Appliances,—Safety—Part 2–24: Particular Requirements for Refrigerating Appliances, Ice-Cream Appliances and Ice-Makers, Second edition, dated April 28, 2017.

The Director of the Federal Register approves the incorporation by reference of the material under ''Use Conditions'' in the table ''SUBSTITUTES THAT ARE ACCEPTABLE SUBJECT TO USE CONDITIONS'' (5 U.S.C. 552(a) and 1 CFR part 51). Copies of UL Standards 471, 484, 541, and 60335–2–24, may be purchased by mail at: COMM 2000, 151 Eastern Avenue, Bensenville, IL 60106; Email: *orders@shopulstandards.com;* Telephone: 1–888–853–3503 in the U.S. or Canada (other countries dial 1–415–352–2178); internet address: *http://www.shopulstandards.com/Catalog.aspx*.

You may inspect a copy at U.S. EPA's Air Docket; EPA West Building, Room 3334; 1301 Constitution Ave. NW, Washington, DC or at the National Archives and Records Administration (NARA). For questions regarding access to these standards, the telephone number of EPA'S Air Docket is 202–566–1742. For information on the availability of this material at NARA, call 202–741–6030, or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html*.

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[FR Doc. 2018–16773 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0352; FRL–9978–83]

Spinetoram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinetoram in or on tea, dried and tea, instant. Dow AgroSciences, LLC., requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 8, 2018. Objections and requests for hearings must be received on or before October 9, 2018, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2017–0352, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP

Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2017–0352 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before October 9, 2018. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2017–0352, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of October 23, 2017 (82 FR 49020) (FRL–9967–37), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 7E8554) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268–1054. The petition requested that 40 CFR 180.635 be amended by establishing tolerances for residues of the insecticide spinetoram, in or on tea, dried at 70 parts per million (ppm) and tea, instant at 70 ppm. That document referenced a summary of the petition prepared by Dow AgroSciences, the registrant, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for spinetoram including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with spinetoram follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Spinetoram and spinosad are considered by EPA to be toxicologically identical for human health risk assessment based on their very similar chemical structures and similarity of the toxicological databases for currently available studies, therefore, the Agency has assessed and summarized the toxicological profile for both together. The primary toxic effect observed from exposure to spinetoram and spinosad was histopathological changes in multiple organs (specific target organs were not identified). Vacuolization of cells and/or macrophages was the most common histopathological finding noted across the toxicological database with the dog being the most sensitive species. In addition to the numerous organs observed with histopathological changes, anemia was noted in several studies. There was no evidence of increased quantitative or qualitative susceptibility from spinetoram or spinosad exposure. In developmental studies, no maternal or developmental effects were seen in rats or rabbits. In the rat reproduction toxicity studies, offspring toxicity (decreased litter size,

survival, and body weights with spinosad; increased incidence of late resorptions and post-implantation loss with spinetoram) was seen in the presence of parental toxicity (increased organ weights, mortality, and histopathological findings) at approximately the same dose for both chemicals. Dystocia and/or other parturition abnormalities were observed with both spinetoram and spinosad in the reproduction toxicity studies. There was no evidence of neurotoxicity, immunotoxicity, or carcinogenicity from spinetoram exposure.

Specific information on the studies received and the nature of the adverse effects caused by spinetoram as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document ''*Spinosad/Spinetoram. Human Health Risk Assessment in Support of Proposed Spinetoram Tolerance for Residues in/on Imported Tea*'' *at page 8 in docket ID number EPA–HQ–OPP–2017–0352 and in document* ''*Spinosad/Spinetoram. Draft Human Health Risk Assessment for Registration Review,*'' at pages 12–17 in docket ID number EPA–HQ–OPP–2011–0666.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

Spinetoram and spinosad should be considered toxicologically identical in the same manner that metabolites are generally considered toxicologically identical to the parent. As a result, studies from both toxicological databases were considered for endpoint selection.

A summary of the toxicological endpoints for spinetoram used for human risk assessment is shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR SPINETORAM/SPINOSAD FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All populations) ..	A dose and endpoint of concern attributable to a single dose was not observed.		
Chronic dietary (All populations)	NOAEL = 2.49 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.0249 mg/kg/day. cPAD = 0.0249 mg/kg/day.	Chronic Toxicity—Dog (Spinetoram). LOAEL = 5.36/5.83 mg/kg/day (males/females) based on arteritis and necrosis of the arterial walls of the epididymides in males and of the thymus, thyroid, larynx, and urinary bladder in females.
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 4.9 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE <100.	Subchronic Oral Toxicity—Dog Study (with spinosad). LOAEL = 9.73 mg/kg/day based on microscopic changes in multiple organs, clinical signs of toxicity, decreases in body weights and food consumption, and biochemical evidence of anemia and liver damage.
Dermal (All durations)	No hazard was identified for dermal exposure; therefore, a quantitative dermal assessment is not needed.		
Inhalation short-term (1 to 30 days) and Intermediate-Term (1–6 months).	Inhalation (or oral) study NOAEL = 4.9 mg/kg/day (inhalation assumed equivalent to oral). UF_A = 10x UF_H = 10x FQPA SF = 1x	Residential LOC for MOE <100.	Subchronic Oral Toxicity—Dog Study (with spinosad). LOAEL = 9.73 mg/kg/day based on microscopic changes in multiple organs, clinical signs of toxicity, decreases in body weights and food consumption, and biochemical evidence of anemia and liver damage.
Cancer (Oral, dermal, inhalation).	Classified as ''not likely to be carcinogenic to humans.''		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population-adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_{DB} = to account for the absence of data or other data deficiency. UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to spinetoram and spinosad, EPA considered exposure under the petitioned-for tolerances as well as all existing spinetoram tolerances in 40 CFR 180.635 as well as existing spinosad tolerances. With the exception

of tea, spinosad is registered for application to all of the same crops as spinetoram, with similar pre-harvest and retreatment intervals, and application rates greater than or equal to spinetoram. Further, both active ingredients control the same pest species. For this reason, EPA has concluded it would overstate exposure to assume that residues of both spinosad and spinetoram would appear on the same food. The risk assessment included commodities that have tolerances for both spinosad and spinetoram as well as commodities where only spinosad tolerances are established. EPA aggregated exposure by assuming that all commodities, with the exception of tea, contain spinosad (because side-by-side spinetoram and spinosad residue data indicated that spinetoram residues were less than or equal to spinosad residues); for tea, EPA assumed spinetoram residues were present. EPA assessed dietary exposures from spinetoram in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No such effects were identified in the toxicological studies for spinetoram or spinosad; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA NHANES/WWEIA (2003–2008). As to residue levels in food, EPA assumed 100 percent crop treated (PCT), average field-trial residues or tolerance-level residues for crop commodities, average residues from the livestock feeding studies, spinosad residue estimates for fish/shellfish (residues of spinetoram in fish/shellfish are expected to be insignificant), and experimental or default processing factors.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that spinetoram does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use PCT information in the dietary assessment for spinetoram. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such Data Call-Ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening-level water exposure models in the dietary exposure analysis and risk assessment for spinetoram and spinosad in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of spinetoram and spinosad. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the surface water concentration calculator (SWCC) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of spinetoram for acute exposures are estimated to be 25.9 parts per billion (ppb) for surface water and below the levels of detection for ground water. For chronic exposures for non-cancer assessments, the spinetoram EDWCs are estimated to be 19.3 ppb for surface water and well below the levels of detection for ground water. EDWCs of spinosad for acute exposures are estimated to be 30.6 ppb for surface water and below the levels of detection for ground water. For chronic exposures for noncancer assessments, the spinetoram EDWCs are estimated to be 22.8 ppb for surface water and below the levels of detection for ground water.

Modeled estimates of drinking water concentration were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 22.8 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

EPA assessed residential exposure using the following assumptions: The use on tea will not result in residential exposure; however, spinetoram and spinosad are currently registered for uses that could result in residential exposures including home lawns and pet (cats/kittens) spot-on applications; therefore, there is potential for residential handler and post-application exposures to both spinetoram and spinosad. Since spinosad and spinetoram control the same pests, EPA concludes that these products will not be used for the same uses in combination with each other and thus combining spinosad and spinetoram residential exposures would overstate exposure. EPA assessed residential exposure for both spinosad and spinetoram using the most conservative residential exposure scenarios for either chemical.

EPA assessed the following ''worst-case'' residential exposure scenarios as: (1) Adult residential handler (inhalation exposure from applications to lawns and turf) and (2) child (1–<2 years) (hand-to-mouth exposures from post-application exposure to turf). Because EPA's level of concern for spinetoram is a MOE below 100, the MOEs for both of these residential exposure scenarios are not of concern. In addition, the short-term assessment is protective of intermediate-term exposure as the short- and intermediate-term PODs are identical. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide.*

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found spinetoram to share a common mechanism of toxicity with any other substances, and spinetoram does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that spinetoram does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There is no evidence of increased prenatal or postnatal susceptibility.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for spinetoram is adequate for FQPA SF consideration.

ii. There is no evidence of neurotoxicity from spinetoram exposure.

iii. There is no evidence that spinetoram results in increased pre- or post-natal susceptibility in rats or rabbits.

iv. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in assessing exposures and these assessments will not underestimate the exposure and risks posed by spinetoram.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, spinetoram is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to spinetoram from food and water will utilize 72% of the cPAD for children 1–2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of spinetoram is not expected; therefore, the chronic dietary estimate represents the chronic aggregate estimate.

3. *Short- and Intermediate-term risk.* Short- and Intermediate-term aggregate exposures takes into account short-term and intermediated-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Spinetoram is currently registered for uses that could result in short- and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short- and intermediate-term residential exposures to spinetoram.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 780 for adults (handler) and 200 for children (post-application). Because EPA's level of concern for spinetoram is a MOE below 100, these MOEs are not of concern. In addition, the short-term assessment is protective of intermediate-term exposure as the short- and intermediate-term PODs are identical.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, spinetoram is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to spinetoram residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available for both plant and livestock commodities. Method GRM 05.03 (HPLC/MS/MS) is an acceptable method for the determination of spinetoram residues in a variety of crops. Methods GRM 05.15 and GRM 06.08 (HPLC/MS) are acceptable methods for determination of spinetoram residues in bovine and poultry tissues, milk, cream, and eggs. Both methods are available to enforce the tolerance expression.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: *residuemethods@epa.gov.*

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for spinetoram.

V. Conclusion

Therefore, tolerances are established for residues of spinetoram, expressed as the combined residues of XDE–175–J: 1-*H*-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-α-*L*-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino) tetrahydro-6-methyl-2*H*-pyran-2-yl] oxy]-9-ethyl-2,3,3a,4,5,5a,5b,6,9,10, 11,12,13,14,16a,16b-hexadecahydro 14-methyl-, (2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*, 14*R*,16a*S*,16b*R*); XDE–175–L: 1*H*-as-indaceno[3,2-d]oxacyclododecin-7,15-dione, 2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-α-*L*-mannopyranosyl)oxy]-13-[[(2*R*,5*S*,6*R*)-5-(dimethylamino) tetrahydro-6-methyl-2*H*-pyran-2-yl]oxy]-9-ethyl-2,3,3a,5a,5b,6,9,10,11,12,13,14, 16a,16b-tetradecahydro-4,14-dimethyl-(2*S*,3a*R*,5a*S*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*S*); ND–J: (2*R*,3a*R*,5a*R*,5b*S*,9*S*, 13*S*,14*R*,16a*S*,16b*R*)-9-ethyl-14-methyl-13 [[(2*S*,5*S*,6*R*)-6-methyl-5-(methylamino)tetrahydro-2*H*-pyran-2-yl]oxy]-7,15-dioxo-2,3,3a,4,5,5a,5b,6, 7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1*H*-as-indaceno[3,2-

d]oxacyclododecin-2-yl 6-deoxy-3-O-ethyl-2,4-di-O-methyl-α-*L*-mannopyranoside; and NF–J: (2*R*,3*S*,6*S*)-6-([(2*R*,3a*R*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-2-[(6-deoxy-3-O-ethyl-2,4-di-O-methyl-α-*L*-mannopyranosyl) oxy]-9-ethyl-14-methyl-7,15-dioxo-2,3,3a,4,5,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-1*H*-as-indaceno[3,2-d]oxacyclododecin-13-yl]oxy)-2-methyltetrahydro-2*H*-pyran-3-yl(methyl)formamide, in or on tea, dried at 70 parts per million (ppm) and tea, instant at 70 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule 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**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 24, 2018.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.635 add alphabetically the entries for ''Tea, dried''; and ''Tea, instant''; and footnote 1 to the table in paragraph (a) to read as follows:

§ 180.635 Spinetoram; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Tea, dried [1]	70
Tea, instant [1]	70
* * * * *	

[1] There are no U.S. registrations as of August 8, 2018 for use on tea.

* * * * *

[FR Doc. 2018–16989 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 83, No. 153
Wednesday, August 8, 2018

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 ENERGY

10 CFR Part 830

RIN 1992–AA57

Nuclear Safety Management

AGENCY: Office of Environment, Health, Safety and Security, U.S. Department of Energy.

ACTION: Notice of proposed rulemaking and notice of public meetings.

SUMMARY: The Department of Energy (DOE or the Department) publishes a proposed rule to amend regulations concerning nuclear safety management. These regulations govern the conduct of DOE contractors, DOE personnel, and other persons conducting activities (including providing items and services) that affect, or may affect, the safety of DOE nuclear facilities. The proposed revisions reflect the experience gained in the implementation of the regulations over the past seventeen years, with specific improvements to the process for facility hazard categorization, the unreviewed safety question process, and the review and approval of safety documentation. The proposed revisions are intended to enhance operational efficiency while maintaining robust safety performance.

DATES: Public comment on this proposed rule will be accepted until October 9, 2018. For dates and more information on the public meetings for this proposed rulemaking, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: You may submit comments, identified by RIN 1992–AA57, by any of the following methods:

1. *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

2. *Email: Rulemaking.830@hq.doe.gov.* Include RIN 1992–AA57 in the subject line of the email. Please include the full body of your comments in the text of the message or as an attachment.

3. *Mail:* U.S. Department of Energy, Office of Nuclear Safety, AU–30, 1000 Independence Avenue SW, Washington, DC 20585.

Due to potential delays in DOE's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit comments electronically to ensure timely receipt.

FOR FURTHER INFORMATION CONTACT: Mr. Garrett Smith, U.S. Department of Energy, Office of Nuclear Safety, AU–30, 1000 Independence Avenue SW, Washington, DC 20585; (301) 903–2996 or *nuclearsafety@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: Public meetings for this proposed rulemaking will be held in:

1. Richland, WA at the HAMMER Federal Training Facility, Building 6091, Room 10, 2890 Horn Rapids Road, Richland, WA, on August 16th, 2018.

2. Albuquerque, NM at the Albuquerque Marriott, Sandia Room, 2101 Louisiana Blvd. NE, Albuquerque, NM, on September 6th, 2018.

3. Oak Ridge, TN at the Oak Ridge Associated Universities, Pollard Technology Conference Center Auditorium, 210 Badger Avenue, Oak Ridge, TN, on September 25th, 2018.

4. Aiken, SC at the University of South Carolina—Aiken, Business and Education Building, Room 124, 471 University Parkway, Aiken, SC, on September 27th, 2018.

All public meetings will be held from 1 p.m. to 4:30 p.m. and from 6 p.m. to 8:30 p.m. local time. Interested persons who wish to speak at the public meeting should telephone the Office of Nuclear Safety, (301) 903–2996, by 4:30 p.m. Eastern Time on August 13th, 2018 for Richland, WA, on August 31st, 2018 for Albuquerque, NM, on September 18th, 2018 for Oak Ridge, TN, and on September 20th, 2018 for Aiken, SC. Each presentation is limited to 20 minutes.

I. Introduction and Background

A. Introduction

Pursuant to the Atomic Energy Act of 1954, as amended (the AEA), the Department of Energy (DOE or the Department) owns and leases nuclear and non-nuclear facilities at various locations in the United States. These facilities are operated either by DOE or by contractors with DOE oversight. Activities at these facilities include, but are not limited to: Research, testing, production, disassembly, or transporting nuclear materials. DOE regulations governing nuclear safety at these facilities are set forth in the Nuclear Safety Management rule (10 CFR part 830). The regulations were issued in response to external assessments from the National Academy of Sciences (NAS), the enactment of the Price-Anderson Amendments Act of 1988 (PAAA), and DOE efforts to improve safety at DOE nuclear facilities. Aspects of 10 CFR part 830 were finalized and issued from 1994 to 2001, covering core safety requirements for quality assurance and facility safety basis. Over the past 17 years, DOE has gained considerable experience in the implementation of 10 CFR part 830, and is proposing to modify the requirements to incorporate that experience and help ensure more effective safety performance.

B. Procedural History of the Rule

On December 9, 1991, DOE published Procedural Rules for DOE Nuclear Activities (56 FR 64290) and a Notice of Proposed Rulemaking and Public Hearing (1991 Notice, 56 FR 64316) to add Parts 820 and 830 to Title 10 of the Code of Federal Regulation (CFR).[1] Title

[1] The Department proposed 10 CFR part 820 (Part 820), Procedural Rules for DOE Nuclear Activities, to establish the procedural requirements for enforcement activities in accordance with PAAA. On August 17, 1993, the Department issued the Procedural Regulations for DOE Nuclear Activities in final form as 10 CFR part 820 (58 FR 43680). Part 820 establishes the procedures for DOE enforcement

10 CFR part 830 was proposed to establish safety management requirements for DOE nuclear facilities. DOE issued, as final, the sections of 10 CFR part 830 related to the initial provisions (§§ 830.1–830.7) and Subpart A—General Provisions, (§§ 830.100–830.120) on April 5, 1994 (1994 Notice, 59 FR 15843).

The Department issued a Notice of Limited Reopening of the Comment Periods for the remaining topics to be addressed in 10 CFR part 830 on August 31, 1995, and for a second, unrelated, rule (Reopening Notice, 60 FR 45381).

On October 10, 2000, the Department published an Interim Final Rule and Opportunity for Public Comment (65 FR 60291) which amended the nuclear safety regulations to (1) establish and maintain safety bases for Hazard Category 1, 2, and 3 DOE nuclear facilities and perform work in accordance with safety bases, and (2) clarify that the quality assurance work process requirements apply to standards and controls adopted to meet regulatory or contract requirements that may affect nuclear safety (Interim Final Rule). The Interim Final Rule was also issued to provide further opportunity for public comment on the rule.

Following the public comment period, the Department issued a Final Rule on January 10, 2001 (66 FR 1810).

II. Discussion of Proposed Rule

A. Discussion of Key Proposed Changes

1. DOE Standard 1027—Section 830.202 of the regulations requires that DOE nuclear facilities be categorized consistent with DOE–STD–1027–92 (''*Hazard Categorization and Accident Analysis Techniques for compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports,*'' Change Notice 1, September 1997). The Department continues to believe that the methodology in DOE–STD–1027–92 Ch 1 is sufficient and supports the categorization of DOE nuclear facilities. In 2001, when Subpart B of 10 CFR part 830 was issued, not every Hazard Category 1, 2, and 3 DOE nuclear facility was categorized using a standardized methodology, and therefore consistent application of the cited reference, without change, was appropriate.

DOE now proposes, after two decades of experience in facility categorization using DOE–STD–1027–92, Ch 1, to amend § 830.202(b)(3) by adding ''or successor document''. This change would allow the Department to revise the standard to include up-to-date research, data, and DOE experience with implementation. This would be consistent with DOE's practice to periodically evaluate and revise DOE Technical Standards and would follow the development, review, and approval process described in DOE Order 252.1A, *Technical Standards Program.* The Technical Standards Program process requires concurrence from all affected Departmental elements prior to issuance of any standard.

DOE also proposes to amend Section C, Scope, of Appendix A to remove the reference to the specific version of DOE–STD–1027, for consistency with the revision in § 830.202. DOE would also remove Table 1 of Appendix A and replace that table with a definition for Hazard Category 1, 2, and 3 DOE nuclear facilities in § 830.3 that references DOE–STD–1027–92 or successor document. The removal of Table 1 would allow successor revisions to more clearly link the determination of Hazard Category 1, 2, 3, and below hazard category 3 to the methodology in the Standard. The concept that Hazard Category 1 will have higher potential consequences and Hazard Category 3 will have lower potential consequences will be maintained throughout all successor documents of DOE–STD–1027.

2. Unreviewed Safety Question (USQ) Process—A situation or potential situation outside the bounds of the current safety analysis for a Hazard Category 1, 2, or 3 nuclear facility (as documented in its approved safety analysis) constitutes an Unreviewed Safety Question under the current regulations. Section 830.203 allows contractors to make changes to the facility, to change site or facility procedures, and to conduct tests and/or experiments without prior DOE approval when these activities do not involve an Unreviewed Safety Question and do not require any change to Technical Safety Requirements.

The proposed change to Appendix A to Subpart B of 10 CFR part 830—General Statement of Safety Basis Policy, H, Unreviewed Safety Questions, would add the sentence, ''The contractor is allowed to make editorial and format changes to its USQ procedure while maintaining DOE approval.'' This proposal would focus the requirement to obtain DOE's approval on changes with the potential to impact on the safety basis of the facility.

DOE also proposes to modify § 830.3, Definitions, by changing the definition for Unreviewed Safety Question (USQ). The current definition includes four situations that define a USQ: (1) The probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the documented safety analysis (DSA) could be increased; (2) The possibility of an accident or malfunction of a different type than any evaluated previously in the documented safety analysis could be created; or (3) A margin of safety could be reduced; or (4) The documented safety analysis may not be bounding or may be otherwise inadequate. As explained in the following paragraphs, the proposed definition would remove the third situation: ''A margin of safety could be reduced''.

The current set of four situations that define an USQ in 10 CFR 830.3 reflected standard nuclear industry practice and was an adaptation of 10 CFR 50.59, changes, tests and experiments, used by the United States Nuclear Regulatory Commission (NRC). The NRC, in 1968, added to § 50.59 the concept of ''margin of safety as defined in the basis for any technical specification is reduced.'' In issuing 10 CFR part 830, DOE modified this question to simply read ''A margin of safety could be reduced''. In addition to adapting the NRC process, DOE included the situation of ''(4) The documented safety analysis may not be bounding or may otherwise be inadequate.''

The NRC, after 30 years of experience implementing § 50.59, issued an October 21, 1998, Notice of Proposed Rulemaking to change the criteria associated with margin of safety, explaining that ''the phrases 'margin of safety' and 'as defined in the basis for any technical specification' in the third criterion have been the subject of differing interpretations because the rule does not define what constitutes a margin of safety or a basis for any technical specification in the context of §§ 50.59 and 72.48. In addition, some have questioned the need for the third criterion on 'margin of safety.' '' The third criterion refers to the existence of two prior questions associated with creation, consequences, and likelihood of accidents and equipment malfunction. The revision to 10 CFR part 50 removing the term ''margin of safety'' from 10 CFR 50.59 was issued as a final rule on October 4, 1999.

DOE's experience with the margin of safety criteria is similar to that expressed by the NRC in its rulemaking, specifically, that the other existing criteria provide sufficient guidance to identify facility and safety basis changes that warrant DOE approval. Feedback from periodic surveys considering a broad-range of USQ determinations indicated that the ''margin of safety''

actions and for issuing civil and criminal penalties for contractor, subcontractor, and supplier violations of DOE nuclear safety requirements.

criterion has not provided benefit independent of the criteria DOE is retaining in the definition of the USQ process. In addition, stakeholder feedback noted that the ''margin of safety'' criterion was subjectively interpreted and often diverted safety resources without a corresponding safety benefit. Therefore, the proposed removal of the criterion related to ''margin of safety'' would enhance DOE and contractor operational effectiveness, without reducing the level of safety provided by the current practice. The current practice allows contractors to conduct certain specified activities without prior DOE approval, when these activities do not cause an Unreviewed Safety Question (and when they do not require Technical Safety Requirements changes).[2]

3. DOE Approval of Annual DSA Updates—As stated above, DOE currently requires the contractor, in § 830.203, Unreviewed Safety Question process, to obtain DOE approval prior to taking any action determined to involve a USQ. Additionally, in § 830.202 Safety basis, DOE requires the contractor to annually submit to DOE either the updated DSA for approval or a letter stating that there have been no changes in the DSA since the prior submission. This effectively requires the contractor to submit changes to the DSA for DOE approval twice. Currently, DOE provides implementation guidance for this approval process in DOE–STD–1104–2016, *Review and Approval of Nuclear Facility Safety Basis and Safety Design Basis Documents,* Section 7.1.2, *Review of Safety Basis Changes and DSA Annual Updates.* The guidance states that ''Review and approval of revisions and annual updates are a matter of endorsing the incorporation of changes in the safety basis since the last approval rather than performing a new assessment of the previously approved safety basis documents.'' While the guidance is clear in the intent to drive focus of DOE's approval to the change identified in the USQ process, the regulations' additional requirement for a second approval has led to considerable implementation challenges, and unnecessary review iterations without providing additional safety benefit.

Therefore, DOE is proposing to change the requirement in § 830.202, Safety basis, to require the current DSA be provided to DOE annually, but not to require DOE approval at that time. Additional guidance would also be included in Appendix A to Subpart B of 10 CFR part 830—General Statement of Safety Basis Policy, F, Documented Safety Analysis, to make clear that DOE's review and approval of the safety analysis is intended to be focused on changes submitted through the USQ process, but may require DOE approval if DOE has reason to believe a portion of the safety basis has substantially changed. DOE would continue to have the authority to review the safety basis at any time. DOE would maintain the ability to direct the contractor to incorporate in the safety basis any changes, conditions, or hazard controls.

4. Definition and Application of New Facilities, Major Modification, Preliminary Documented Safety Analysis, and Existing Facilities—The current definitions of a *New DOE nuclear facility, Major Modification, Preliminary documented safety analysis,* and *Existing DOE nuclear facility* (and applications of those definitions within the rule) reference specific dates related to the issuance of the rule and the need to bring DOE nuclear facilities into the regulatory framework. DOE is proposing to change the definitions to clearly recognize that all current DOE nuclear facilities are already within this regulatory framework and that new DOE nuclear facilities would be those that are in design or under construction that do not yet have a DOE approved safety basis. Additionally, the specific definition of an *existing DOE nuclear facility* is being proposed to be deleted. DOE proposes instead to rely upon a new definition of *Hazard Category 1, 2, and 3 DOE nuclear facilities* and the specific endpoint of a DOE approved safety basis to delineate between a new facility and an existing facility.

DOE also proposes to change the definition of a *Major modification* to remove the completion date of the facility. The definition would rely upon a criteria of a substantial change to the existing safety basis for the facility. This would link the meaning of ''Major modification'' to changes to existing Hazard Category 1, 2, or 3 nuclear facilities via the existence of a safety basis for the facility. Furthermore, additional clarity is proposed within 10 CFR part 830, subpart B, to highlight that the concept of ''Major modification'' would only apply to existing Hazard Category 1, 2, or 3 DOE nuclear facilities (*i.e.,* nuclear facilities with an approved safety basis).

DOE proposes to change the definition of *Preliminary documented safety analysis* to maintain consistency with other proposed changes to the definitions related to nuclear facilities.

B. Proposed Changes in Order of Appearance

The specific proposed changes to 10 CFR part 830 are summarized below in the order in which they appear:

1. In proposed § 830.3 ''Definitions,'' the current definition for *Existing DOE nuclear facility* would be deleted, a definition for *Hazard Category 1, 2, and 3 DOE nuclear facilities* has been proposed, and there would be a modification of the current definition of *New Hazard Category 1, 2, and 3 DOE nuclear facility.* These changes are designed to improve the delineation between new and existing facilities. The definition for *Major modification* would be changed to remove the effective date associated with the original issuance of the rule. The definition for *Preliminary documented safety analysis* would be changed to better reflect the intent of preliminary documented safety analysis being associated with Hazard Category 1, 2, or 3 DOE nuclear facilities rather than all DOE nuclear facilities. The definition for *Safety management system* would be changed to include the specific title of 48 CFR 970.5223–1, Integration of environment, safety, and health into work planning and execution. The definition for *Unreviewed Safety Question (USQ)* would be changed by adding ''or'' to the end of (2), deleting ''(3) A margin of safety could be reduced; or'', and renumbering (4) as (3).

2. In proposed § 830.201 ''Performance of Work,'' current § 830.201 would be changed by adding ''DOE-approved'' to modify safety basis to maintain consistency with § 830.207, DOE approval of safety basis.

3. Proposed § 830.202(b)(3) would be changed to add ''or successor document'' to modify DOE–STD–1027–92 (''Hazard Categorization and Accident Analysis Techniques for compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports,'' Change Notice 1, September 1997). This proposed change would allow DOE to modify the methodology used to perform hazard categorization consistent with DOE's policy of maintaining technical standards to reflect updated knowledge and methods. Current § 830.202(c)(2) would be changed to read, ''(2) Annually provide DOE the current documented safety analysis or a letter stating that

[2] DOE's implementation guidance associated with these criteria is DOE G 424.1–1B Chg 2, Implementation Guide for Use in Addressing Unreviewed Safety Question Requirements. Based on the four criteria defining a situation involving a USQ in 10 CFR part 830, DOE G 424.1–1B Chg 2 contains seven questions. The last question related to the concept of the margin of safety. If DOE adopts this proposal in a final rule, DOE would also conduct a process to consider removal of the question from the DOE Guide.

there have been no changes in the documented safety analysis since the prior submittal; and''. These proposed changes reflect the removal of the requirement for DOE to annually approve the documented safety analysis, and are intended to focus DOE's approval on the existing requirement to approve changes through the USQ process.

4. In proposed § 830.203 ''Unreviewed safety question process,'' current § 830.203(a) would be changed by adding ''DOE-approved'' as a modifier to USQ, and by changing the word ''process'' to ''procedure''. These proposed changes are to clarify the connection between references to the DOE-approved procedure in proposed § 830.203(a), § 830.203(b), and § 830.203(c). Current § 830.203(b) would be deleted, since DOE no longer has existing facilities operating outside of 10 CFR part 830. In the current § 830.203(c), which is proposed to be redesignated as § 830.203(b), the word ''new'' has been proposed to be moved to match a proposed change in the definition of New Hazard Category 1, 2, and 3 nuclear facility, and ''207(d)'' would be changed to ''207(a)'' to reflect changes to § 830.207. Current § 830.203(d) would be redesignated as § 830.203(c). Current § 830.203(e) would be redesignated as § 830.203(d). Current § 830.203(f) would be redesignated as § 830.203(e), ''submit'' would be replaced by ''provide'', and ''submissions'' would be replaced by ''submittal'' to better reflect that the document is being given to DOE for review, but not for approval. Current § 830.203(g) would be redesignated as § 830.203(f), and the text would be changed to read ''initiated to meet paragraph (f)(1) of this section'' consistent with citation changes in this section.

5. In proposed § 830.204 ''Documented safety analysis,'' current § 830.204(a) would be updated by changing ''Table 2'' to ''Table 1'' to reflect the deletion of Table 1 and re-numbering of subsequent tables.

6. In proposed § 830.206 ''Preliminary documented safety analysis,'' current § 830.206 would be changed to read ''Prior to construction of a new Hazard Category 1, 2, or 3 DOE nuclear facility or a major modification to an existing Hazard Category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the design and construction of the new facility or major modification must:'' To reflect changes to the definitions in § 830.3. Current § 830.206(b)(1) would be changed to add, '', or successor document'' as a modifier to ''DOE Order 420.1, Facility Safety'' to reflect the ongoing updates to the current version of the DOE order.

7. In proposed § 830.207 ''DOE approval of safety basis,'' current § 830.207(a) would be deleted, as DOE no longer has existing Hazard Category 1, 2, or 3 facilities operated outside of 10 CFR part 830. Current § 830.207(b) would be changed by adding ''updated or amended'' to modify ''safety basis'', moving the word ''existing'' to before the phrase ''Hazard Category 1, 2, or 3 DOE nuclear facility'' to better match the revised definition, and by deleting ''in effect on October 10, 2000, or as approved by DOE at a later date'' to reflect that all Hazard Category 1, 2, or 3 DOE nuclear facilities already operate within 10 CFR part 830. Current § 830.207(c) would be deleted, as DOE no longer has existing Hazard Category 1, 2, or 3 facilities operated outside of 10 CFR part 830. Current § 830.207(d) would be redesignated as § 830.207(a) and updated to reflect the changes in definitions in § 830.3. As a result, the proposed § 830.207(a) would now read as: ''With respect to a new Hazard Category 1, 2, or 3 DOE nuclear facility or a major modification to an existing Hazard Category 1, 2, or 3 DOE nuclear facility, a contractor may not begin operation of the facility or modification prior to the issuance of a safety evaluation report in which DOE approves the safety basis for the facility or modification.''

8. In proposed Appendix A to Subpart B to 10 CFR part 830—General Statement of Safety Basis Policy current ''A. Introduction'' would be modified by replacing a reference to an outdated DOE Policy with a specific statement that reflects current DOE policy and would now read as follows, ''This Appendix does not create any new requirements and should be used consistently with DOE's policy that work be conducted safely and efficiently and in a manner that ensures protection of workers, the public, and the environment.''

9. In proposed Appendix A to Subpart B to 10 CFR part 830—General Statement of Safety Basis Policy current ''C. Scope, 1.'' would be changed by replacing the reference to ''DOE–STD–1027–92 Change Notice 1, September 1997'' with a general reference to DOE–STD–1027 to reflect the proposed change to allow successor versions of DOE–STD–1027 to be used, the reference to ''Table 1'' would be deleted to reflect the proposed deletion of Table 1. The proposed sentences now would read, ''A contractor must establish and maintain a safety basis for a Hazard Category 1, 2, or 3 DOE nuclear facility because these facilities have the potential for significant radiological consequences. DOE–STD–1027 sets forth the methodology for categorizing a DOE nuclear facility based on the inventory of radioactive materials.'' Current ''C. Scope, 2.'' Would be changed to delete the parenthetical reference to ''including radiological facilities'', and by adding ''DOE'' to the reference to Hazard Category 1, 2, and 3 nuclear facilities to match changes to definitions within § 830.3. Current ''C. Scope'' Table 1 is proposed for deletion for consistency with the proposal to allow use of subsequent versions of DOE–STD–1027, since Table 1 references the specific content of DOE–STD–1027–92, Change Notice 1, September 1997.

10. In proposed Appendix A to Subpart B to 10 CFR part 830—General Statement of Safety Basis Policy, current ''E. Enforcement of Safety Basis Requirements, 4.'' would be changed by deleting the word ''however'' to improve clarity.

11. In proposed Appendix A to Subpart B to 10 CFR part 830—General Statement of Safety Basis Policy current ''F. Documented Safety Analysis, 3.'' would be changed by adding ''as: (1) part of the initial submittal; (2) when revisions are submitted as part of a positive USQ or major modification; (3) if DOE has reason to believe a portion of the safety basis to be inadequate, or; (4) if DOE has reason to believe a portion of the safety basis has substantially changed. DOE will review the DSA'' to better define when and why DOE would review a DSA. This change is proposed to be consistent with proposed changes to DOE's requirement to annually approve the DSA. Current ''F. Documented Safety Analysis, 3.'' would also be changed by adding ''in the Safety Evaluation Report'' to the end of the last sentence in that section, which currently reads, ''A documented safety analysis must contain any conditions or changes required by DOE.'' This change is proposed to clarify how DOE directs conditions and changes required by DOE. Additionally, Current ''F. Documented Safety Analysis, 3.'' would be changed by adding the following sentences, ''Generally, DOE's review of the annual submittal may be limited to ensuring that the results of USQs have been adequately incorporated into the DSA. If additional changes are proposed by the contractor and included in the annual update that have not been previously approved by DOE or have not been evaluated as a part of the USQ process, DOE must review and approve these changes. DOE has the authority to review the safety basis at any time.''

This proposed change is in support of focusing DOE's approval of changes in the DSA to the incorporation of USQ's or as DOE determines are necessary to maintain safe operations, rather than the previous annual process. Current ''F. Documented Safety Analysis, 4.'' would be changed by renumbering the reference to ''Table 2'' to ''Table 1'' to reflect the deletion of Table 1. Current ''F. Documented Safety Analysis'' would be changed by changing the title of ''Table 2'' to ''Table 1'' to reflect the deletion of Table 1. Current ''F. Documented Safety Analysis, 5.'' would be changed by renumbering the reference to ''Table 2'' to ''Table 1'' to reflect the deletion of Table 1, by changing the reference to the definition of nuclear facility to re-state the existing definition within § 830.3 instead of paraphrasing the definition, by renumbering the reference to ''Table 3'' to ''Table 2'' to reflect the deletion of Table 1, and by replacing ''specific nuclear facilities'' with ''terms'' in reference to the content within Table 1. Current ''F. Documented Safety Analysis'' would be changed by renumbering the title of ''Table 3'' to ''Table 2'' to reflect the proposed deletion of Table 1 and changing the reference to ''Table 2'' to ''Table 1'' to reflect the proposed deletion of Table 1. Current ''F. Documented Safety Analysis, 6.'' would be changed to delete the phrase ''If construction begins after December 11, 2000'' and by adding ''or successor document'' as a modifier to ''DOE Order 420.1, Facility Safety'' to reflect the ongoing updates to the current version of the DOE order.

12. In proposed Appendix A to Subpart B to 10 CFR part 830—General Statement of Safety Basis Policy current ''G. Hazard Controls, 2.'' would be changed to add ''or successor document'' as a modifier to ''DOE Order 420.1, Facility Safety'' to reflect the ongoing updates to the current version of the DOE order. Current ''G. Hazard Controls, 4.'' would be changed to update the reference to DOE Guide 423.1–1B and by adding, ''or successor document'' to reflect the ongoing updates to the current version of the DOE guide. Current ''G. Hazard Controls, 4.'' would be changed by changing the reference to ''Table 4'' to ''Table 3'' to reflect the proposed deletion of Table 1. Current ''G. Hazard Controls'' would be changed by changing the title of the table from ''Table 4'' to ''Table 3'' to reflect the proposed deletion of Table 1.

13. In proposed Appendix A to Subpart B to 10 CFR part 830—General Statement of Safety Basis Policy current ''H. Unreviewed Safety Questions, 3.'' Would be changed to update the reference to DOE Guide 424.1–1B Chg 2, to update the title of the referenced guide to ''Implementation Guide for Use in Addressing Unreviewed Safety Question Requirements,'' to add ''or successor document'' to reflect the ongoing updates to the current version of the DOE guide, and by adding the sentence, ''The contractor is allowed to make editorial and format changes to its USQ procedure while maintaining DOE approval.'' The additional sentence wold be provided to better delineate those aspects of the USQ process on which DOE approval focuses.

14. Throughout 10 CFR part 830, the term ''Hazard Category'' would be capitalized to improve consistency with the usage within the DOE regulatory structure.

III. Public Comment Procedures

A. Written Comments

Interested persons are invited to participate in this proceeding by submitting data, views, or arguments. Written comments should be submitted to the address, and in the form, indicated in the **ADDRESSES** section of this notice of proposed rulemaking. To help DOE review the comments, interested persons are asked to refer to specific proposed rule provisions, if possible.

If you submit information that you believe to be exempt by law from public disclosure, you should submit one complete copy, as well as one copy from which the information claimed to be exempt by law from public disclosure has been deleted. DOE is responsible for the final determination with regard to disclosure or nondisclosure of the information and for treating it accordingly under the DOE Freedom of Information regulations at 10 CFR 1004.11.

B. Public Meetings

Public meetings will be held at the times, dates, and places indicated at the start of the **SUPPLEMENTARY INFORMATION** section of this notice of proposed rulemaking. Any person who is interested in making an oral presentation should make a phone request to the person and telephone number in the **SUPPLEMENTARY INFORMATION** section by 4:30 p.m. on the date specified for making such requests. The person should provide a daytime phone number where he or she can be reached. Each oral presentation will be limited to 20 minutes. Persons making an oral presentation are requested to bring 3 copies of their prepared statement to the meeting and submit them to the registration desk prior to the meeting.

IV. Regulatory Review

A. Review Under Executive Order 12866

This notice of proposed rulemaking has been determined not to be a significant regulatory action under Executive Order 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (Oct. 4, 1993). Accordingly, this notice of proposed rulemaking was not subject to review by the Office of Information and Regulatory Affairs of the Office of Management and Budget.

B. Review Under Executive Orders 13771 and 13777

On January 30, 2017, the President issued Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs.'' That Order stated the policy of the executive branch is to be prudent and financially responsible in the expenditure of funds, from both public and private sources. The Order stated it is essential to manage the costs associated with the governmental imposition of private expenditures required to comply with Federal regulations. This proposed rule is expected to be an E.O. 13771 deregulatory action.

Additionally, on February 24, 2017, the President issued Executive Order 13777, ''Enforcing the Regulatory Reform Agenda.'' The Order required the head of each agency designate an agency official as its Regulatory Reform Officer (RRO). Each RRO oversees the implementation of regulatory reform initiatives and policies to ensure that agencies effectively carry out regulatory reforms, consistent with applicable law. Further, E.O. 13777 requires the establishment of a regulatory task force at each agency. The regulatory task force is required to make recommendations to the agency head regarding the repeal, replacement, or modification of existing regulations, consistent with applicable law. At a minimum, each regulatory reform task force must attempt to identify regulations that:

(i) Eliminate jobs, or inhibit job creation;

(ii) Are outdated, unnecessary, or ineffective;

(iii) Impose costs that exceed benefits;

(iv) Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies;

(v) Are inconsistent with the requirements of Information Quality Act, or the guidance issued pursuant to that Act, in particular those regulations that rely in whole or in part on data, information, or methods that are not

publicly available or that are insufficiently transparent to meet the standard for reproducibility; or

(vi) Derive from or implement Executive Orders or other Presidential directives that have been subsequently rescinded or substantially modified.

DOE concludes that this final rule is consistent with the directives set forth in these executive orders. This provisions in this proposed rule are intended, as described in section II, to enhance operational efficiency while maintaining robust safety performance at DOE nuclear facilities.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (Aug. 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website (*http://energy.gov/gc/office-general-counsel*).

DOE has reviewed this proposed rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. The proposed rule would incorporate the experience of more than a decade of implementation to improve the effectiveness of the DOE nuclear safety regulatory framework while maintaining safety performance. Requirements that are considered duplicative or of little value have been proposed to be removed. DOE is proposing four key changes in this proposed rule, as described in II. Discussion of Proposed Rule, A. Discussion of Key Proposed Changes.

The changes in this proposed rule are all expected to reduce burden on affected DOE contractors. On this basis, DOE certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared a regulatory flexibility analysis for this rulemaking. DOE's certification and supporting statement of factual basis will be provided to the Chief Counsel for Advocacy of the Small Business Administration pursuant to 5 U.S.C. 605(b).

D. Paperwork Reduction Act

The information collection necessary to administer DOE's nuclear safety program under 10 CFR part 830 is subject to OMB approval under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* The information collection provisions of this rule are not substantially different from those contained in DOE contracts with DOE prime contractors covered by this rule and were previously approved by the Office of Management and Budget (OMB) and under OMB Control No. 1910–0300. Public reporting burden for the certification is estimated to average 1.91 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

E. National Environmental Policy Act

DOE has determined that this proposed rule is covered under the Categorical Exclusion in DOE's National Environmental Policy Act regulations at paragraph A.5 of Appendix A to Subpart D, 10 CFR part 1021, which applies to rulemaking that interprets or amends an existing rule or regulation without changing the environmental effect of the rule or regulation that is being amended. The proposed rule would amend DOE's regulations by removing duplicative approval requirements, updating definitions, and increasing the efficiency of internal processes. These proposed amendments are primarily procedural and would not change the environmental effect of 10 CFR part 830. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

F. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For regulatory actions likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. (This policy is also available at *http://energy.gov/gc/office-general-counsel*.) DOE examined this proposed rule according to UMRA and its statement of policy and has tentatively determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure by State, local, and Tribal government, in the aggregate, or by the private sector, of $100 million or more in any year. Accordingly, no further assessment or analysis is required under UMRA.

G. Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999, 5 U.S.C. 601 note, requires Federal agencies to issue a Family Policymaking Assessment for any proposed rule that may affect family wellbeing. While this proposed rule would apply to individuals who may be members of a family, the rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

H. Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (Aug. 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined this proposed rule and has determined that it would not preempt State law and

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. No further action is required by Executive Order 13132.

I. Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (Feb. 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this proposed rule meets the relevant standards of Executive Order 12988.

J. Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001, 44 U.S.C. 3516 note, provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to the Office of Information and Regulatory Affairs (OIRA) a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use. This regulatory action has been determined to not be a significant regulatory action, and it would not have an adverse effect on the supply, distribution, or use of energy. Thus, this action is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

V. Approval of the Office of the Secretary

The Secretary of Energy has approved the publication of this proposed rule.

List of Subjects in 10 CFR Part 830

Administrative practice and procedure, DOE contracts, Environment, Federal buildings and facilities, Government contracts, Nuclear materials, Nuclear power plants and reactors, Nuclear safety, Penalties, Public health, Reporting and recordkeeping requirements, and Safety.

Issued in Washington, DC, on August 1, 2018.

Dan Brouillette,

Deputy Secretary of Energy.

For the reasons stated in the preamble, DOE proposes to revise 10 CFR part 830 to read as follows:

PART 830—NUCLEAR SAFETY MANAGEMENT

Sec.

Authority: 42 U.S.C. 2201; 42 U.S.C. 7101 *et seq.;* and 50 U.S.C. 2401 *et seq.*

§ 830.1 Scope.

This part governs the conduct of DOE contractors, DOE personnel, and other persons conducting activities (including providing items and services) that affect, or may affect, the safety of DOE nuclear facilities.

§ 830.2 Exclusions.

This part does not apply to:

(a) Activities that are regulated through a license by the Nuclear Regulatory Commission (NRC) or a State under an Agreement with the NRC, including activities certified by the NRC under section 1701 of the Atomic Energy Act (Act);

(b) Activities conducted under the authority of the Director, Naval Nuclear Propulsion, pursuant to Executive Order 12344, as set forth in Public Law 106–65;

(c) Transportation activities which are regulated by the Department of Transportation;

(d) Activities conducted under the Nuclear Waste Policy Act of 1982, as amended, and any facility identified under section 202(5) of the Energy Reorganization Act of 1974, as amended; and

(e) Activities related to the launch approval and actual launch of nuclear energy systems into space.

§ 830.3 Definitions.

(a) The following definitions apply to this part:

Administrative controls means the provisions relating to organization and management, procedures, recordkeeping, assessment, and reporting necessary to ensure safe operation of a facility.

Bases appendix means an appendix that describes the basis of the limits and other requirements in technical safety requirements.

Critical assembly means special nuclear devices designed and used to sustain nuclear reactions, which may be subject to frequent core and lattice configuration change and which frequently may be used as mockups of reactor configurations.

Criticality means the condition in which a nuclear fission chain reaction becomes self-sustaining.

Design features means the design features of a nuclear facility specified in the technical safety requirements that, if altered or modified, would have a significant effect on safe operation.

Document means recorded information that describes, specifies, reports, certifies, requires, or provides data or results.

Documented safety analysis means a documented analysis of the extent to which a nuclear facility can be operated safely with respect to workers, the public, and the environment, including a description of the conditions, safe boundaries, and hazard controls that provide the basis for ensuring safety.

Environmental restoration activities means the process(es) by which contaminated sites and facilities are identified and characterized and by which contamination is contained, treated, or removed and disposed.

Fissionable materials means a nuclide capable of sustaining a neutron-induced chain reaction (*e.g.,* uranium-233, uranium-235, plutonium-238, plutonium-239, plutonium-241, neptunium-237, americium-241, and curium-244).

Graded approach means the process of ensuring that the level of analysis, documentation, and actions used to comply with a requirement in this part are commensurate with:

(i) The relative importance to safety, safeguards, and security;

(ii) The magnitude of any hazard involved;

(iii) The life cycle stage of a facility;

(iv) The programmatic mission of a facility;

(v) The particular characteristics of a facility;

(vi) The relative importance of radiological and nonradiological hazards; and

(vii) Any other relevant factor.

Hazard means a source of danger (*i.e.,* material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation).

Hazard Category 1, 2, and 3 DOE nuclear facilities means nuclear facilities that meet the criteria for their respective hazard category consistent with the provisions of DOE–STD–1027–92, Change Notice 1, or successor document. Hazard Category 1, 2, and 3 DOE nuclear facilities are required to have safety bases established in accordance with Subpart B of this part. Hazard categories are based on their radioactive material inventories and the potential consequences to the public, workers, and the environment. Hazard Category 1 represents the highest potential consequence and Hazard Category 3 represents the lowest potential consequence of the facilities required to establish safety bases.

Hazard controls means measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment, including

(i) Physical, design, structural, and engineering features;

(ii) Safety structures, systems, and components;

(iii) Safety management programs;

(iv) Technical safety requirements; and

(v) Other controls necessary to provide adequate protection from hazards.

Item is an all-inclusive term used in place of any of the following: Appurtenance, assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, or support systems.

Limiting conditions for operation means the limits that represent the lowest functional capability or performance level of safety structures, systems, and components required for safe operations.

Limiting control settings means the settings on safety systems that control process variables to prevent exceeding a safety limit.

Low-level residual fixed radioactivity means the remaining radioactivity following reasonable efforts to remove radioactive systems, components, and stored materials. The remaining radioactivity is composed of surface contamination that is fixed following chemical cleaning or some similar process; a component of surface contamination that can be picked up by smears; or activated materials within structures. The radioactivity can be characterized as low-level if the smearable radioactivity is less than the values defined for removable contamination by 10 CFR part 835, Appendix D, Surface Contamination Values, and the hazard analysis results show that no credible accident scenario or work practices would release the remaining fixed radioactivity or activation components at levels that would prudently require the use of active safety systems, structures, or components to prevent or mitigate a release of radioactive materials.

Major modification means a modification to a DOE nuclear facility that substantially changes the existing safety basis for the facility.

New Hazard Category 1, 2, and 3 DOE nuclear facility means a Hazard Category 1, 2, or 3 DOE nuclear facility that is in design or under construction that does not yet have a DOE approved safety basis.

Nonreactor nuclear facility means those facilities, activities or operations that involve, or will involve, radioactive and/or fissionable materials in such form and quantity that a nuclear or a nuclear explosive hazard potentially exists to workers, the public, or the environment, but does not include accelerators and their operations and does not include activities involving only incidental use and generation of radioactive materials or radiation such as check and calibration sources, use of radioactive sources in research and experimental and analytical laboratory activities, electron microscopes, and X-ray machines.

Nuclear facility means a reactor or a nonreactor nuclear facility where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established by this Part.

Operating limits means those limits required to ensure the safe operation of a nuclear facility, including limiting control settings and limiting conditions for operation.

Preliminary documented safety analysis means documentation prepared in connection with the design and construction of a new Hazard Category 1, 2, or 3 DOE nuclear facility or a major modification to an existing Hazard Category 1, 2, or 3 DOE nuclear facility that provides a reasonable basis for the preliminary conclusion that the nuclear facility can be operated safely through the consideration of factors such as:

(i) The nuclear safety design criteria to be satisfied;

(ii) A safety analysis that derives aspects of design that are necessary to satisfy the nuclear safety design criteria; and

(iii) An initial listing of the safety management programs that must be developed to address operational safety considerations.

Process means a series of actions that achieves an end or result.

Quality means the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality assurance means all those actions that provide confidence that quality is achieved.

Quality Assurance Program (QAP) means the overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Reactor means any apparatus that is designed or used to sustain nuclear chain reactions in a controlled manner such as research, test, and power reactors, and critical and pulsed assemblies and any assembly that is designed to perform subcritical experiments that could potentially reach criticality; and, unless modified by words such as containment, vessel, or core, refers to the entire facility, including the housing, equipment and associated areas devoted to the operation and maintenance of one or more reactor cores.

Record means a completed document or other media that provides objective evidence of an item, service, or process.

Safety basis means the documented safety analysis and hazard controls that provide reasonable assurance that a DOE nuclear facility can be operated safely in a manner that adequately protects workers, the public, and the environment.

Safety class structures, systems, and components means the structures, systems, or components, including portions of process systems, whose preventive or mitigative function is necessary to limit radioactive hazardous material exposure to the public, as determined from safety analyses.

Safety evaluation report means the report prepared by DOE to document:

(i) The sufficiency of the documented safety analysis for a Hazard Category 1, 2, or 3 DOE nuclear facility;

(ii) The extent to which a contractor has satisfied the requirements of Subpart B of this part; and

(iii) The basis for approval by DOE of the safety basis for the facility, including any conditions for approval.

Safety limits means the limits on process variables associated with those safety class physical barriers, generally passive, that are necessary for the intended facility function and that are required to guard against the uncontrolled release of radioactive materials.

Safety management program means a program designed to ensure a facility is operated in a manner that adequately protects workers, the public, and the environment by covering a topic such as: Quality assurance; maintenance of safety systems; personnel training; conduct of operations; inadvertent criticality protection; emergency preparedness; fire protection; waste management; or radiological protection of workers, the public, and the environment.

Safety management system means an integrated safety management system established consistent with 48 CFR 970.5223–1, *Integration of environment, safety, and health into work planning and execution.*

Safety significant structures, systems, and components means the structures, systems, and components which are not designated as safety class structures, systems, and components, but whose preventive or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses.

Safety structures, systems, and components means both safety class structures, systems, and components and safety significant structures, systems, and components.

Service means the performance of work, such as design, manufacturing, construction, fabrication, assembly, decontamination, environmental restoration, waste management, laboratory sample analyses, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

Surveillance requirements means requirements relating to test, calibration, or inspection to ensure that the necessary operability and quality of safety structures, systems, and components and their support systems required for safe operations are maintained, that facility operation is within safety limits, and that limiting control settings and limiting conditions for operation are met.

Technical safety requirements (TSRs) means the limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and the hazards identified in the documented safety analysis for the facility: Safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix.

Unreviewed Safety Question (USQ) means a situation where:

(i) The probability of the occurrence or the consequences of an accident or the malfunction of equipment important to safety previously evaluated in the documented safety analysis could be increased;

(ii) The possibility of an accident or malfunction of a different type than any evaluated previously in the documented safety analysis could be created; or

(iii) The documented safety analysis may not be bounding or may be otherwise inadequate.

Unreviewed Safety Question process means the mechanism for keeping a safety basis current by reviewing potential unreviewed safety questions, reporting unreviewed safety questions to DOE, and obtaining approval from DOE prior to taking any action that involves an unreviewed safety question.

Use and application provisions means the basic instructions for applying technical safety requirements.

(b) Terms defined in the Act or in 10 CFR part 820 and not defined in this section of the rule are to be used consistent with the meanings given in the Act or in 10 CFR part 820.

§ 830.4 General requirements.

(a) No person may take or cause to be taken any action inconsistent with the requirements of this part.

(b) A contractor responsible for a nuclear facility must ensure implementation of, and compliance with, the requirements of this part.

(c) The requirements of this part must be implemented in a manner that provides reasonable assurance of adequate protection of workers, the public, and the environment from adverse consequences, taking into account the work to be performed and the associated hazards.

(d) If there is no contractor for a DOE nuclear facility, DOE must ensure implementation of, and compliance with, the requirements of this part.

§ 830.5 Enforcement.

The requirements in this part are DOE Nuclear Safety Requirements and are subject to enforcement by all appropriate means, including the imposition of civil and criminal penalties in accordance with the provisions of 10 CFR part 820.

§ 830.6 Recordkeeping.

A contractor must maintain complete and accurate records as necessary to substantiate compliance with the requirements of this part.

§ 830.7 Graded approach.

Where appropriate, a contractor must use a graded approach to implement the requirements of this part, document the basis of the graded approach used, and submit that documentation to DOE. The graded approach may not be used in implementing the unreviewed safety question (USQ) process or in implementing technical safety requirements.

Subpart A—Quality Assurance Requirements

§ 830.120 Scope.

This subpart establishes quality assurance requirements for contractors conducting activities, including providing items or services that affect, or may affect, nuclear safety of DOE nuclear facilities.

§ 830.121 Quality Assurance Program (QAP).

(a) Contractors conducting activities, including providing items or services, that affect, or may affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the Quality Assurance criteria in § 830.122.

(b) The contractor responsible for a DOE nuclear facility must:

(1) Submit a QAP to DOE for approval and regard the QAP as approved 90 days after submittal, unless it is approved or rejected by DOE at an earlier date.

(2) Modify the QAP as directed by DOE.

(3) Annually submit any changes to the DOE-approved QAP to DOE for approval. Justify in the submittal why the changes continue to satisfy the quality assurance requirements.

(4) Conduct work in accordance with the QAP.

(c) The QAP must:

(1) Describe how the quality assurance criteria of § 830.122 are satisfied.

(2) Integrate the quality assurance criteria with the Safety Management System, or describe how the quality assurance criteria apply to the Safety Management System.

(3) Use voluntary consensus standards in its development and implementation, where practicable and consistent with contractual and regulatory requirements, and identify the standards used.

(4) Describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of § 830.122.

§ 830.122 Quality assurance criteria.

The QAP must address the following management, performance, and assessment criteria:

(a) *Criterion 1—Management/Program.* (1) Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work.

(2) Establish management processes, including planning, scheduling, and providing resources for the work.

(b) *Criterion 2—Management/Personnel Training and Qualification.* (1) Train and qualify personnel to be capable of performing their assigned work.

(2) Provide continuing training to personnel to maintain their job proficiency.

(c) *Criterion 3—Management/Quality Improvement.* (1) Establish and implement processes to detect and prevent quality problems.

(2) Identify, control, and correct items, services, and processes that do not meet established requirements.

(3) Identify the causes of problems and work to prevent recurrence as a part of correcting the problem.

(4) Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.

(d) *Criterion 4—Management/Documents and Records.* (1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.

(2) Specify, prepare, review, approve, and maintain records.

(e) *Criterion 5—Performance/Work Processes.* (1) Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory or contract requirements, using approved instructions, procedures, or other appropriate means.

(2) Identify and control items to ensure their proper use.

(3) Maintain items to prevent their damage, loss, or deterioration.

(4) Calibrate and maintain equipment used for process monitoring or data collection.

(f) *Criterion 6—Performance/Design.* (1) Design items and processes using sound engineering/scientific principles and appropriate standards.

(2) Incorporate applicable requirements and design bases in design work and design changes.

(3) Identify and control design interfaces.

(4) Verify or validate the adequacy of design products using individuals or groups other than those who performed the work.

(5) Verify or validate work before approval and implementation of the design.

(g) *Criterion 7—Performance/Procurement.* (1) Procure items and services that meet established requirements and perform as specified.

(2) Evaluate and select prospective suppliers on the basis of specified criteria.

(3) Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

(h) *Criterion 8—Performance/Inspection and Acceptance Testing.* (1) Inspect and test specified items, services, and processes using established acceptance and performance criteria.

(2) Calibrate and maintain equipment used for inspections and tests.

(i) *Criterion 9—Assessment/Management Assessment.* Ensure managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

(j) *Criterion 10—Assessment/Independent Assessment.* (1) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance, and to promote improvement.

(2) Establish sufficient authority, and freedom from line management, for the group performing independent assessments.

(3) Ensure persons who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.

Subpart B—Safety Basis Requirements

§ 830.200 Scope.

This Subpart establishes safety basis requirements for Hazard Category 1, 2, and 3 DOE nuclear facilities.

§ 830.201 Performance of work.

A contractor must perform work in accordance with the DOE-approved safety basis for a Hazard Category 1, 2, or 3 DOE nuclear facility and, in particular, with the hazard controls that ensure adequate protection of workers, the public, and the environment.

§ 830.202 Safety basis.

(a) The contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must establish and maintain the safety basis for the facility.

(b) In establishing the safety basis for a Hazard Category 1, 2, or 3 DOE

nuclear facility, the contractor responsible for the facility must:

(1) Define the scope of the work to be performed;

(2) Identify and analyze the hazards associated with the work;

(3) Categorize the facility consistent with DOE–STD–1027–92 (''Hazard Categorization and Accident Analysis Techniques for compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports,'' Change Notice 1, September 1997), or successor document;

(4) Prepare a documented safety analysis for the facility; and

(5) Establish the hazard controls upon which the contractor will rely to ensure adequate protection of workers, the public, and the environment.

(c) In maintaining the safety basis for a Hazard Category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the facility must:

(1) Update the safety basis to keep it current and to reflect changes in the facility, the work and the hazards as they are analyzed in the documented safety analysis;

(2) Annually provide DOE the current documented safety analysis or a letter stating that there have been no changes in the documented safety analysis since the prior submittal; and

(3) Incorporate in the safety basis any changes, conditions, or hazard controls directed by DOE.

§ 830.203 Unreviewed safety question process.

(a) The contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must establish, implement, and take actions consistent with a DOE-approved USQ procedure that meets the requirements of this section.

(b) The contractor responsible for a new Hazard Category 1, 2, or 3 DOE nuclear facility must submit for DOE approval a procedure for its USQ process on a schedule that allows DOE approval in a safety evaluation report issued pursuant to section 207(a) of this Part.

(c) The contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must implement the DOE-approved USQ procedure in situations where there is a:

(1) Temporary or permanent change in the facility as described in the existing documented safety analysis;

(2) Temporary or permanent change in the procedures as described in the existing documented safety analysis;

(3) Test or experiment not described in the existing documented safety analysis; or

(4) Potential inadequacy of the documented safety analysis because the analysis potentially may not be bounding or may be otherwise inadequate.

(d) A contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must obtain DOE approval prior to taking any action determined to involve a USQ.

(e) The contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must annually provide to DOE a summary of the USQ determinations performed since the prior submittal.

(f) If a contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility discovers or is made aware of a potential inadequacy of the documented safety analysis, it must:

(1) Take action, as appropriate, to place or maintain the facility in a safe condition until an evaluation of the safety of the situation is completed;

(2) Notify DOE of the situation;

(3) Perform a USQ determination and notify DOE promptly of the results; and

(4) Submit the evaluation of the safety of the situation to DOE prior to removing any operational restrictions initiated to meet paragraph (f)(1) of this section.

§ 830.204 Documented safety analysis.

(a) The contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must obtain approval from DOE for the methodology used to prepare the documented safety analysis for the facility unless the contractor uses a methodology set forth in Table 1 of Appendix A to this Part.

(b) The documented safety analysis for a Hazard Category 1, 2, or 3 DOE nuclear facility must, as appropriate for the complexities and hazards associated with the facility:

(1) Describe the facility (including the design of safety structures, systems and components) and the work to be performed;

(2) Provide a systematic identification of both natural and man-made hazards associated with the facility;

(3) Evaluate normal, abnormal, and accident conditions, including consideration of natural and man-made external events, identification of energy sources or processes that might contribute to the generation or uncontrolled release of radioactive and other hazardous materials, and consideration of the need for analysis of accidents which may be beyond the design basis of the facility;

(4) Derive the hazard controls necessary to ensure adequate protection of workers, the public, and the environment, demonstrate the adequacy of these controls to eliminate, limit, or mitigate identified hazards, and define the process for maintaining the hazard controls current at all times and controlling their use;

(5) Define the characteristics of the safety management programs necessary to ensure the safe operation of the facility, including (where applicable) quality assurance, procedures, maintenance, personnel training, conduct of operations, emergency preparedness, fire protection, waste management, and radiation protection; and

(6) With respect to a nonreactor nuclear facility with fissionable material in a form and amount sufficient to pose a potential for criticality, define a criticality safety program that:

(i) Ensures that operations with fissionable material remain subcritical under all normal and credible abnormal conditions;

(ii) Identifies applicable nuclear criticality safety standards; and

(iii) Describes how the program meets applicable nuclear criticality safety standards.

§ 830.205 Technical safety requirements.

(a) A contractor responsible for a Hazard Category 1, 2, or 3 DOE nuclear facility must:

(1) Develop technical safety requirements that are derived from the documented safety analysis;

(2) Prior to use, obtain DOE approval of technical safety requirements and any change to technical safety requirements; and

(3) Notify DOE of any violation of a technical safety requirement.

(b) A contractor may take emergency actions that depart from an approved technical safety requirement when no actions consistent with the technical safety requirement are immediately apparent, and when these actions are needed to protect workers, the public or the environment from imminent and significant harm. Such actions must be approved by a certified operator for a reactor or by a person in authority as designated in the technical safety requirements for nonreactor nuclear facilities. The contractor must report the emergency actions to DOE as soon as practicable.

(c) A contractor for an environmental restoration activity may follow the provisions of 29 CFR 1910.120 or 1926.65 to develop the appropriate hazard controls (rather than the provisions for technical safety requirements in paragraph (a) of this section), provided the activity involves either:

(1) Work not done within a permanent structure, or

(2) The decommissioning of a facility with only low-level residual fixed radioactivity.

§ 830.206 Preliminary documented safety analysis.

Prior to construction of a new Hazard Category 1, 2, or 3 DOE nuclear facility or a major modification to an existing Hazard Category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the design and construction of the new facility or major modification must:

(a) Prepare a preliminary documented safety analysis for the facility, and

(b) Obtain DOE approval of:

(1) The nuclear safety design criteria to be used in preparing the preliminary documented safety analysis unless the contractor uses the design criteria in DOE Order 420.1, Facility Safety, or successor document; and

(2) The preliminary documented safety analysis before the contractor can procure materials or components or begin construction; provided that DOE may authorize the contractor to perform limited procurement and construction activities without approval of a preliminary documented safety analysis if DOE determines that the activities are not detrimental to public health and safety and are in the best interests of DOE.

§ 830.207 DOE approval of safety basis.

(a) With respect to a new Hazard Category 1, 2, or 3 DOE nuclear facility or a major modification to an existing Hazard Category 1, 2, or 3 DOE nuclear facility, a contractor may not begin operation of the facility or modification prior to the issuance of a safety evaluation report in which DOE approves the safety basis for the facility or modification.

(b) Pending issuance of a safety evaluation report in which DOE approves an updated or amended safety basis for an existing Hazard Category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the facility must continue to perform work in accordance with the DOE-approved safety basis for the facility and maintain the existing safety basis consistent with the requirements of this Subpart.

Appendix A to Subpart B to Part 830—General Statement of Safety Basis Policy

A. Introduction

This appendix describes DOE's expectations for the safety basis requirements of 10 CFR part 830, acceptable methods for implementing these requirements, and criteria DOE will use to evaluate compliance with these requirements. This Appendix does not create any new requirements and should be used consistently with DOE's policy that work be conducted safely and efficiently and in a manner that ensures protection of workers, the public, and the environment.

B. Purpose

1. The safety basis requirements of part 830 require the contractor responsible for a DOE nuclear facility to analyze the facility, the work to be performed, and the associated hazards and to identify the conditions, safe boundaries, and hazard controls necessary to protect workers, the public and the environment from adverse consequences. These analyses and hazard controls constitute the safety basis upon which the contractor and DOE rely to conclude that the facility can be operated safely. Performing work consistent with the safety basis provides reasonable assurance of adequate protection of workers, the public, and the environment.

2. The safety basis requirements are intended to further the objective of making safety an integral part of how work is performed throughout the DOE complex. Developing a thorough understanding of a nuclear facility, the work to be performed, the associated hazards and the needed hazard controls is essential to integrating safety into management and work at all levels. Performing work in accordance with the safety basis for a nuclear facility is the realization of that objective.

C. Scope

1. A contractor must establish and maintain a safety basis for a Hazard Category 1, 2, or 3 DOE nuclear facility because these facilities have the potential for significant radiological consequences. DOE–STD–1027 sets forth the methodology for categorizing a DOE nuclear facility based on the inventory of radioactive materials.

2. Unlike the quality assurance requirements of part 830 that apply to all DOE nuclear facilities the safety basis requirements only apply to Hazard Category 1, 2, and 3 DOE nuclear facilities and do not apply to nuclear facilities below Hazard Category 3.

D. Integrated Safety Management

1. The safety basis requirements are consistent with integrated safety management. DOE expects that, if a contractor complies with the Department of Energy Acquisition Regulation (DEAR) clause on integration of environment, safety, and health into work planning and execution (48 CFR 970.5223–1, Integration of Environment, Safety and Health into Work Planning and Execution) and the DEAR clause on laws, regulations, and DOE directives (48 CFR 970.5204–2, Laws, Regulations and DOE Directives), the contractor will have established the foundation to meet the safety basis requirements.

2. The processes embedded in a safety management system should lead to a contractor establishing adequate safety bases and safety management programs that will meet the safety basis requirements of this Subpart. Consequently, the DOE expects if a contractor has adequately implemented integrated safety management, few additional requirements will stem from this Subpart and, in such cases, the existing safety basis prepared in accordance with integrated safety management provisions, including existing DOE safety requirements in contracts, should meet the requirements of this Subpart.

3. DOE does not expect there to be any conflict between contractual requirements and regulatory requirements. In fact, DOE expects that contract provisions will be used to provide more detail on implementation of safety basis requirements such as preparing a documented safety analysis, developing technical safety requirements, and implementing a USQ process.

E. Enforcement of Safety Basis Requirements

1. Enforcement of the safety basis requirements will be performance oriented. That is, DOE will focus its enforcement efforts on whether a contractor operates a nuclear facility consistent with the safety basis for the facility and, in particular, whether work is performed in accordance with the safety basis.

2. As part of the approval process, DOE will review the content and quality of the safety basis documentation. DOE intends to use the approval process to assess the adequacy of a safety basis developed by a contractor to ensure that workers, the public, and the environment are provided reasonable assurance of adequate protection from identified hazards. Once approved by DOE, the safety basis documentation will not be subject to regulatory enforcement actions unless DOE determines that the information which supports the documentation is not complete and accurate in all material respects, as required by 10 CFR 820.11. This is consistent with the DOE enforcement provisions and policy in 10 CFR part 820.

3. DOE does not intend the adoption of the safety basis requirements to affect the existing quality assurance requirements or the existing obligation of contractors to comply with the quality assurance requirements. In particular, in conjunction with the adoption of the safety basis requirements, DOE revised the language in 10 CFR 830.122(e)(1) to make clear that hazard controls are part of the work processes to which a contractor and other persons must adhere when performing work. This obligation to perform work consistent with hazard controls adopted to meet regulatory or contract requirements existed prior to the adoption of the safety basis requirements and is both consistent with and independent of the safety basis requirements.

4. A documented safety analysis must address all hazards (that is, both radiological and nonradiological hazards) and the controls necessary to provide adequate protection to the public, workers, and the environment from these hazards. Section 234A of the Atomic Energy Act only authorizes DOE to issue civil penalties for violations of requirements related to nuclear safety. Therefore, DOE will impose civil penalties for violations of the safety basis requirements (including hazard controls) only if they are related to nuclear safety.

F. Documented Safety Analysis

1. A documented safety analysis must demonstrate the extent to which a nuclear facility can be operated safely with respect to workers, the public, and the environment.

2. DOE expects a contractor to use a graded approach to develop a documented safety analysis and describe how the graded approach was applied. The level of detail, analysis, and documentation will reflect the complexity and hazards associated with a particular facility. Thus, the documented safety analysis for a simple, low hazard facility may be relatively short and qualitative in nature, while the documented safety analysis for a complex, high hazard facility may be quite elaborate and more quantitative. DOE will work with its contractors to ensure a documented safety analysis is appropriate for the facility for which it is being developed.

3. Because DOE has ultimate responsibility for the safety of its facilities, DOE will review each documented safety analysis as: (1) Part of the initial submittal; (2) when revisions are submitted as part of a positive USQ or major modification; (3) if DOE has reason to believe a portion of the safety basis to be inadequate, or; (4) if DOE has reason to believe a portion of the safety basis has substantially changed. DOE will review the DSA to determine whether the rigor and detail of the documented safety analysis are appropriate for the complexity and hazards expected at the nuclear facility. In particular, DOE will evaluate the documented safety analysis by considering the extent to which the documented safety analysis (1) satisfies the provisions of the methodology used to prepare the documented safety analysis and (2) adequately addresses the criteria set forth in 10 CFR 830.204(b). DOE will prepare a Safety Evaluation Report to document the results of its review of the documented safety analysis. A documented safety analysis must contain any conditions or changes required by DOE in the Safety Evaluation Report. Generally, DOE's review of the annual submittal may be limited to ensuring that the results of USQs have been adequately incorporated into the DSA. If additional changes are proposed by the contractor and included in the annual update that have not been previously approved by DOE or have not been evaluated as a part of the USQ process, DOE must review and approve these changes. DOE has the authority to review the safety basis at any time.

4. In most cases, the contract will provide the framework for specifying the methodology and schedule for developing a documented safety analysis. Table 1 sets forth acceptable methodologies for preparing a documented safety analysis.

TABLE 1

The contractor responsible for:	May prepare its document safety analysis by:
(1) A DOE reactor	Using the method in U.S. Nuclear Regulatory Commission Regulatory Guide 1.70, Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants, or successor document.
(2) A DOE nonreactor nuclear facility	Using the method in DOE–STD–3009, Change Notice No. 1, January 2000, Preparation Guide for U.S. Department of Energy Nonreactor Nuclear Facility Safety Analysis Reports, July 1994, or successor document.
(3) A DOE nuclear facility with a limited operational life.	Using the method in either: (1) DOE–STD–3009–, Change Notice No. 1, January 2000, or successor document, or (2) DOE–STD–3011–94, Guidance for Preparation of DOE 5480.22 (TSR) and DOE 5480.23 (SAR) Implementation Plans, November 1994, or successor document.
(4) The deactivation or the transition surveillance and maintenance of a DOE nuclear facility.	Using the method in either: (1) DOE–STD–3009, Change Notice No. 1, January 2000, or successor document, or (2) DOE–STD–3011–94 or successor document.
(5) The decommissioning of a DOE nuclear facility.	(1) Using the method in DOE–STD–1120–98, Integration of Environment, Safety, and Health into Facility Disposition Activities, May 1998, or successor document; (2) Using the provisions in 29 CFR 1910.120 (or 29 CFR 1926.65 for construction activities) for developing Safety and Health Programs, Work Plans, Health and Safety Plans, and Emergency Response Plans to address public safety, as well as worker safety; and (3) Deriving hazard controls based on the Safety and Health Programs, the Work Plans, the Health and Safety Plans, and the Emergency Response Plans.
(6) A DOE environmental restoration activity that involves either work not done within a permanent structure or the decommissioning of a facility with only low-level residual fixed radioactivity.	(1) Using the method in DOE–STD–1120–98 or successor document, and (2) Using the provisions in 29 CFR 1910.120 (or 29 CFR 1926.65 for construction activities) for developing a Safety and Health Program and a site-specific Health and Safety Plan (including elements for Emergency Response Plans, conduct of operations, training and qualifications, and maintenance management).
(7) A DOE nuclear explosive facility and the nuclear explosive operations conducted therein..	Developing its documented safety analysis in two pieces: (1) A Safety Analysis Report for the nuclear facility that considers the generic nuclear explosive operations and is prepared in accordance with DOE–STD–3009, Change Notice No. 1, January 2000, or successor document, and (2) A Hazard Analysis Report for the specific nuclear explosive operations prepared in accordance with DOE–STD–3016–99, Hazards Analysis Reports for Nuclear Explosive Operations, February 1999, or successor document.
(8) A DOE Hazard Category 3 nonreactor nuclear facility.	Using the methods in Chapters 2, 3, 4, and 5 of DOE–STD–3009, Change Notice No. 1, January 2000, or successor document to ad- dress in a simplified fashion: (1) The basic description of the facility/activity and its operations, including safety structures, systems, and components; (2) A qualitative hazards analysis; and (3) The hazard controls (consisting primarily of inventory limits and safety management programs) and their bases.
(9) Transportation activities	(1) Preparing a Safety Analysis Report for Packaging in accordance with DOE–O–460.1A, Packaging and Transportation Safety, October 2, 1996, or successor document and (2) Preparing a Transportation Safety Document in accordance with DOE–G–460.1–1, Implementation Guide for Use with DOE O 460.1A, Packaging and Transportation Safety, June 5, 1997, or successor document.
(10) Transportation and onsite transfer of nuclear explosives, nuclear components, Navel nuclear fuel elements, Category I and Category II special nuclear materials, special assemblies, and other materials of national security.	(1) Preparing a Safety Analysis Report for Packaging in accordance with DOE–O–461.1, Packaging and Transportation of Materials of National Security Interest, September 29, 2000, or successor document and (2) Preparing a Transportation Safety Document in accordance with DOE–M–461.1–1, Packaging and Transfer of Materials of National Security Interest Manual, September 29, 2000, or successor document.

5. Table 1 refers to specific types of nuclear facilities. These references are not intended to constitute an exhaustive list of the specific types of nuclear facilities. Part 830 defines nuclear facility broadly to include reactor or a nonreactor nuclear facilities where an activity is conducted for or on behalf of DOE and includes any related area, structure, facility, or activity to the extent necessary to ensure proper implementation of the requirements established by this Part. The only exceptions are those facilities specifically excluded such as accelerators. Table 2 defines the terms referenced in Table 1 that are not defined in 10 CFR 830.3.

TABLE 2

For purposes of Table 1:	Means:
(1) Deactivation	The process of placing a facility in a stable and known condition, including the removal of hazardous and radioactive materials.
(2) Decontamination	The removal or reduction of residual radioactive and hazardous materials by mechanical, chemical, or other techniques to achieve a stated objective or end condition.
(3) Decommissioning	Those actions taking place after deactivation of a nuclear facility to retire it from service and includes surveillance and maintenance, decontamination, and/or dismantlement.
(4) Environmental restoration activities	The process by which contaminated sites and facilities are identified and characterized and by which existing contamination is contained, or removed and disposed.
(5) Generic nuclear explosive operation	A characterization that considers the collective attributes (such as special facility system requirements, physical weapon characteristics, or quantities and chemical/physical forms of hazardous materials) for all projected nuclear explosive operations to be conducted at a facility.
(6) Nuclear explosive facility	A nuclear facility at which nuclear operations and activities involving a nuclear explosive may be conducted.
(7) Nuclear explosive operation	Any activity involving a nuclear explosive, including activities in which main-charge, high-explosive parts and pits are collocated.
(8) Nuclear facility with a limited operational life	A nuclear facility for which there is a short remaining operational period before ending the facility's mission and initiating deactivation and decommissioning and for which there are no intended additional missions other than cleanup.
(9) Specific nuclear explosive operation	A specific nuclear explosive subjected to the stipulated steps of an individual operation, such as assembly or disassembly.
(10) Transition surveillance and maintenance activities.	Activities conducted when a facility is not operating or during deactivation, decontamination, and decommissioning operations when surveillance and maintenance are the predominant activities being conducted at the facility. These activities are necessary for satisfactory containment of hazardous materials and protection of workers, the public, and the environment. These activities include providing periodic inspections, maintenance of structures, systems, and components, and actions to prevent the alteration of hazardous materials to an unsafe state.

6. The contractor responsible for the design and construction of a new Hazard Category 1, 2, or 3 DOE nuclear facility or a major modification to an existing Hazard Category 1, 2, or 3 DOE nuclear facility must prepare a preliminary documented safety analysis. A preliminary documented safety analysis can ensure that substantial costs and time are not wasted in constructing a nuclear facility that will not be acceptable to DOE. If a contractor is required to prepare a preliminary documented safety analysis, the contractor must obtain DOE approval of the preliminary documented safety analysis prior to procuring materials or components or beginning construction. DOE, however, may authorize the contractor to perform limited procurement and construction activities without approval of a preliminary documented safety analysis if DOE determines that the activities are not detrimental to public health and safety and are in the best interests of DOE. DOE Order 420.1, or successor document, sets forth acceptable nuclear safety design criteria for use in preparing a preliminary documented safety analysis. As a general matter, DOE does not expect preliminary documented safety analyses to be needed for activities that do not involve significant construction such as environmental restoration activities, decontamination and decommissioning activities, specific nuclear explosive operations, or transition surveillance and maintenance activities.

G. Hazard Controls

1. Hazard controls are measures to eliminate, limit, or mitigate hazards to workers, the public, or the environment. They include: (1) Physical, design, structural, and engineering features; (2) safety structures, systems, and components; (3) safety management programs; (4) technical safety requirements; and (5) other controls necessary to provide adequate protection from hazards.

2. The types and specific characteristics of the safety management programs necessary for a DOE nuclear facility will be dependent on the complexity and hazards associated with the nuclear facility and the work being performed. In most cases, however, a contractor should consider safety management programs covering topics such as quality assurance, procedures, maintenance, personnel training, conduct of operations, criticality safety, emergency preparedness, fire protection, waste management, and radiation protection. In general, DOE Orders set forth DOE's expectations concerning specific topics. For example, DOE Order 420.1, or successor document provides DOE's expectations with respect to fire protection and criticality safety.

3. Safety structures, systems, and components require formal definition of minimum acceptable performance in the documented safety analysis. This is accomplished by first defining a safety function, then describing the structure, systems, and components, placing functional requirements on those portions of the structures, systems, and components required for the safety function, and identifying performance criteria that will ensure functional requirements are met. Technical safety requirements are developed to ensure the operability of the safety structures, systems, and components and define actions to be taken if a safety structure, system, or component is not operable.

4. Technical safety requirements establish limits, controls, and related actions necessary for the safe operation of a nuclear facility. The exact form and contents of technical safety requirements will depend on the circumstances of a particular nuclear facility as defined in the documented safety analysis for the nuclear facility. As appropriate, technical safety requirements may have sections on: (1) Safety limits; (2) operating limits; (3) surveillance requirements; (4) administrative controls; (5) use and application; and (6) design features. It may also have an appendix on the bases for the limits and requirements. DOE Guide 423.1–1B, Implementation Guide for Use in Developing Technical Safety Requirements, or successor document, provides a complete description of what technical safety requirements should contain and how they should be developed and maintained.

5. DOE will examine and approve the technical safety requirements as part of preparing the safety evaluation report and reviewing updates to the safety basis. As with all hazard controls, technical safety requirements must be kept current and reflect changes in the facility, the work and the hazards as they are analyzed in the documented safety analysis. In addition, DOE expects a contractor to maintain technical safety requirements, and other hazard controls as appropriate, as controlled documents with an authorized users list.

6. Table 3 sets forth DOE's expectations concerning acceptable technical safety requirements.

TABLE 3

As appropriate for a particular DOE nuclear facility, the section of the technical safety requirements on:	Will provide information on:
(1) Safety limits	The limits on process variables associated with those safety class physical barriers, generally passive, that are necessary for the intended facility function and that are required to guard against the uncontrolled release of radioactive materials. The safety limit section describes, as precisely as possible, the parameters being limited, states the limit in measurable units (pressure, temperature, flow, etc.), and indicates the applicability of the limit. The safety limit section also describes the actions to be taken in the event that the safety limit is exceeded. These actions should first place the facility in the safe, stable condition attainable, including total shutdown (except where such action might reduce the margin of safety) or should verify that the facility already is safe and stable and will remain so. The technical safety requirement should state that the contractor must obtain DOE authorization to restart the nuclear facility following a violation of a safety limit. The safety limit section also establishes the steps and time limits to correct the out-of-specification condition.
(2) Operating limits	Those limits which are required to ensure the safe operation of a nuclear facility. The operating limits section may include subsections on limiting control settings and limiting conditions for operation.
(3) Limiting control settings	The settings on safety systems that control process variables to prevent exceeding a safety limit. The limited control settings section normally contains the settings for automatic alarms and for the automatic or non-automatic initiation of protective actions related to those variables associated with the function of safety class structures, systems, or components if the safety analysis shows that they are relied upon to mitigate or prevent an accident. The limited control settings section also identifies the protective actions to be taken at the specific settings chosen in order to correct a situation automatically or manually such that the related safety limit is not exceeded. Protective actions may include maintaining the variables within the requirements and repairing the automatic device promptly or shutting down the affected part of the process and, if required, the entire facility.
(4) Limiting conditions for operations	The limits that represent the lowest functional capability or performance level of safety structures, systems, and components required to perform an activity safely. The limiting conditions for operation section describes, as precisely as possible, the lowest functional capability or performance level of equipment required for continued safe operation of the facility. The limiting conditions for operation section also states the action to be taken to address a condition not meeting the limiting conditions for operation section. Normally this simply provides for the adverse condition being corrected in a certain time frame and for further action if this is impossible.
(5) Surveillance requirements	Requirements relating to test, calibration, or inspection to assure that the necessary operability and quality of safety structures, systems, and components is maintained; that facility operation is within safety limits; and that limiting control settings and limiting conditions for operation are met. If a required surveillance is not successfully completed, the contractor is expected to assume the systems or components involved are inoperable and take the actions defined by the technical safety requirement until the systems or components can be shown to be operable. If, however, a required surveillance is not performed within its required frequency, the contractor is allowed to perform the surveillance within 24 hours or the original frequency, whichever is smaller, and confirm operability.
(6) Administrative controls	Organization and management, procedures, recordkeeping, assessment, and reporting necessary to ensure safe operation of a facility consistent with the technical safety requirement. In general, the administrative controls section addresses (1) the requirements associated with administrative controls, (including those for reporting violations of the technical safety requirement); (2) the staffing requirements for facility positions important to safe conduct of the facility; and (3) the commitments to the safety management programs identified in the documented safety analysis as necessary components of the safety basis for the facility.
(7) Use and application provisions	The basic instructions for applying the safety restrictions contained in a technical safety requirement. The use and application section includes definitions of terms, operating modes, logical connectors, completion times, and frequency notations.
(8) Design features	Design features of the facility that, if altered or modified, would have a significant effect on safe operation.
(9) Bases appendix	The reasons for the safety limits, operating limits, and associated surveillance requirements in the technical safety requirements. The statements for each limit or requirement shows how the numeric value, the condition, or the surveillance fulfills the purpose derived from the safety documentation. The primary purpose for describing the basis of each limit or requirement is to ensure that any future changes to the limit or requirement is done with full knowledge of the original intent or purpose of the limit or requirement.

H. Unreviewed Safety Questions

1. The USQ process is an important tool to evaluate whether changes affect the safety basis. A contractor must use the USQ process to ensure that the safety basis for a DOE nuclear facility is not undermined by changes in the facility, the work performed, the associated hazards, or other factors that support the adequacy of the safety basis.

2. The USQ process permits a contractor to make physical and procedural changes to a nuclear facility and to conduct tests and experiments without prior approval, provided these changes do not cause a USQ. The USQ process provides a contractor with the flexibility needed to conduct day-to-day operations by requiring only those changes and tests with a potential to impact the safety basis (and therefore the safety of the nuclear facility) be approved by DOE. This allows DOE to focus its review on those changes significant to safety. The USQ process helps keep the safety basis current by ensuring appropriate review of and response to situations that might adversely affect the safety basis.

3. DOE Guide 424.1–1B Chg 2, Implementation Guide for Use in Addressing Unreviewed Safety Question Requirements, or successor document provides DOE's expectations for a USQ process. The contractor must obtain DOE approval of its procedure used to implement the USQ process. The contractor is allowed to make editorial and format changes to its USQ procedure while maintaining DOE approval.

I. Functions and Responsibilities

1. The DOE Management Official for a DOE nuclear facility (that is, the Assistant Secretary, the Assistant Administrator, or the Office Director who is primarily responsible for the management of the facility) has primary responsibility within DOE for ensuring that the safety basis for the facility is adequate and complies with the safety basis requirements of Part 830. The DOE Management Official is responsible for ensuring the timely and proper (1) review of all safety basis documents submitted to DOE and (2) preparation of a safety evaluation report concerning the safety basis for a facility.

2. DOE will maintain a public list on the internet that provides the status of the safety basis for each Hazard Category 1, 2, or 3 DOE nuclear facility and, to the extent practicable, provides information on how to obtain a copy of the safety basis and related documents for a facility.

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NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 702

RIN 3133–AE90

Risk-Based Capital—Supplemental Rule

AGENCY: National Credit Union Administration (NCUA).

ACTION: Proposed rule.

SUMMARY: The NCUA Board (Board) is seeking comment on a proposed rule that would amend the NCUA's previously revised regulations regarding prompt corrective action (PCA). The proposal would delay the effective date of the NCUA's October 29, 2015 final rule regarding risk-based capital (2015 Final Rule) for one year, moving the effective date from January 1, 2019 to January 1, 2020. During the extended delay period, the NCUA's current PCA requirements would remain in effect. The proposal would also amend the definition of a ''complex'' credit union adopted in the 2015 Final Rule for risk-based capital purposes by increasing the threshold level for coverage from $100 million to $500 million. These proposed changes would provide covered credit unions and the NCUA with additional time to prepare for the rule's implementation, and would exempt an additional 1,026 credit unions from the rule without subjecting the National Credit Union Share Insurance Fund (NCUSIF) to undue risk.

DATES: Comments must be received by September 7, 2018.

ADDRESSES: You may submit written comments, identified by RIN 3133–AE90, by any of the following methods (Please send comments by one method only):

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *NCUA website: http://www.ncua.gov/Legal/Regs/Pages/PropRegs.aspx.* Follow the instructions for submitting comments.
- *Email:* Address to *regcomments@ncua.gov.* Include ''[Your name]—Comments on Proposed Rule: Risk-Based Capital—Supplemental Proposal'' in the email subject line.
- *Fax:* (703) 518–6319. Use the subject line described above for email.
- *Mail:* Address to Gerard Poliquin, Secretary of the Board, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428.
- *Hand Delivery/Courier:* Same as mail address.

You can view all public comments on the NCUA's website at *http://www.ncua.gov/Legal/Regs/Pages/PropRegs.aspx* as submitted, except for those we cannot post for technical reasons. The NCUA will not edit or remove any identifying or contact information from the public comments submitted. You may inspect paper copies of comments in the NCUA's law library at 1775 Duke Street, Alexandria, Virginia 22314, by appointment weekdays between 9 a.m. and 3 p.m. To make an appointment, call (703) 518–6546, or send an email to *OGCMail@ncua.gov.*

FOR FURTHER INFORMATION CONTACT: *Policy and Analysis:* Julie Cayse, Director, Division of Risk Management, Office of Examination and Insurance, at (703) 518–6360; Kathryn Metzker, Loss/Risk Analyst, Division of Risk Management, Office of Examination and Insurance, at (703) 548–2456; Julie Decker, Loss/Risk Analyst, Division of Risk Management, Office of Examination and Insurance, at (703) 518–3684; Aaron Langley, Risk Management Officer, Division of Analytics and Surveillance, Office of Examination and Insurance, at (703) 518–6387; *Legal:* John Brolin, Staff Attorney, Office of General Counsel, at (703) 518–6540; or by mail at National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NCUA's primary mission is to ensure the safety and soundness of federally insured credit unions. The agency performs this function by examining and supervising all federal credit unions, participating in the examination and supervision of federally insured, state-chartered credit unions in coordination with state regulators, and insuring members' accounts at federally insured credit unions.[1] In its role as administrator of the NCUSIF, the NCUA insures and regulates approximately 5,573 federally insured credit unions, holding total assets exceeding $1.4 trillion and representing approximately 111 million members.[2]

At its October 2015 meeting, the Board issued the 2015 Final Rule to amend Part 702 of the NCUA's PCA regulations to require that credit unions taking certain risks hold capital commensurate with those risks.[3] The risk-based capital provisions of the 2015 Final Rule apply only to federally insured, natural-person credit unions with quarter-end total assets exceeding $100 million. The overarching intent of the 2015 Final Rule is to reduce the likelihood that a relatively small number of high-risk outlier credit unions would exhaust their capital and cause large losses to the NCUSIF. Under

[1] As of December 31, 2017, within the nine states that allow privately insured credit unions, approximately 116 state-chartered credit unions are privately insured and are not subject to the NCUA's regulation and oversight.

[2] Based on December 31, 2017 Call Report Data.

[3] 80 FR 66625 (Oct. 29, 2015).

the Federal Credit Union Act (FCUA), federally insured credit unions are collectively responsible for replenishing losses to the NCUSIF.[4]

The 2015 Final Rule restructures the NCUA's PCA regulations and makes various revisions, including amending the agency's current risk-based net worth requirement by replacing the risk based net worth ratio with a new risk-based capital ratio for federally insured, natural-person credit unions (credit unions). The risk-based capital requirements set forth in the 2015 Final Rule are more consistent with the NCUA's risk-based capital ratio measure for corporate credit unions and, as the law requires, are more comparable to the regulatory risk-based capital measures used by the Federal Deposit Insurance Corporation (FDIC), Board of Governors of the Federal Reserve System, and Office of the Comptroller of Currency (Other Banking Agencies). The 2015 Final Rule also eliminates several provisions in the NCUA's current PCA regulations, including provisions related to the regular reserve account, risk-mitigation credits, and alternative risk weights.

The 2015 Final Rule is currently set to become effective on January 1, 2019. The NCUA delayed the effective date until January 1, 2019 to provide credit unions and the NCUA sufficient time to make the necessary adjustments, such as systems, processes, and procedures; to reduce the burden on affected credit unions.

II. Legal Authority

In 1998, Congress enacted the Credit Union Membership Access Act (CUMAA).[5] Section 301 of CUMAA added section 216 to the FCUA,[6] which required the Board to adopt by regulation a system of PCA to restore the net worth of credit unions that become inadequately capitalized.[7] Section 216(b)(1)(A) requires the Board to adopt by regulation a system of PCA for federally insured credit unions ''consistent with'' section 216 of the FCUA and ''comparable to'' section 38 of the Federal Deposit Insurance Act (FDI Act).[8] Section 216(b)(1)(B) requires that the Board, in designing the PCA system, also take into account the ''cooperative character of credit unions'' (*i.e.,* credit unions are not-for-profit cooperatives that do not issue capital stock, must rely on retained earnings to build net worth, and have boards of directors that consist primarily of volunteers).[9] The Board initially implemented the required system of PCA in 2000,[10] primarily in Part 702 of the NCUA's Regulations, and most recently made substantial updates to the regulation in October 2015.[11]

The purpose of section 216 of the FCUA is to ''resolve the problems of [federally] insured credit unions at the least possible long-term loss to the [NCUSIF].'' [12] To carry out that purpose, Congress set forth a basic structure for PCA in section 216 that consists of three principal components: (1) A framework combining mandatory actions prescribed by statute with discretionary actions developed by the NCUA; (2) an alternative system of PCA to be developed by the NCUA for credit unions defined as ''new;'' and (3) a risk-based net worth requirement to apply to credit unions the NCUA defines as ''complex.''

Among other things, section 216(c) of the FCUA requires the NCUA to use a credit union's net worth ratio to determine its classification among five ''net worth categories'' set forth in the FCUA.[13] Section 216(o) generally defines a credit union's ''net worth'' as its retained earnings balance,[14] and a credit union's ''net worth ratio,'' as the ratio of its net worth to its total assets.[15] As a credit union's net worth ratio declines, so does its classification among the five net worth categories, thus subjecting it to an expanding range of mandatory and discretionary supervisory actions.[16]

Section 216(d)(1) of the FCUA requires that the NCUA's system of PCA include, in addition to the statutorily defined net worth ratio requirement applicable to federally insured natural-person credit unions, ''a risk-based net worth [17] requirement for insured credit unions that are complex, as defined by the Board. . . .'' [18] The FCUA directs the NCUA to base its definition of ''complex'' credit unions ''on the portfolios of assets and liabilities of credit unions.'' [19] It also requires the NCUA to design a risk-based net worth requirement to apply to such ''complex'' credit unions.[20]

III. Proposed Rule

Under § 702.103 of the NCUA's 2015 Final Rule, a credit union is defined as ''complex'' and the NCUA's risk-based capital ratio measure is applicable only if the credit union's quarter-end total assets exceed $100 million, as reflected in its most recent Call Report. Consistent with the spirit and intent of Executive Order 13777, the NCUA further analyzed the impact of the NCUA's risk-based capital requirements and the portfolios of assets and liabilities of credit unions to identify potential ways to reduce regulatory burden on credit unions.[21]

Based on the NCUA's analysis, which is discussed in more detail below, the Board believes that $500 million in total assets would be a more appropriate threshold level for defining a complex credit union, and therefore subjecting it to the risk-based capital requirement. Increasing the threshold level to $500 million in assets would reduce

[4] *See* 12 U.S.C. 1782(c)(2)(A) (The FCUA requires that each federally insured credit unions to pay a federal share insurance premium equal to a percentage of the credit union's insured shares to ensure that the NCUSIF has sufficient reserves to pay potential share insurance claims by credit union members, and to provide assistance in connection with the liquidation or threatened liquidation of federally insured credit unions in troubled condition.).

[5] Public Law 105–219, 112 Stat. 913 (1998).

[6] 12 U.S.C. 1790d.

[7] The risk-based net worth requirement for credit unions meeting the definition of ''complex'' was first applied on the basis of data in the Call Report reflecting activity in the first quarter of 2001. 65 FR 44950 (July 20, 2000). The NCUA's risk-based net worth requirement has been largely unchanged since its implementation, with the following limited exceptions: revisions were made to the rule in 2003 to amend the risk-based net worth requirement for MBLs, 68 FR 56537 (Oct. 1, 2003); revisions were made to the rule in 2008 to incorporate a change in the statutory definition of ''net worth,'' 73 FR 72688 (Dec. 1, 2008); revisions were made to the rule in 2011 to expand the definition of ''low-risk assets'' to include debt instruments on which the payment of principal and interest is unconditionally guaranteed by NCUA, 76 FR 16234 (Mar. 23, 2011); and revisions were made in 2013 to exclude credit unions with total assets of $50 million or less from the definition of ''complex'' credit union, 78 FR 4033 (Jan. 18, 2013).

[8] 12 U.S.C. 1790d(b)(1)(A); *see also* 12 U.S.C. 1831o (Section 38 of the FDI Act setting forth the PCA requirements for banks).

[9] 12 U.S.C. 1790d(b)(1)(B).

[10] 12 CFR part 702; *see also* 65 FR 8584 (Feb. 18, 2000) *and* 65 FR 44950 (July 20, 2000).

[11] 80 FR 66625 (Oct. 29, 2015).

[12] 12 U.S.C. 1790d(a)(1).

[13] 12 U.S.C. 1790d(c).

[14] 12 U.S.C. 1790d(o)(2).

[15] 12 U.S.C. 1790d(o)(3).

[16] 12 U.S.C. 1790d(c)–(g); 12 CFR 702.204(a)–(b).

[17] For purposes of this rulemaking, the term ''risk-based net worth requirement'' is used in reference to the statutory requirement for the Board to design a capital standard that accounts for variations in the risk profile of complex credit unions. The term ''risk-based capital ratio'' is used to refer to the specific standards established in the 2015 Final Rule to function as criteria for the statutory risk-based net worth requirement. The term ''risk-based capital ratio'' is also used by the Other Banking Agencies and the international banking community when referring to the types of risk-based requirements that are addressed in the 2015 Final Rule. This change in terminology throughout the proposal would have no substantive effect on the requirements of the FCUA, and is intended only to reduce confusion for the reader.

[18] 12 U.S.C. 1790d(d)(1).

[19] 12 U.S.C. 1790d(d).

[20] *Id.*

[21] The Board has always intended to periodically review the threshold of a complex credit union, as noted in the preamble to the 2015 proposed Risk Based Capital Rule. 80 FR 4339, 4378 (January 27, 2015).

regulatory burden on credit unions by more closely tailoring the applicability of the NCUA's risk-based capital requirement to cover only those credit unions that, if they failed, individually could present an undue risk of loss to the NCUSIF. This amendment would exempt an additional 1,026 credit unions—a total of 90 percent [22] of all credit unions—from the 2015 Final Rule's risk-based capital requirements. However, approximately 85 percent of the complex assets and liabilities and 76 percent of the total assets in the credit union system would still be subject to the risk-based capital requirement.[23] Accordingly, consistent with requirements of section 216(d)(1) of the FCUA, proposed § 702.103 would provide that, for purposes of § 702.102, a credit union is defined as ''complex,'' and a risk-based capital ratio requirement is applicable, only if the credit union's quarter-end total assets exceed $500 million, as reflected in its most recent Call Report.

Under the 2015 Final Rule, the NCUA determined that credit unions exceeding the $100 million asset-size threshold had portfolios of assets and liabilities that were complex based on the products and services in which such credit unions engaged. As explained further below, the $100 million asset-size threshold was developed as a proxy measure based on a detailed analysis performed by the NCUA. The threshold set forth a clear demarcation line, above which the NCUA determined all credit unions engaged in complex activities, and where almost all such credit unions (99 percent) were involved in multiple complex activities.[24] The NCUA continues to believe that using a single asset-size threshold is appropriate, as it is clear, logical, and easy to administer. Moreover, using a single asset-size threshold provides regulatory relief for smaller institutions, and eliminates the potential unintended consequences of having a checklist of activities that would determine complexity on an institution-by-institution basis.

The $100 million asset threshold adopted in the 2015 Final Rule for determining whether a credit union is complex was based on a complexity index (original complexity index or OCI). The OCI counted the number of complex products and services provided by credit unions based on the following indicators:

- Member Business Loans
- Participation Loans
- Interest-Only Loans
- Indirect Loans
- Real Estate Loans
- Non-Federally Guaranteed Student Loans
- Investments with Maturities of Greater than Five Years (where the investments are greater than one percent of total assets)
- Non-Agency Mortgage-Backed Securities
- Non-Mortgage Related Securities With Embedded Options
- Collateralized Mortgage Obligations/Real Estate Mortgage Investment Conduits
- Commercial Mortgage-Related Securities
- Borrowings (Draws Against Lines of Credit, Borrowing Repurchase Transactions, Other Notes, Promissory Notes, and Interest Payable)
- Repurchase Transactions
- Derivatives
- Internet Banking

As discussed in more detail in the 2015 Final Rule, these products and services were determined by the NCUA to be good indicators of complexity.[25]

To define ''complex'' credit unions for the 2015 Final Rule, the NCUA used the original complexity index to analyze June 30, 2014 and March 31, 2015 Call Report data. Based on the OCI, for credit unions with more than $100 million in assets, 100 percent engaged in offering at least one complex activity; 99 percent engaged in two or more complex activities; and 87 percent engaged in four or more complex activities. Accordingly, the Board determined it was appropriate to set the asset size threshold for ''complex'' credit unions at $100 million in total assets, subjecting credit unions with more than $100 million in assets to the NCUA's risk-based capital requirements.

As discussed in more detail below, the OCI did not take into account the volume of the complex activity engaged in by such credit unions.

Following a careful review of the 2015 Final Rule by the NCUA's regulatory reform task force,[26] the Board is now proposing to revise the original complexity index (revised complexity index or RCI), and to apply a new complexity ratio (complexity ratio or CR) for analyzing the portfolios of assets and liabilities of credit unions to determine which are ''complex.'' The RCI would amend 6 of the indicators in the original complexity index so the index will more accurately reflect ''complexity'' in credit unions and take into account certain regulatory changes that were made after the 2015 Final Rule was approved. The revised complexity index would be the same as the original complexity index, with the following six changes:

- Replace the indicator for ''member business loans'' with an indicator for ''commercial loans'' to reflect changes to the NCUA's member business lending rule,[27] and current Call Report data collection requirements.
- Replace the indicator for ''participation loans'' (which included participation loans sold and participation loans held) with an indicator for ''participation loans sold'' to restrict the indicator to the most complex component of participation loans.
- Replace the indicator for ''interest-only loans'' to exclude first-lien mortgages. The remaining interest only loans include complex payment options. For example, only requiring monthly payments of interest during draw periods.
- Remove the indicator for ''internet banking'' because it has become a typical mechanism for members to transact business with most credit unions, with 78 percent of credit unions engaging in some type of internet banking. Also, it is not an asset or liability—therefore there is no suitable way to translate the volume into a financial measure for purposes of defining complex.
- Remove the indicator for ''investments with maturities greater than five years (where the investments are greater than one percent of total assets)'' because the indicator is adequately captured in the other index components.
- Replace the indicator for ''real estate loans (where the loans are greater than five percent of assets and/or sold mortgages)'' with an indicator for ''sold

[22] Based on December 31, 2017 Call Report data. For comparison, if the threshold were to remain at $100 million about 72 percent of all credit unions would be exempt.

[23] For comparison, if the threshold were to remain at $100 million about 98 percent of the complex assets and liabilities and 93 percent of the total assets in the credit union system would be subject to the risk based capital requirement.

[24] 80 FR 66625, 66663 (Oct. 29, 2015).

[25] 80 FR 66625, 66663 (Oct. 29, 2015). The 2015 Final Rule states ''For the purpose of defining a complex credit union, assets include tangible and intangible items that are economic resources (products and services) that are expected to produce economic benefit (income), and liabilities are obligations (expenses) the credit union has to outside parties. The Board recognizes there are products and services—which under GAAP are reflected as the credit unions' portfolio of assets and liabilities—in which credit unions are engaged that are inherently complex based on the nature of their risk and the expertise and operational demands necessary to manage and administer such activities effectively. Thus, credit unions offering such products and services have complex portfolios of assets and liabilities for purposes of NCUA's risk-based net worth requirement.''

[26] *See* 82 FR 39702, 39706 (Aug. 22, 2017).

[27] *See* 12 CFR 723.2; *and* 81 FR 13529, 13538 (March 14, 2016).

mortgages'' to account for the most complex component of real estate loans.

The NCUA believes the revised complexity index would provide a more accurate methodology, based on the assets and liabilities of credit unions, for identifying when credit unions engage in complex activities and defining credit unions as ''complex.'' Table 1 shows that, among credit unions with $500 million or more in total assets, 100 percent engage in at least one complex activity, and 96 percent engage in three or more complex activities.

TABLE 1—REVISED COMPLEXITY INDEX BY ASSET CATEGORY, 2017Q4 CALL REPORT DATA

Asset category	Number of credit unions	Average index value	Median index value	Index >=1 (%)	Index >=2 (%)	Index >=3 (%)	Index >=5 (%)	Index >=6 (%)
<$100M	4,016	0.8	0.0	41	21	10	2	1
$100M–$250M	692	3.7	4.0	98	89	73	32	16
$250M–$500M	334	4.9	5.0	99	96	88	57	40
$500M–$750M	149	5.7	6.0	100	98	96	73	53
$750M–$1B	95	6.1	7.0	100	100	97	79	64
$1B+	287	7.0	7.0	100	98	96	88	77

In addition to the revised complexity index, the NCUA is also proposing to use a ratio of complex assets and liabilities to total assets (complexity ratio or CR) to evaluate the extent to which credit unions are involved in complex activities. The CR, when used in conjunction with the revised complexity index, takes into account the volume of the complex activity engaged in by complex credit unions and provides a more accurate measure of credit union complexity.[28] The numerator of the CR would be the dollar value sum of the complex assets and the liabilities held by a credit union, where complex assets and liabilities are determined using the same complexity indicators as used in the RCI. The denominator of the CR would be the total assets of the credit union.

As shown in Table 2 below, credit unions with greater than $500 million in total assets hold complex assets and liabilities as a larger share of their total assets than smaller credit unions. The complexity ratio increases from 23 percent among credit unions with less than $500 million in assets to 40 percent among credit unions with more than $500 million in assets. Of the $497 billion in complex assets and liabilities in the credit union system, $423 billion (85 percent)—the majority of complex assets and liabilities in the credit union system—are held among credit unions with more than $500 million in assets.[29]

TABLE 2—COMPLEXITY RATIO BY ASSET CATEGORIES, 2017Q4 CALL REPORT DATA

Asset category	Number of credit unions	Complex assets and liabilities	Total assests	Complex ratio (%)	Share of complex A & L in the credit union system (%)	Cumulative share of complex A & L in the credit union system (%)
<$500M	5,042	74,600	330,545	23	15	15
>$500M	531	422,553	1,048,289	40	85	100

Table 3 below shows the share of credit unions in each asset category above various complex ratio thresholds. Larger credit unions are much more likely to have a significant share of their balance sheet in complex assets and liabilities. Nearly all credit unions (95 percent) with more than $500 million in assets have complex assets and liabilities greater than 10 percent of their total assets, and 66 percent have complex assets and liabilities greater than 30 percent of their total assets.

TABLE 3—COMPLEXITY RATIO ABOVE VARIOUS THRESHOLDS BY ASSET CATEGORIES, 2017Q4

Asset category	Complex ratio >10%	Complex ratio >20%	Complex ratio >30%
<$500M	29	18	11
>$500M	95	84	66

[28] *See* 80 FR 66625, 66661 (Oct. 29, 2015) (As pointed out by at least one commenter, credit unions should not be considered complex unless complex activities are undertaken in significant volumes. The commenter provided the following example: A credit union that lends a member $60,000 to purchase new equipment for his bakery is engaged in member business lending, but that credit union should not be designated as complex by virtue of that single loan—assuming it is not a significant share of the credit union's assets.).

[29] Credit unions with assets between $250 million and $500 million hold a higher share of their portfolio in complex assets (32 percent) than the entire group of credit unions below $500 million in assets (23 percent), but it remains below the share of complex assets in credit unions above $500 million in assets (40 percent).

In general, two-thirds of credit unions with more than $500 million in total assets have complex assets and liabilities ratios above 30 percent. Only 11 percent of credit unions with less than $500 million have complexity ratios above 30 percent.[30]

Using both the revised complexity index and the complexity ratio to determine the appropriate threshold for defining complex credit unions would exclude approximately 90 percent of credit unions from the risk-based capital requirement, while still covering approximately 76 percent of the assets held by federally insured credit unions.[31] Moreover, the revised definition of a complex credit union would not represent undue risk to the NCUSIF, nor significantly decrease the level of complex assets and liabilities covered by the risk-based capital requirement. Even though the percent of total assets covered by the rule would fall from 93 percent [32] to 76 percent when compared to the $100 million threshold adopted in the 2015 Final Rule,[33] 85 percent of complex assets and liabilities would still be covered.

In addition, if the historical trends in changes to the composition of the credit union community continue, the share of total assets covered by the rule will rise in the future, potentially reaching 90 percent of total assets within the next 10 years. Also, the higher asset threshold still captures those credit unions that, if they failed, individually could present an undue risk of loss to the NCUSIF. In addition, if the historical trends in changes to the composition of the credit union community continue and historical probability of failure and loss given failure rates (excluding fraud related failures) for credit unions with total assets between $100 and $500 million and those with total assets over $500 million remain the same, total losses to the NCUSIF over the next 10 years would likely be significantly larger for credit unions with more than $500 million in assets than for those with assets between $100 million and $500 million.

TABLE 4—CREDIT UNIONS BOUND BY RISK-BASED CAPITAL, 2017Q4 CALL REPORT DATA

Asset category	Number of complex credit unions bound by risk-based capital	Capital required over the net worth ratio (million)	Total assets (billion)
Assets $100M–$500M	284	$165	$69
Assets >$500M	221	635	370
Total	505	800	439

Under the 2015 Final Rule, an estimated 505 credit unions would face higher required capital levels as a result of risk-based capital requirements. These 505 credit unions have total assets of $439 billion and the 2015 Final Rule would raise their required capital levels by approximately $800 million above what is required by the net worth ratio.[34] Under this proposal, the 284 credit unions with assets between $100 and $500 million would no longer have higher required capital levels as a result of risk-based capital requirements. However, as reflected in Table 4, this proposal would maintain most of the credit union assets subject to higher capital requirements, and incremental capital required by risk-based capital, under the 2015 Final Rule.

Exempting credit unions with assets between $100 million and $500 million represents approximately 16 percent of the total assets of credit unions with required capital levels above what is required by the net worth ratio, and about 21 percent of the incremental capital the system is required to hold under the 2015 Final Rule. However, this proposal still encompasses approximately 84 percent of the total assets of credit unions with required capital levels above what is required by the net worth ratio, and almost 80 percent of the incremental capital the system is required to hold under the 2015 Final Rule.

Under the 2015 Final Rule, a net of 20 credit unions with total assets of $11.5 billion would have a lower PCA classification with a capital shortfall of $84 million.[35] Under this proposal, 6 credit unions (net) with total assets of $8.8 billion would have a lower PCA classification and a capital deficiency of $71 million. Therefore, this proposal encompasses approximately 80 percent of the downgraded credit union assets and approximately 85 percent of the capital shortfall for these institutions.

The Board also notes the NCUSIF is much stronger today than it was in 2015 when the agency passed the 2015 Final Rule. The equity ratio of the NCUSIF was 1.29 percent in 2015. In 2018, the NCUSIF equity ratio will be 1.39 percent even after an equity distribution of $736 million is paid to credit unions. The total funds held in the NCUSIF will be approximately $16 billion after the equity distribution this year, about $3.5 billion more than the $12.4 billion held in the fund in 2015.

The NCUA will continue to address any deficiencies in the capital levels of credit unions with $500 million or less in assets through the examination process.[36] Sound capital levels are vital to the long-term health of all credit unions. Credit unions need to hold capital commensurate with their risk. Balancing proper capital accumulation with product offering and pricing strategies helps ensure credit unions are able to provide affordable member services over time. Credit unions are already expected to incorporate into their business models and strategic plans provisions for maintaining prudent levels of capital.

[30] Credit unions with assets between $250 million and $500 million are more likely to have a CR greater than 10 percent (88 percent) than the entire group of credit unions below $500 million in assets (29 percent), but it remains below the share of complex assets in credit unions above $500 million in assets (95 percent). Further, the difference widens significantly for CRs above 10 percent. Less than half (47 percent) of credit unions with assets between $250 million and $500 million have a CR greater than 30 percent, whereas over two-thirds of credit unions with more than $500 million in assets have a CR greater than 30 percent.

[31] Based on December 31, 2017 Call Report data.

[32] Based on December 31, 2017 Call Report data, 93 percent of credit union assets would be covered based on the $100 million threshold established by the 2015 Final Rule.

[33] Based on December 31, 2017 Call Report data.

[34] Based on December 31, 2017 Call Report data. It is important to note that almost all of these credit unions already hold enough capital to meet either the risk-based capital requirements or the net-worth-based capital requirements.

[35] Based on December 31, 2017 Call Report Data.

[36] *See, e.g.,* § 702.102(b) (Authorizes the NCUA Board to reclassify a well-capitalized credit union as adequately capitalized and may require an adequately capitalized or undercapitalized credit union to comply with certain mandatory or discretionary supervisory actions as if it were classified in the next lower capital category.).

Also, the Board wants to clarify for commenters that the standard under the Regulatory Flexibility Act for how the NCUA defines a ''small credit union'' [37] is different from the standard under the FCUA for how the agency defines ''complex credit union'' for purposes of the risk-based net worth requirement.[38] While both definitions currently use an asset threshold of greater than $100 million in total assets, the thresholds were arrived at using different methodologies. The methodologies necessarily vary to address the different applicable statutory provisions.[39] This proposal addresses and amends only the NCUA's definition of ''complex'' credit unions as that term is defined under the 2015 Final Rule. It does not address or propose to amend the NCUA's current definition of ''small credit unions'' for purposes of the Regulatory Flexibility Act.[40]

V. Effective Date of the 2015 Final Rule

The Board initially established the effective date of the 2015 Final Rule as January 1, 2019 to provide credit unions and the NCUA with an extended period to make necessary adjustments to systems, processes, and procedures, and to reduce the burden on affected credit unions in meeting the new requirements. Based on feedback from the credit union community and agency staff, and that the agency is proposing to change the definition of complex credit union, the Board believes it is necessary and beneficial to delay the effective date of the 2015 Final Rule as amended by this proposal by one year. Extending the effective date would provide covered credit unions additional time to adjust systems, processes, and procedures; and would help smooth the transition for complex credit unions affected by the requirements of the 2015 Final Rule.

Until the 2015 Final Rule's effective date, the NCUA's current PCA regulation will remain in effect. The NCUA will continue to enforce the capital standards currently in place and address any supervisory concerns through existing regulatory and supervisory mechanisms. The Board believes that, given the facts above, extending the implementation period of the 2015 Final Rule for an additional year would be reasonable and would not pose undue risk to the NCUSIF. Accordingly, the Board proposes to change the effective date for the 2015 Final Rule, and any changes to that rule finalized as part of this rulemaking, from January 1, 2019 to January 1, 2020.

VI. Impact of the Proposed Regulation

The proposed rule will lower the overall impact of the 2015 Final Rule by reducing the number of credit unions subject to the risk-based capital requirements of the rule. By increasing the threshold for defining a complex credit union from more than $100 million to more than $500 million in assets, an additional 1,026 credit unions would be exempt from the 2015 Final Rule's risk-based capital requirements. This represents significant burden relief for these relatively small credit unions, as half of them have assets of $190 million or less. The proposed new definition of complex credit union would exempt a total of 90 percent (5,042) of all credit unions as of December 31, 2017.[41] For comparison, if the threshold were to remain at $100 million only about 72 percent of all credit unions would be exempt.

While under this proposal 9 out of 10 credit unions would be exempt, these institutions only hold 24 percent of total assets in the credit union system and 15 percent of complex assets and liabilities.[42] Thus, approximately 85 percent of the complex assets and liabilities and 76 percent of the total assets in the credit union system would still be subject to the risk based capital requirement.[43]

The credit unions that would be defined as complex under this proposal have estimated aggregate and average risk-based capital ratios of 16.8 and 17.2 percent, respectively. The aggregate risk-weighted assets to total assets ratio is 63 percent for complex credit unions under this proposal.[44] Table 5 shows the distribution of estimated risk-based capital ratios for all complex credit unions based on this proposed rule.

TABLE 5—DISTRIBUTION OF ESTIMATED RISK BASED CAPITAL RATIOS FOR COMPLEX CREDIT UNIONS

RBC Ratio	<10%	10–13%	13–16%	16–20%	20–30%	30–50%	>50%
Number of CUs	7	110	153	144	101	14	2

As shown in Table 5 above, most complex credit unions will have a risk-based capital ratio well in excess of the 10 percent level required to be well capitalized. Under this proposal, six complex credit unions with total assets of $8.8 billion would have a lower capital classification, with a capital shortfall of approximately $71 million.[45] Overall, 98.7 percent of all complex credit unions are well capitalized under this proposed rule.

Credit unions often hold some margin above regulatory capital requirements. Table 6 below provides a comparison of the margins complex credit unions currently hold in excess of both the net worth ratio requirement and the risk-based capital requirement.

[37] NCUA Interpretative Ruling and Policy Statement 15–1, available at *https://www.ncua.gov/regulation-supervision/Pages/rules/interpretive-rulings-policy-statements.aspx*.

[38] 80 FR 66625, 66663–66664 (October 29, 2015).

[39] *Compare* 80 FR 66663–66664, *with* 80 FR 57512, 57514-57516 (Sept. 24, 2015).

[40] 5 U.S.C. 601 *et seq.*

[41] This proposal would limit risk-based capital requirements to only credit unions with assets of more than $500 million compared to the Other Banking Agencies' risk-based capital standards that apply to banks of all sizes. As of December 31, 2017, there were 1,450 and 4,294 FDIC-insured banks with assets of $100 million and $500 million or less, respectively.

[42] Credit unions with assets between $100 million and $500 million make up 17 percent of assets in the credit union system, and only hold 13 percent of complex assets and liabilities.

[43] For comparison, if the threshold were to remain at $100 million about 98 percent of the complex assets and liabilities and 93 percent of the total assets in the credit union system would still be subject to the risk-based capital requirement.

[44] By way of comparison, the bank aggregate total risk-weighted assets to total assets ratio is 72.4 percent as of December 31, 2017. Further, complex credit unions maintain a median risk-based capital ratio of 15.8 percent compared to a bank median risk-based capital ratio of 15.9 percent. Bank comparisons exclude banks with less than $50 million in total assets and more than $60 billion in total assets to arrive at a more comparable asset profile to credit unions.

[45] Of the 531 impacted credit unions, only 7, or 1.3 percent, would have less than the 10 percent risk-based capital requirement to be well capitalized. Of these, one has a net worth ratio less than 7 percent and is therefore not a new downgrade in capital classification, but already categorized as less than well capitalized. If the asset threshold for the definition of complex credit union remained at $100 million, a net of 20 credit unions with total assets of $11.5 billion would have a lower capital classification, with a capital shortfall of approximately $84 million.

TABLE 6—DISTRIBUTION OF NET WORTH RATIO AND RISK-BASED CAPITAL RATIO FOR COMPLEX CREDIT UNIONS UNDER THIS PROPOSAL

Number of CUs	Less than well capitalized	Well capitalized to well + 2%	Well capitalized +2% to + 3.5%	Well capitalized +3.5% to + 5%	Greater than well capitalized + 5%
Net Worth Ratio	<7%	7%–9%	9%–10.5%	10.5%–12%	>12%
RBC Ratio	<10%	10%–12%	12%–13.5%	13.5%–15%	>15%
Net Worth Ratio	2	90	166	141	132
RBC Ratio	7	54	82	88	300

Both measures indicate the large majority of complex credit unions hold margins well above the levels required to be well-capitalized.

The NCUA also analyzed complex credit unions to determine whether the net worth or risk-based capital requirement would require a credit union to hold more dollars of capital. Table 7 below summarizes the distribution of credit unions by the ratio of risk-weighted assets to total assets for credit unions bound by each capital requirement.

TABLE 7—DISTRIBUTION OF RISK-WEIGHTED ASSETS TO TOTAL ASSETS RATIOS FOR COMPLEX CREDIT UNIONS BY GOVERNING CAPITAL REQUIREMENT

	Total number	Average (%)	Risk weighted assets/total assets					
			<50%	50–60%	60–70%	70–80%	80–90%	>90%
Number Bound by Net Worth Ratio	310	58.9	49	101	147	10	2	1
Number Bound by Risk Based Capital	221	71.9	0	3	81	128	6	3

Forty-two percent of complex credit unions (221 complex credit unions with $370.3 billion in total assets) are estimated to have a higher minimum capital requirement in terms of dollars under the risk-based capital ratio than the net worth ratio.[46] These 221 complex credit unions have a notably higher risk profile than the other 310 complex credit unions. The ratio of average risk weighted assets to total assets for the 221 complex credit unions is 72 percent, compared with 59 percent for the remaining 310 complex credit unions. Therefore, relative to what qualifies as capital for risk-based capital purposes, these institutions must hold more net worth in dollars to achieve a well-capitalized designation over what the net worth ratio requires.

In addition, despite holding a greater share of risk-weighted assets, the risk-based capital-bound group of 221 complex credit unions also has, on average, a net worth ratio that is 100 basis point below the net worth ratio of the other 310 complex credit unions.[47] Table 7 highlights the distribution of credit unions by risk weighted assets to total assets depending on whether the risk-based capital requirement necessitates more capital than the net worth ratio. The risk-based capital-bound group of 221 complex credit unions would have to retain more net worth in dollars than what is currently required due to the net worth ratio to satisfy the well-capitalized threshold. However, over 97 percent (215) of these institutions already hold more than enough capital to meet the risk-based capital requirement.

VI. Request for Comment

The Board is requesting comment on all aspects of the changes proposed in this proposed rule. In particular, the agency requests comments on:

1. Whether the definition of a complex credit union, as defined under § 701.103 of the 2015 Final Rule, should be amended to increase the threshold level for coverage from *more than $100 million in total assets* to *more than $500 million in total assets*?

2. Whether the implementation date for the 2015 Final Rule should be amended to extend the effective date of the rule until January 1, 2020?

VII. Regulatory Procedures

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that, in connection with a notice of proposed rulemaking, an agency prepare and make available for public comment an initial regulatory flexibility analysis that describes the impact of a proposed rule on small entities. A regulatory flexibility analysis is not required, however, if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (defined for purposes of the RFA to include credit unions with assets less than $100 million) [48] and publishes its certification and a short, explanatory statement in the **Federal Register** together with the rule.

The proposed amendments to the 2015 Final Rule and part 702 would only affect complex credit unions, which are those with greater than $100 million in assets under the 2015 Final Rule and would be amended to cover only those with greater than $500 million in assets under this proposal. As a result, credit unions with $100 million or less in total assets would not be affected by this proposal. Accordingly, the NCUA certifies that this proposal will not have a significant economic impact on a substantial number of small credit unions.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (PRA) applies to rulemakings in which an agency by rule creates a new paperwork burden on regulated entities or modifies an existing burden.[49] For purposes of the PRA, a paperwork burden may take the form of a reporting, disclosure, or recordkeeping requirement, each referred to as an

[46] The required dollar amount for risk based capital is calculated as [(risk-weighted assets times 10 percent) − allowance for loan losses − equity acquired in merger + total adjusted retained earnings acquired through business combinations + NCUA share insurance capitalization deposit + goodwill + identifiable intangible assets] − (total assets × 7 percent). Complex credit unions in Table 7 are categorized by whichever calculation results in a higher dollar volume.

[47] The average net worth ratio is 10.3 percent for the 212 complex credit unions bound by risk-based capital while the average net worth ratio for the 310 complex credit unions bound by the net worth ratio is 11.4 percent.

[48] *See* 80 FR 57512 (Sept. 24, 2015).

[49] 44 U.S.C. 3507(d).

information collection. The NCUA may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The proposed changes to part 702 would increase the asset size of credit unions identified as complex from greater than $100 million to greater than $500 million. This change would reduce the number of credit unions who must comply with recordkeeping requirements prescribed by § 702.101(b). Therefore, the burden cleared under OMB number 3133–0191 will be revised to reflect the reduction in the number of respondents.[50]

Title of Information Collection: Prompt Corrective Action—Risk-Based Capital.

OMB Control Number: 3133–0191.

Affected Public: Private Sector: Not-for-profit institutions—Complex Credit Unions.

Estimated Number of Respondents: 531.

Estimated Number of Responses per Respondent: 1.

Estimated Hours per Response: 40.

Estimated Total Annual Burden Hours: 21,240.

By exempting credit unions with assets between $100 million and $500 million, the NCUA estimates that the burden under this proposed rule would be 41,040 fewer hours.

The Board invites comment on (a) whether the collections of information are necessary for the proper performance of the agency's function, including practical utility; (b) the accuracy of estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information being collected, and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

All comments are a matter of public record. Comments regarding the information collection requirements of this rule should be sent to (1) Dawn Wolfgang, NCUA PRA Clearance Officer, National Credit Union Administration, 1775 Duke Street, Suite 5080, Alexandria, Virginia 22314, or Fax No. 703–519–8572, or Email at *PRAcomments@ncua.gov* and the (2) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for NCUA, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission,@OMB.EOP.gov.*

Submission of comments. The NCUA considers comments by the public on this proposed collection of information in:

- Evaluating whether the proposed collection of information is necessary for the proper performance of the functions of the NCUA, including whether the information will have a practical use;
- Evaluating the accuracy of the NCUA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of 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.

Executive Order 13132

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on state and local interests. The NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the principles of the executive order to adhere to fundamental federalism principles. This proposed rule reduces the number of federally insured natural-person credit unions, including federally insured, state-chartered natural-person credit unions that would be subject to the 2015 Final Rule. It may have, to some degree, a 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. It does not, however, rise to the level of material impact for purposed of Executive Order 13132.

Assessment of Federal Regulations and Policies on Families

The NCUA has determined that this proposed rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999, Public Law 105–277, 112 Stat. 2681 (1998).

[50] Proposed revisions to OMB control number 3133–0191 have been submitted to OMB for approval in accordance with 5 CFR 1320.11.

List of Subjects in 12 CFR Part 702

Credit unions, Reporting and recordkeeping requirements.

By the National Credit Union Administration Board on August 2, 2018.

Gerard Poliquin,

Secretary of the Board.

For the reasons discussed above, the Board proposes to further amend 12 CFR part 702, as amended in a final rule at 80 FR 66625 (Oct. 29, 2015), effective January 1, 2019, as follows:

PART 702—CAPITAL ADEQUACY

■ 1. The authority citation for part 702 continues to read as follows:

Authority: 12 U.S.C. 1766(a), 1790d.

§ 702.103 [Amended]

■ 2. Amend § 702.103 by removing the words ''one hundred million dollars ($100,000,000)'' and add in their place ''five hundred million dollars ($500,000,000).''

[FR Doc. 2018–16888 Filed 8–7–18; 8:45 am]

BILLING CODE 7535–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0722; Product Identifier 2017–SW–104–AD

RIN 2120–AA64

Airworthiness Directives; Bell Helicopter Textron Canada Limited Helicopters

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede airworthiness directive (AD) 2015–22–02 for Bell Helicopter Textron Canada Limited (Bell) Model 429 helicopters. AD 2015–22–02 requires inspecting the tail rotor (TR) pitch link assemblies. This proposed AD would retain the inspections of AD 2015–22–02 and would require replacing certain pitch link bearings. Since we issued AD 2015–22–02, Bell has introduced a new design bearing. The actions of this proposed AD are intended to prevent an unsafe condition on these products.

DATES: We must receive comments on this proposed AD by October 9, 2018.

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

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov*. Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0722; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the Transport Canada AD, the economic evaluation, any comments received, and other information. The street address for Docket Operations (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this final rule, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at *http://www.bellcustomer.com/files/*. You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *david.hatfield@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

We issued AD 2015–22–02, Amendment 39–18306 (80 FR 65618, October 27, 2015) (AD 2015–22–02), for Bell Model 429 helicopters with a TR pitch link assembly part number (P/N) 429–112–101 or 429–112–103 installed. AD 2015–22–02 requires repetitively inspecting each inboard and outboard TR pitch link assembly for axial or radial bearing play every 50 hours time-in-service (TIS), performing a dimensional inspection of the TR pitch link if there is axial or radial bearing play, and replacing the TR pitch link before further flight if there is any wear beyond allowable limits. AD 2015–22–02 was prompted by Emergency AD No. CF–2015–16, dated July 2, 2015, and Emergency AD No. CF–2015–16R1, dated August 6, 2015, issued by Transport Canada, to correct an unsafe condition for Bell Model 429 helicopters. Transport Canada advised of several occasions where the TR pitch link spherical bearings experienced early and accelerated wear.

Actions Since AD 2015–22–02 Was Issued

Since we issued AD 2015–22–02, Transport Canada has issued AD No. CF–2015–16R2, dated April 17, 2017, which supersedes AD CF–2015–16R1. According to Transport Canada, Bell has reported that the TR pitch link assembly can be rotated during the 50-hour inspections to extend the serviceability life of the bearings. Transport Canada AD No. CF–2015–16R2 requires modified inspection procedures for the spherical bearings and requires replacing the TR pitch link bearings (or the TR pitch link assembly) with spherical bearings manufactured after January 12, 2015. Transport Canada AD No. CF–2015–16R2 also requires re-identifying TR pitch link assemblies with a different P/N after installing the new bearings. We propose to issue this AD to make similar changes.

FAA's Determination

These helicopters have been approved by the aviation authority of Canada and are approved for operation in the United States. Pursuant to our bilateral agreement with Canada, Transport Canada, its technical representative, has notified us of the unsafe condition described in the Transport Canada AD. We are proposing this AD because we evaluated all information provided by Transport Canada and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Related Service Information

Bell has issued Alert Service Bulletin No. 429–15–16, Revision B, dated June 15, 2016. This service information contains procedures for repetitively inspecting the TR pitch link assembly until it is upgraded by replacing the TR pitch link bearings.

AD Requirements

This proposed AD would require performing a dimensional inspection of the spherical bearings for axial and radial play and inspecting the TR pitch link assembly sealant for pin holes, voids, and excessive thickness. These inspections would be required within 50 hours TIS and thereafter at intervals not exceeding 50 hours TIS.

This proposed AD would also require replacing any spherical bearing manufactured before January 13, 2015, that has exceeded 250 hours TIS or that has an unknown number of hours TIS, and re-identifying the P/N of the TR pitch link assembly.

Differences Between This Proposed AD and the Transport Canada AD

The Transport Canada AD requires the bearing inspection within 10 hours TIS or before exceeding 60 hours TIS since new, whichever occurs later. This proposed AD would require the bearing inspection within 50 hours TIS. The Transport Canada AD also requires replacing certain bearings within 200 hours TIS after the initial bearing inspection or within 250 hours TIS since new, whichever occurs first. This proposed AD would require replacing the bearing within 200 hours of the initial inspection or at the next 50 hour TIS inspection if the hours TIS of a pitch link assembly exceed 250 hours TIS or are unknown.

Interim Action

We consider this proposed AD to be an interim action. If final action is later

identified, we might consider further rulemaking then.

Costs of Compliance

We estimate that this proposed AD would affect 85 helicopters of U.S. Registry. We estimate that operators may incur the following costs in order to comply with this proposed AD. At an average labor rate of $85 per hour, inspecting the TR pitch link assemblies would require 2 work-hours for a cost of $170 per helicopter and $14,450 for the U.S. fleet per inspection cycle. Replacing both spherical bearings in each TR pitch link assembly would require 3 work-hours, and required parts would cost $3,088, for a cost of $3,343 per helicopter and $284,155 for the U.S. fleet.

According to Bell's service information some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage by Bell. Accordingly, we have included all costs in our cost estimate.

Authority for This Rulemaking

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

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

Regulatory Findings

We determined that this proposed AD will not have federalism implications under Executive Order 13132. This proposed 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, I certify that this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2015–22–02, Amendment 39–18306 (80 FR 65618, October 27, 2015), and adding the following new AD:

Bell Helicopter Textron Canada Limited: Docket No. FAA–2018–0722; Product Identifier 2017–SW–104–AD.

(a) Applicability

This AD applies to Model 429 helicopters with a pitch link assembly part number (P/N) 429–012–112–101, 429–012–112–103, 429–012–112–101FM, or 429–012–112–103FM installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as a worn pitch link. This condition, if not corrected, could result in pitch link failure and subsequent loss of control of the helicopter.

(c) Affected ADs

This AD replaces AD 2015–22–02, Amendment 39–18306 (80 FR 65618, October 27, 2015).

(d) Comments Due Date

We must receive comments by October 9, 2018.

(e) Compliance

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

(f) Required Actions

(1) Within 50 hours time-in-service (TIS) and thereafter at intervals not to exceed 50 hours TIS:

(i) Perform a dimensional inspection of each inboard and outboard pitch link assembly for axial and radial bearing play. With a 10X or higher power magnifying glass, inspect the bearing liner for a crack, deterioration of the liner, and extrusion of the liner from the plane. If there is axial or radial play that exceeds allowable limits, or if there is a crack, deterioration of the liner, or extrusion of the liner, before further flight, replace the bearing.

(ii) Inspect the pitch link assembly sealant for pin holes and voids and to determine if the sealant thickness is 0.025 inch (0.64 mm) or less, extends over the roll staked lip by 0.030 inch (0.76 mm) or more, and is clear of the bearing ball. If there is a pin hole or void, or if the sealant exceeds 0.026 inch (0.66 mm), does not extend over the roll staked lip by 0.030 inch (0.76 mm) or more, or is not clear of the bearing ball, before further flight, replace the bearing.

(2) For pitch link assembly part number (P/N) 429–012–112–101, 429–012–112–103, 429–012–112–101FM, and 429–012–112–103FM, within 200 hours TIS following the initial inspection required by paragraph (f)(1) of this AD, or if the hours TIS of a pitch link assembly exceed 250 hours TIS or are unknown, at the next 50 hour TIS inspection required by paragraph (f)(1) of this AD:

(i) Replace each bearing P/N 429–312–107–103 with a date of manufacture before January 13, 2015, with a bearing P/N 429–312–107–103 that was manufactured on or after January 13, 2015.

(ii) Using a white permanent fine point marker or equivalent, re-identify the pitch link assembly:

(A) Re-identify P/N 429–012–112–101 and 429–012–112–101FM as 429–012–112–111FM.

(B) Re-identify P/N 429–012–112–103 and 429–012–112–103FM as 429–012–112–113FM.

(iii) Apply a coating of DEVCON 2–TON (C–298) or equivalent over the new P/N.

(g) Special Flight Permits

Special flight permits are prohibited.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov*.

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

(i) Additional Information

(1) Bell Alert Service Bulletin No. 429–15–16, Revision B, dated June 15, 2016, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact Bell Helicopter Textron Canada Limited, 12,800 Rue de l'Avenir, Mirabel, Quebec J7J1R4; telephone (450) 437–2862 or (800) 363–8023; fax (450) 433–0272; or at *http://www.bellcustomer.com/files/*. You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in Transport Canada AD No. CF–2015–16R2, dated April 17, 2017. You may view the Transport Canada AD on the internet at *http://www.regulations.gov* in the AD Docket.

(j) Subject

Joint Aircraft Service Component (JASC) Code: 6720 Tail Rotor Control System.

Issued in Fort Worth, Texas, on July 23, 2018.

Scott A. Horn,

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

[FR Doc. 2018–16637 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0669; Product Identifier 2017–SW–041–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters (Previously Eurocopter France)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 2016–25–19 for Airbus Helicopters (previously Eurocopter France) Model AS350B3 and EC130B4 helicopters. AD 2016–25–19 requires inspecting the pilot's and co-pilot's throttle twist for proper operation. This proposed AD would retain the requirements of AD 2016–25–19 and add certain model helicopters to the applicability. The actions of this proposed AD are intended to address the unsafe condition on these helicopters.

DATES: We must receive comments on this proposed AD by October 9, 2018.

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

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov*. Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0669; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received and other information. The street address for Docket Operations (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this proposed rule, contact Airbus Helicopters, 2701 N. Forum Drive, Grand Prairie, TX 75052; telephone (972) 641–0000 or (800) 232–0323; fax (972) 641–3775; or at *http://www.helicopters.airbus.com/website/en/ref/Technical-Support_73.html*. You may review service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: George Schwab, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *george.schwab@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, we will consider all comments we receive on or before the closing date for comments. We will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. We may change this proposal in light of the comments we receive.

Discussion

We issued AD 2016–25–19, Amendment 39–18745 (81 FR 95854, December 29, 2016) (AD 2016–25–19), for Airbus Helicopters Model AS350B3 and EC130B4 helicopters with the ARRIEL 2B1 engine with the two-channel Full Authority Digital Engine Control (FADEC) and with new twist grip modification (MOD) 073254 (for the Model AS350B3 helicopter) or MOD 073773 (for the Model EC130B4 helicopter). AD 2016–25–19 requires repetitively inspecting the wiring, performing an insulation test, inspecting the pilot and copilot throttle twist grip controls, and testing the pilot and copilot throttle twist grip controls for proper functioning. AD 2016–25–19 was prompted by AD No. 2013–0191–E, dated August 22, 2013 (EASA AD 2013–0191–E), issued by EASA, which is the Technical Agent for the Member States of the European Union. EASA advised that the switches in the engine ''IDLE'' or ''FLIGHT'' control system could be affected by the corrosive effects of a salt-laden atmosphere, which could lead to engine power loss. EASA AD 2013–0191–E required repetitive inspections for corrosion, application of corrosion protection on the switches, and testing of the insulation and switches of the engine idle and flight control system. The actions required in AD 2016–25–19 are intended to prevent unintended touchdown to the ground at a flight-idle power setting during a practice autorotation, damage to the helicopter, and injury to occupants.

Actions Since AD 2016–25–19 Was Issued

Since we issued AD 2016–25–19, EASA issued AD No. 2017–0052, dated March 24, 2017, which superseded EASA AD No. 2013–0191–E, dated August 22, 2013. EASA advised that Airbus Helicopters had added

clarifications to the operational procedure, introduced a modification to apply water-tight protection to the microswitch connectors, and extended the applicability to helicopters with a Turbomecca ARRIEL 2D engine installed.

EASA subsequently issued AD No. 2017–0059, dated April 6, 2017, which superseded EASA AD No. 2017–0052 to correct the applicability by including Model EC130T2 helicopters.

FAA's Determination

These helicopters have been approved by the aviation authority of France and are approved for operation in the United States. Pursuant to our bilateral agreement with France, EASA, its technical representative, has notified us of the unsafe condition described in its AD. We are proposing this AD because we evaluated all known relevant information and determined that an unsafe condition is likely to exist or develop on other products of the same type design.

Related Service Information Under 1 CFR Part 51

We reviewed one document that co-publishes three Emergency Alert Service Bulletin (EASB) identification numbers: No. 05.00.61, Revision 3, dated June 15, 2015, for Model AS350B3 helicopters; No. 05.00.41, Revision 2, dated June 15, 2015, for the non-FAA type certificated Model AS550C3 helicopter; and No. 05A009, Revision 3, dated June 15, 2015, for Model EC130B4 helicopters. EASB Nos. 05.00.61 and 05A009 are incorporated by reference in AD 2016–25–19 and will be retained for the requirements of this proposed AD. EASB No. 05.00.41 is not incorporated by reference in AD 2016–25–19 and will not be incorporated by reference in this proposed AD. This service information applies to helicopters with an Arriel 2B1 engine installed and describes procedures for a functional check and installation of protection for micro-contacts (microswitches) 53Ka, 53Kb, and 65K (IDLE/FLIGHT mode).

We also reviewed one document that co-publishes three EASB identification numbers: No. 05.00.77, Revision 1, dated June 15, 2015, for Model AS350B3 helicopters; No. 05.00.52, Revision 1, dated June 15, 2015, for the non-FAA type certificated Model AS550C3 helicopter; and No. 05A014, Revision 1, dated June 15, 2015, for Model EC130T2 helicopters. EASB Nos. 05.00.77 and 05A014 will be incorporated by reference in this proposed AD. EASB No. 05.00.52 will not be incorporated by reference in this proposed AD. This service information applies to helicopters with an Arriel 2D engine installed and describes procedures for a check of the protection for micro-contacts (microswitches) 53Ka, 53Kb, and 65K (IDLE/FLIGHT mode).

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.

Proposed AD Requirements

This proposed AD would retain the inspection requirements of AD 2016–25–19 but would add Model AS350B3 helicopters with an Arriel 2D engine installed and Model EC130T2 helicopters.

Differences Between This Proposed AD and the EASA AD

The EASA AD requires the initial inspections within 10 flight hours or 7 days; this proposed AD requires compliance before the next autorotation training flight or before 100 hours time-in-service, whichever occurs earlier, as the unsafe condition only occurs when transitioning the throttle in flight from flight to idle and back to flight, such as during a practice autorotation.

Additionally, the EASA AD requires installing Airbus Helicopters modification 074263; this proposed AD does not as it does not correct the unsafe condition.

Interim Action

We consider this proposed AD to be an interim action. If final action is later identified, we might consider further rulemaking then.

Costs of Compliance

We estimate that this proposed AD would affect 692 helicopters of U.S. Registry.

We estimate that operators will incur the following costs in order to comply with this proposed AD. At an average labor rate of $85 per work hour, it would take about 4 work hours for the inspections and any necessary maintenance, for a total cost of $340 per helicopter and $235,280 for the U.S. fleet per inspection cycle.

Authority for This Rulemaking

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

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

Regulatory Findings

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, 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 to the extent that it justifies making a regulatory distinction; and

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2016–25–19, Amendment 39–18745 (81 FR 95854, December 29, 2016), and adding the following new AD:

Airbus Helicopters (Previously Eurocopter France): Docket No. FAA–2018–0669; Product Identifier 2017–SW–041–AD.

(a) Applicability

This AD applies to the following helicopters, certificated in any category:

(1) Model AS350B3 helicopters with an ARRIEL 2B1 engine with the two-channel Full Authority Digital Engine Control (FADEC) and with new twist grip modification (MOD) 073254 or with an ARRIEL 2D engine installed;

(2) Model EC130B4 helicopters with an ARRIEL 2B1 engine with the two-channel FADEC and with new twist grip MOD 073773 installed; and

(3) Model EC130T2 helicopters with an ARRIEL 2D engine installed.

(b) Unsafe Condition

This AD defines the unsafe condition as failure of one of the two contactors, 53Ka or 53Kb, which can prevent switching from ''IDLE'' mode to ''FLIGHT'' mode during autorotation training making it impossible to recover from a practice autorotation and compelling the pilot to continue the autorotation to the ground. This condition could result in unintended touchdown to the ground at a flight-idle power setting during a practice autorotation, damage to the helicopter, and injury to occupants.

(c) Affected ADs

This AD replaces AD 2016–25–19, Amendment 39–18745 (81 FR 95854, December 29, 2016).

(d) Comments Due Date

We must receive comments by October 9, 2018.

(e) Compliance

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

(f) Required Actions

(1) Before the next practice autorotation or within 100 hours time-in-service (TIS), whichever occurs first, inspect the wiring, perform an insulation test, inspect the pilot and copilot throttle twist grip controls, and test the pilot and copilot throttle twist grip controls for proper functioning by following the Accomplishment Instructions, paragraph 3.B.1 through 3.B.6, of Airbus Helicopters Emergency Alert Service Bulletin (EASB) No. 05.00.61, Revision 3, dated June 15, 2015, for Model AS350B3 helicopters with an ARRIEL 2B1 engine; EASB No. 05.00.77, Revision 1, dated June 15, 2015, for Model AS350B3 helicopters with an ARRIEL 2D engine; EASB No. 05A009, Revision 3, dated June 15, 2015, for Model EC130B4 helicopters; or EASB No. 05A014, Revision 1, dated June 15, 2015, for Model EC130T2 helicopters, as appropriate for your model helicopter.

(2) Repeat the inspections in paragraph (f)(1) of this AD at intervals not to exceed the following compliance times. For purposes of this AD, salt laden conditions exist when a helicopter performs a flight from a takeoff and landing area, heliport, or airport less than 0.5 statute mile from salt water or performs a flight within 0.5 statute mile from salt water below an altitude of 1,000 ft. above ground or sea level.

(i) For helicopters that have operated in salt laden conditions since the previous inspection required by this AD, at intervals not to exceed 330 hours TIS.

(ii) For helicopters that have not operated in salt laden conditions since the previous inspection required by this AD, at intervals not to exceed 660 hours TIS.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: George Schwab, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, 10101 Hillwood Parkway, Fort Worth, Texas 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov*.

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

(h) Additional Information

The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2017–0059, dated April 6, 2017. You may view the EASA AD on the internet at *http://www.regulations.gov* in the AD Docket.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 7697 Engine Control System Wiring.

Issued in Fort Worth, Texas, on July 11, 2018.

Scott A. Horn,

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

[FR Doc. 2018–16494 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2018–0153; FRL–9981–76—Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Amendment to Control of Emissions of Volatile Organic Compounds From Consumer Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of Maryland. This revision pertains to Code of Maryland Regulations (COMAR) 26.11.32—Control of Emissions of Volatile Organic Compounds (VOCs) from Consumer Products. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 7, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2018–0153 at *http://www.regulations.gov,* or via email to Susan Spielberger, Associate Director, Office of Air Planning and Programs, *Spielberger.Susan@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Gregory Becoat (215) 814–2036, or by email at *becoat.gregory@epa.gov.*

SUPPLEMENTARY INFORMATION: On November 16, 2017, the Maryland Department of Environment (MDE) submitted a revision to its SIP for COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products. The amendment is part of Maryland's strategy to achieve and maintain the 8-hour ozone national ambient air quality standards (NAAQS) throughout the State.

I. Background

EPA has designated certain areas within Maryland as nonattainment for the 2008 ozone NAAQS. *See* 40 CFR

81.321. Also, all of Maryland is included in the Ozone Transport Region (OTR) and is therefore treated as a moderate nonattainment area for ozone. *See* CAA section 184(a), (b)(2), 42 U.S.C. 7511c(a), (b)(2). Therefore, Maryland must continue to enact regulations to gain further reductions of the emissions of VOCs, a class of compounds that are precursors to ground-level ozone. Ozone is formed in the atmosphere by photochemical reactions between VOCs and oxides of nitrogen (NO_X) in the presence of sunlight. In order to reduce ozone concentrations, the CAA requires control of VOC and NO_X emission sources to achieve VOC and/or NO_X emission reductions in nonattainment areas.

In December 1999, EPA identified emission reduction shortfalls in several severe 1-hour ozone nonattainment areas, including those located in the OTR. The Ozone Transport Commission (OTC) developed model rules for a number of source categories. One of the model rules was to reduce VOC emissions from consumer products. The OTC model rules are based on existing rules developed by the California Air Resources Board (CARB) in 2001 (See ''OTC Model Rule for Consumer Products,'' issued March 28, 2001, revised November 29, 2001, and April 23, 2002), which were then analyzed and modified by OTC-formed workgroups to address emission reduction needs in the OTR. The 2001 OTC model rule set VOC emission limits on nearly 80 percent of the consumer product categories. Maryland adopted the 2001 OTC model rule for consumer products under COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, on August 18, 2003. EPA approved Maryland's adopted regulation COMAR 26.11.32 as part of the SIP on December 8, 2004 (69 FR 70895). The OTC model rule for consumer products was amended on September 19, 2006, based upon changes by CARB in 2005. Maryland adopted the amended 2006 OTC model rule for consumer products under COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, on June 8, 2007.

The amended model rule added fourteen consumer product categories with new product category definitions and VOC limits; revised one previously regulated category with a more restrictive VOC limit; and established additional requirements for two previously regulated categories. EPA approved Maryland's amended regulation into the SIP on December 10, 2007 (72 FR 69621). Maryland again amended its consumer products regulation and on October 18, 2010 (75 FR 63717), EPA approved Maryland's SIP revision to COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products. This SIP revision added and amended definitions; added VOC content limits for an additional 11 categories of consumer products; and revised the VOC content limits for one category of consumer products that was already regulated.

MDE's November 16, 2017 SIP revision asks EPA to approve into the SIP recent amendments to COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, in order to institute the requirements of the 2010 and 2014 OTC model rules for consumer products. The 2010 and 2014 model rules were developed as part of a regional effort to attain and maintain the 8-hour ozone NAAQS, and reduce 8-hour ozone levels. The 2010 OTC model rule reflected changes made by the 2006 CARB rule. The 2014 OTC model rule reflected changes made by the 2009 CARB rule. The OTC model rules further enhance VOC standards for specific consumer products and introduces VOC standards for new products. The amendments to COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, consists of updates to the VOC content limits and standards for a variety of consumer product categories, including personal care products, household products, automotive cleaners, and adhesives. The regulations set forth content and labeling requirements for flammable multi-purpose solvents and paint thinners. In addition, the regulations prohibit the sale, offer for sale, supply, or manufacture for use in the State of certain products manufactured on or after January 1 that contain methylene chloride, perchloroethylene, or trichloroethylene. These products include any bathroom and tile cleaner, construction panel and floor covering adhesive, electronic cleaner labeled ''Energized Electronic Equipment use only,'' general purpose cleaner, or oven or grill cleaner. The amendments also establish VOC standards for 11 new consumer product categories. In addition, the amendments further strengthen the VOC standards for 15 consumer product categories based on improved reformulations of these products that are capable of achieving lower VOC emissions while demonstrating an ability to maintain performance specifications for the products. The amendments also incorporate new definitions and numerous modifications to existing definitions to improve clarity. In particular, MDE amended the structure of the definition, exemptions, and VOC standard for the artist's thinner/solvent consumer product category without changing the regulatory language, which remains consistent with the 2009 CARB rule and the 2014 OTC model rule.

It is important to note that the 2006 CARB rule eliminated the ''hair styling gel'' category and now considers gels to fall under ''hair styling product—all other forms.'' Moving gels under the ''hair styling product—all other forms'' category reduced the VOC limit from 6 to 2 percent VOC by weight. The 2014 OTC model rule did not address this amendment as intended; however, MDE amended ''hair styling gel'' to be included under the ''hair styling product—all other forms'' category to meet the VOC limit of 2 percent VOC by weight in order to remain consistent with CARB.

II. Summary of SIP Revision and EPA Analysis

The SIP revision consists of Maryland's revision to regulations .01–.06, .08, .12, .14, .16, and the addition of a new regulation .05–1, under COMAR 26.11.32—Control of Emissions of VOCs from Consumer Products. Generally, the regulations establish or amend VOC content limits and standards for a variety of consumer product categories, including personal care products, household products, automotive cleaners, and adhesives, in order to be consistent with the CARB and OTC model rules. The regulations also, among other things:

1. Set forth content and labeling requirements for flammable multi-purpose solvent and paint thinner;

2. prohibit the sale, offer for sale, supply, or manufacture for use in the State of specified products that contain methylene chloride, perchloroethylene, or trichloroethylene, which are compounds that are potential carcinogens; and

3. make various updates to the applicability provisions, documents incorporated by reference, definitions, reporting requirements, exemptions, and test methods.

Substantial amendments were made to COMAR 26.11.32.04—Standards—General, to establish that a person may not sell, supply, offer for sale, or manufacture for sale in the State a consumer product that contains VOCs in excess of limits specified in COMAR 26.11.32.04B based on the CARB and OTC model rules. The following 11

consumer products categories were added, including the VOC standards limits in parentheses based on percent VOC by weight: (1) Dual Purpose Air freshener/Disinfectant, Aerosol (60); (2) Anti-Static Product, Aerosol (80); (3) Artist's Solvent/Thinner (3); (4) Automotive Windshield Cleaner (35); (5) Disinfectant, Aerosol (70); (6) Disinfectant, Non-Aerosol (1); (7) Multi-Purpose Solvent (3); (8) Paint Thinner (3); (9) Sanitizer, Aerosol (70); (10) Sanitizer, Non-Aerosol (1); and (11) Temporary Hair Color, Aerosol (55).

The following existing 15 consumer products categories were amended, including the VOC content limits in parentheses based on percent VOC by weight: (1) Adhesive—Construction, Panel and Floor (7); (2) Automotive Brake Cleaner (category changed to Brake Cleaner (10); (3) Bathroom and Tile Cleaner, All Other Forms (subcategory changed to Non-Aerosol (1); (4) Carburetor or Fuel-Injection Air Intake Cleaner (10); (5) Engine Degreaser, Aerosol (10); (6) Floor Polish/Wax, Resilient Flooring Material (1); (7) Floor Polish/Wax, Non-resilient Flooring Material (1); (8) Furniture Maintenance Product, All Other Forms (subcategory changed to Non-Aerosol) (3); (9) General Purpose Cleaner, Aerosol (8); (10) General Purpose Degreaser, Aerosol (10); and (11) Laundry Starch/Sizing/Fabric Finish Product (4.5); (12) Nail Polish Remover (1); (13) Oven or Grill Cleaner, Non-Aerosol (subcategory changed to Non-Aerosol) (4); (14) Oven or Grill Cleaner, Aerosol (8); and (15) Shaving Gel (4).

In addition to these revised and new standards, Maryland added a requirement for ''flammable and extremely flammable multi-purpose solvent and paint thinner,'' to meet the formulated California VOC limits. The revision will continue to help Maryland attain and maintain the eight-hour ozone standard for the 2008 NAAQS. The revision is expected to result in estimated statewide VOC emissions reduction potential of approximately 6.3 tons per day through the implementation of standards for new and existing forms of consumer products. This estimate is based on the proposed emissions benefit methodology of CARB and OTC model rules.

Further details of Maryland's regulation revisions and the CARB and OTC model rules for consumer products can be found in the docket of this proposed rulemaking EPA–R03–OAR–2018–0153 on *www.regulations.gov.*

III. Proposed Action

EPA is proposing to approve MDE's amendments to COMAR 26.11.32—Control of Emissions of VOCs from Consumer Products, that adopts the VOC limits established in the 2010 and 2014 OTC model rules for consumer products, based on the 2006 and 2009 CARB rules; respectively (with the exception of the previously discussed ''hair styling gel'' category). The OTR estimated regional VOC emission reductions of approximately 15 percent if all OTR states, including Maryland, adopts the 2010 and 2014 model rules. EPA's review of this material indicates that the revisions made to COMAR 26.11.32—Control of Emissions of VOCs from Consumer Products, meet the SIP revision requirements of the CAA. EPA is proposing to approve the State of Maryland's SIP revision for the control of emissions of VOCs from consumer products, which was submitted on November 19, 2017. EPA is soliciting public comments on the proposed adoption of these changes into the Maryland SIP.

IV. Incorporation by Reference

In this proposed rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference the specific provisions of the Maryland rule discussed in section II of this preamble. EPA has made, and will continue to make, these materials generally available through *http://www.regulations.gov* and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

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

In addition, this proposed rule, to approve amendments to the State of Maryland's COMAR 26.11.32—Control of Emissions of Volatile Organic Compounds from Consumer Products, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Consumer products, Incorporation by reference, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: July 24, 2018.

Cecil Rodrigues,

Acting Regional Administrator, Region III.

[FR Doc. 2018–16776 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2018–0413; FRL–9981–73—Region 9]

Revisions to California State Implementation Plan; South Coast Air Quality Management District; Stationary Source Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing action on a revision to the South Coast Air Quality Management District (SCAQMD or District) portion of the California State Implementation Plan (SIP). We are proposing a conditional approval of an update to provisions governing issuance of permits for stationary sources, including review and permitting of major sources and major modifications under part D of title I of the Clean Air Act (CAA). Specifically, the revision pertains to SCAQMD Rule 1325—*Federal $PM_{2.5}$ New Source Review Program.* We are taking comments on this proposal and a final action will follow.

DATES: Any comments must arrive by September 7, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2018–0413 at *http://www.regulations.gov,* or via email to *R9AirPermits@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Laura Yannayon, EPA Region 9, (415) 972–3534, *yannayon.laura@epa.gov.*

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

Table of Contents

I. The State's Submittal

A. What rule did the State submit?

Table 1 lists the rule addressed by this proposal with the date it was adopted by SCAQMD and submitted by the California Air Resources Board (CARB), the governor's designee for California SIP submittals. Rule 1325 contains the District's New Source Review (NSR) permit program applicable to new and modified major sources emitting fine particulate matter ($PM_{2.5}$) and $PM_{2.5}$ precursors.

TABLE 1—SUBMITTED RULE

Rule No.	Rule title	Amended	Submitted
1325	Federal $PM_{2.5}$ New Source Review Program	11/4/16	5/8/17

On November 1, 2017, CARB's May 8, 2017 submittal of Rule 1325 was deemed to meet the completeness criteria in 40 CFR part 51, appendix V. Completeness criteria must be met before formal EPA review.

B. Are there other versions of this rule?

The current SIP contains a version of Rule 1325—*Federal $PM_{2.5}$ New Source Review Program,* approved into the SIP on May 1, 2015 (80 FR 24821). Consistent with the District's stated intent to have the submitted rule replace the existing SIP-approved rule in its entirety, EPA's conditional approval of the rule identified above in Table 1 would have the effect of entirely superseding our prior approval of the same rule in the current SIP-approved program.

C. What is the purpose of the submitted rule?

For areas designated as nonattainment for one or more National Ambient Air Quality Standards (NAAQS), the SIP must include preconstruction permit requirements for new or modified major stationary sources of such nonattainment pollutant(s), commonly referred to as ''Nonattainment New Source Review'' (NNSR). CAA 172(c)(5).

SCAQMD Rule 1325 addresses NNSR permit requirements for major sources of $PM_{2.5}$. Rule 1325 has been amended to address SCAQMD's reclassification from a Moderate to a Serious $PM_{2.5}$ nonattainment area and to implement additional provisions pertaining to precursors, as promulgated in EPA's rule entitled Fine Particulate Matter National Ambient Air Quality Standards: State Implementation Plan Requirements (''2016 Implementation Rule'').[1]

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rule?

Under EPA's 2016 Implementation Rule, which implements the D.C. Circuit court's January 2013 decision in *NRDC* v. *EPA,*[2] areas classified as nonattainment for any $PM_{2.5}$ NAAQS are required to comply with the parts of CAA subpart 4 section 189(e)[3] that require the control of major stationary sources of PM_{10} precursors (and hence under the court decision, $PM_{2.5}$ precursors) ''except where the Administrator determines that such sources do not contribute significantly

[1] 81 FR 58010, August 24, 2016.

[2] 706 F.3d 428 (D.C. Cir. 2013).

[3] This requirement was codified in 40 CFR 51.165(a)(13). See 81 FR 58010, August 24, 2016.

to PM_{10} levels which exceed the standard in the area.'' The 2016 Implementation Rule amended the definitions of (1) Regulated NSR Pollutant with regards to $PM_{2.5}$ precursors; (2) Major Stationary Source with regards to major sources locating in $PM_{2.5}$ nonattainment areas classified as Moderate and Serious; and (3) Significant with regards to emissions of $PM_{2.5}$ precursors. Rule 1325 is subject to these new regulatory requirements.

The SCAQMD is classified as a Moderate nonattainment area for the 2012 $PM_{2.5}$ NAAQS. On January 13, 2016,[4] the SCAQMD was reclassified from a Moderate to a Serious $PM_{2.5}$ nonattainment area for the 2006 $PM_{2.5}$ NAAQS. The major source permitting threshold for a Moderate $PM_{2.5}$ nonattainment area is 100 tons per year (tpy) of direct $PM_{2.5}$ or any $PM_{2.5}$ precursor, and 70 tpy for a Serious $PM_{2.5}$ nonattainment area.

In addition, EPA has reviewed the submitted rule for compliance with: (1) The requirements for SIPs as set forth in CAA section 110(a)(2); (2) the requirements related to SIP revisions in CAA sections 110(l) and 193; (3) the requirements for stationary source preconstruction permitting programs in CAA section 173(a) through (c); and (4) the requirements related to the review and modification of major sources in 40 CFR part 51.165 that pertain to a $PM_{2.5}$ nonattainment area classified as Serious.

B. Does the rule meet the evaluation criteria?

In our previous May 1, 2015 [5] action we evaluated Rule 1325 in accordance with the CAA and regulatory requirements listed in Section II.A of this preamble. In that action, we determined Rule 1325 satisfied the applicable requirements for a $PM_{2.5}$ NNSR permit program. Below we discuss and evaluate the revised portions of submitted Rule 1325 to determine if the revisions meet current applicable requirements for a $PM_{2.5}$ NNSR permit program.

Section (a)—Applicability, contains minor revisions to clarify that the rule applies to major polluting facilities that will emit $PM_{2.5}$ or its precursors in areas federally-designated as nonattainment for $PM_{2.5}$. EPA finds these clarifying revisions approvable.

Section (b)—Definitions, has been revised to update: (1) The effective date of the referenced 40 CFR 51.165(a)(1) definitions; (2) the definition of Major Polluting Facility to include a 70 tpy emissions threshold, effective upon the date of the EPA's approval of the November 4, 2016 amendments to Rule 1325; (3) the definition of Precursors to include volatile organic compounds (VOC) and ammonia, effective upon the date of the EPA's approval of the November 4, 2016 amendments to Rule 1325; and (4) the definition of ''Significant'' to include VOC and ammonia and specify a 40 tpy threshold. EPA finds these revisions approvable, as they are consistent with current applicable requirements for a serious $PM_{2.5}$ nonattainment area.

The definition of Regulated NSR Pollutant was not revised to include VOC and ammonia as $PM_{2.5}$ precursors. Because the definition for the term Major Modification relies on the definition of Regulated NSR Pollutant, Rule 1325 does not satisfy the requirement to include VOC and ammonia as $PM_{2.5}$ precursors when evaluating if a project will result in a major modification, and it is therefore deficient.

Section (f)—Two Year Limit on Facility Exemption has been revised to lower the emissions threshold for this exemption provision from 100 tpy to 70 tpy, effective upon the date of the EPA's approval of the November 4, 2016 amendments to Rule 1325. The provision requires a source to aggregate its $PM_{2.5}$ emissions from any permit actions that occur within a two-year period to determine if emissions exceed 70 tpy; if so, offsets are required for the aggregated emission increase. This provision requiring $PM_{2.5}$ emissions to be aggregated is more stringent that CAA requirements. Therefore, EPA finds this more stringent provision acceptable.

Section (j)—Offset Exemptions for Regulatory Compliance has been added.

This provision allows the Executive Officer to exempt new or modified sources installed solely to comply with District, state or federal air pollution control regulations from the otherwise applicable offset requirements. EPA finds this new provision approvable.

In addition, other minor editorial or conforming edits have been made throughout the rule. EPA finds these revisions approvable.

With respect to procedural requirements, CAA sections 110(a)(2) and 110(l) require that revisions to a SIP be adopted by the state after reasonable notice and public hearing. EPA has promulgated specific procedural requirements for SIP revisions in 40 CFR part 51, subpart V. These requirements include publication of notices by prominent advertisement in the relevant geographic area, a public hearing or notice of an opportunity for a public hearing on the proposed revisions, and a public comment period of at least 30 days.

Based on our review of the public process documentation included in the May 5, 2017 submittal, we find that SCAQMD has provided sufficient evidence of public notice and opportunity for comment and a public hearing prior to adoption and submittal of these rules to EPA.

Section 193 of the Act, which was added by the Clean Air Act Amendments of 1990, includes a clause providing in pertinent part: ''No control requirement in effect, or required to be adopted by an order, settlement agreement, or plan in effect before November 15, 1990, in any area which is a nonattainment area for any air pollutant may be modified after November 15, 1990, in any manner unless the modification insures equivalent or greater emission reductions of such air pollutant.'' Since $PM_{2.5}$ is a NAAQS adopted after 1990, there are no existing $PM_{2.5}$ control requirements that would be subject to the provisions of Section 193 of the CAA. Therefore, for the purposes of our analysis of Rule 1325, we find that Section 193 of the CAA does not apply to this action.

III. Proposed Action and Public Comment

Because the revisions to Rule 1325 do not ensure VOC and ammonia emissions are evaluated to determine if a proposed project will result in a major modification, EPA cannot grant full approval of this rule under section 110(k)(3) of the Act. However, in a letter dated June 26, 2018, the District committed to adopt and submit specific enforceable measures to address this deficiency. The District committed to submit these revisions to CARB within 11 months of the date of EPA's final action. In addition, in a letter dated July 16, 2018, CARB committed to submit the adopted rule revisions to EPA no later than 12 months from the date of EPA's final action. Accordingly, pursuant to section 110(k)(4) of the Act, EPA is proposing a conditional approval of the submitted rule. We are proposing to conditionally approve the submitted rule based on our determination that separate from the deficiency listed above, the rule satisfies the applicable requirements discussed in Section II.A of this action.

In support of this proposed action, we have concluded that our conditional approval of the submitted rule would comply with section 110(l) of the Act because the amended rule, as a whole,

[4] 81 FR 1514, January 13, 2016.

[5] 80 FR 24821.

would not interfere with continued attainment of the NAAQS in the South Coast Air Basin. The intended effect of our proposed conditional approval action is to update the applicable SIP with current SCAQMD rules and provide SCAQMD the opportunity to correct the identified deficiencies, as discussed in their commitment letter dated June 26, 2018. If we finalize this action as proposed, our action would incorporate this rule into the federally enforceable SIP and be codified through revisions to 40 CFR 52.220 (Identification of plan) and 40 CFR 52.119 (Part D conditional approval).

If the State meets its commitment to submit the required measures within 12 months of the date of EPA's final action, Rule 1325 will remain a part of the SIP until EPA takes final action approving or disapproving any subsequently submitted SIP revision. However, if the District fails to submit a revision within the required timeframe, the conditional approval will automatically become a disapproval, and EPA will issue a finding of disapproval. EPA is not required to propose the finding of disapproval.

We will accept comments from the public on this proposal until September 7, 2018. If we take final action to approve the submitted rule, our final action will incorporate this rule into the federally enforceable SIP.

IV. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule, regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the SCAQMD rule listed in Table 1 of this preamble. The EPA has made, and will continue to make, these materials available electronically through *www.regulations.gov* and in hard copy at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

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

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

List of Subjects in 40 CFR Part 52

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

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

Dated: July 24, 2018.

Michael Stoker,

Regional Administrator, Region IX.

[FR Doc. 2018–16877 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2018–0507; FRL–9981–77—Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; NO_X Ozone Season Emissions Caps for Non-Trading Large NO_X Units and Associated Revisions to General Administrative Provisions and Kraft Pulp Mill Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a state implementation plan (SIP) revision submitted by the State of Maryland. This revision (Maryland SIP Revision #18–03) pertains to a new Maryland regulation that establishes ozone season nitrogen oxides (NO_X) emissions caps and other requirements for large non-electric generating units (non-EGU) in Maryland and includes associated revisions to two other Maryland regulations. The revisions will enable Maryland to meet NO_X reduction requirements related to interstate transport of pollution that contributes to other states' nonattainment or interferes with other states' maintenance of the ozone national ambient air quality standards (NAAQS). This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 7, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2018–0507 at *http://www.regulations.gov,* or via email to *spielberger.susan@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia

submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Marilyn Powers, (215) 814–2308, or by email at *powers.marilyn@epa.gov.*

SUPPLEMENTARY INFORMATION: On May 15, 2018, the State of Maryland, through the Maryland Department of the Environment (MDE), submitted for approval into the Maryland SIP new Code of Maryland Regulation (COMAR) 26.11.40—NO_X Ozone Season Emission Caps for Non-Trading Large NO_X Units and revisions to two regulations presently included in the Maryland SIP, COMAR 26.11.01.01—*General Administrative Provisions* and COMAR 26.11.14—*Control of Emissions from Kraft Pulp Mills* to EPA.

I. Background

In October 1998 (63 FR 57356), EPA finalized the ''Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone''—commonly called the NO_X SIP Call. The NO_X SIP Call, issued pursuant to Section 110 of the CAA, was designed to mitigate significant transport of NO_X, one of the precursors of ozone. EPA developed the NO_X Budget Trading Program, an allowance trading program that states could adopt to meet their obligations under the NO_X SIP Call. The NO_X Budget Trading Program allowed electric generating units (EGUs) greater than 25 megawatts and industrial non-electric generating units, such as boilers and turbines, with a rated heat input greater than 250 million British thermal units per hour (MMBtu/hr), referred to as ''large non-EGUs'', to participate in a regional NO_X cap and trade program. The NO_X SIP Call also established specific reduction requirements for other non-EGUs, including cement kilns and stationary internal combustion (IC) engines. On January 10, 2001 (66 FR 1866), EPA approved two Maryland regulations, COMAR 26.11.29—*NO_X Reduction and Trading Program,* and COMAR 26.11.30—*Policies and Procedures Relating to Maryland's NO_X Reduction and Trading Program,* into the Maryland SIP as meeting the requirements of the NO_X SIP Call. Under the approved trading program, large EGUs and large non-EGUs in Maryland participated in a regional cap and trade program that was administered by EPA.

On May 12, 2005, (70 FR 25162), EPA promulgated the Clean Air Interstate Rule (CAIR) to address transported emissions that significantly contributed to downwind states' nonattainment and maintenance of the 1997 ozone and fine particulate matter ($PM_{2.5}$) NAAQS. CAIR required 28 states, including Maryland, to reduce emissions of NO_X and sulfur dioxide (SO_2), which are precursors to ozone and $PM_{2.5}$. Under CAIR, EPA developed separate cap and trade programs for annual NO_X, ozone season NO_X, and annual SO_2 emissions. On April 28, 2006 (71 FR 25328), EPA also promulgated federal implementation plans (FIPs) requiring the EGUs in each affected state, but not large non-EGUs, to participate in the CAIR trading programs. States could comply with the requirements of CAIR by either remaining on the FIP, which applied only to EGUs, or by submitting a CAIR SIP revision that included as trading sources EGUs and the non-EGUs that formerly traded in the NO_X Budget Trading Program under the NO_X SIP Call. EPA discontinued administration of the NO_X Budget Trading Program in 2009 upon the start of the CAIR trading programs.[1] The NO_X SIP Call requirements continued to apply, however, and EGUs that were formerly trading under the NO_X Budget Trading Program continued to meet their NO_X SIP Call requirements under the generally more stringent requirements of the CAIR ozone season trading program. States needed to assess their NO_X SIP Call requirements and take other regulatory action as necessary to ensure that their obligations for the large non-EGUs continued to be met either through submission of a CAIR SIP or other NO_X regulation. EPA has implementing regulations for the NO_X SIP Call at 40 CFR 51.121.

In Maryland, Luke Paper Mill (formerly the Westvaco pulp and paper mill) was the only facility with non-EGUs that were affected by the NO_X SIP Call and which participated in the NO_X Budget Trading Program. When the CAIR NO_X Ozone Season trading program replaced the NO_X Budget Trading Program, Maryland adopted the CAIR program as it applied to large EGUs, but chose not to include the non-EGUs at Luke as participants in the CAIR NO_X Ozone Season trading program.[2] Instead, in 2010, Maryland adopted COMAR 26.11.14.07–*Control of Emissions from Kraft Pulp Mills,* which, among other requirements, included provisions that address the NO_X SIP Call non-EGU requirements in Maryland through a NO_X ozone season tonnage cap of 947 tons for the Luke non-EGUs and monitoring, recordkeeping, and reporting in accordance with 40 CFR part 75. EPA conditionally approved COMAR 26.11.14.07 into the Maryland SIP on August 30, 2016 (81 FR 59486) and took final approval on July 17, 2017 (82 FR 32641).

Subsequent to adoption of COMAR 26.11.14.07, MDE determined that additional applicable units have either started operation or were previously not subject but have become subject to the requirements for non-EGUs under the NO_X SIP Call as the units are greater than 250 MMBtu/hr. A review of the applicability of the NO_X SIP Call to large non-EGUs in the State showed that there are three additional facilities having non-EGUs that are covered under the NO_X SIP Call. MDE adopted new regulation COMAR 26.11.40 to reallocate the NO_X emissions cap among the affected sources, and concurrently revised COMAR 26.11.14.07 to reflect a reduced cap for Luke. The NO_X annual emissions cap for Maryland established for the NO_X SIP Call is 1,013 tons per year of NO_X, as established by EPA in 40 CFR part 97, subpart E, Appendix C.

II. Summary of SIP Revision and EPA Analysis

On May 15, 2018, Maryland, through MDE, submitted for inclusion in the Maryland SIP new regulation COMAR 26.11.40—NO_X *Ozone Season Emission Caps for Non-trading Large NO_X Units*,

[1] CAIR was subsequently vacated and remanded. *See North Carolina* v. *EPA*, 531 F.3d 896 (D.C. Cir. 2008), modified by 550 F.3d 1176 (remanding CAIR). CAIR was replaced with the Cross-State Air Pollution Rule, or CSAPR (76 FR 48208, August 8, 2011), which, after legal challenges, was implemented starting in January 2015. The NO_X Ozone Season Trading Program under CSAPR was replaced in Maryland and most other states by a new trading program for ozone season NO_X under the CSAPR Update rule in January 2017 (81 FR 74504, October 26, 2016).

[2] CAIR became obsolete upon implementation of the CSAPR program. Maryland subsequently took action rescinding its CAIR regulation (COMAR 26.11.28), and submitted a SIP revision to EPA which sought removal of the regulation in its entirety from the approved Maryland SIP. On July 17, 2017 (82 FR 32641), EPA approved the SIP revision removing the CAIR regulation from Maryland's SIP.

and associated revisions to COMAR 26.11.01.01—*General Administrative Provisions,* and COMAR 26.11.14—*Control of Emissions from Kraft Pulp Mills.*

New COMAR 26.11.40 establishes NO_X ozone season tonnage caps and NO_X monitoring requirements for large non-EGUs in the State that are not covered under the Cross-State Air Pollution Rule (CSAPR) to meet requirements of the NO_X SIP Call. Regulation .01 under COMAR 26.11.40 defines the terms used in COMAR 26.11.40, including ''boiler'', ''combined cycle system'', ''combustion turbine'', ''fossil-fuel'', ''fossil fuel-fired'', ''new unit'', ''new unit set-aside'', ''non-trading large NO_X unit'', and ''ozone season''. The definition of non-trading large NO_X unit in Regulation .01 lists two categories of sources: (1) Non-EGUs with a maximum design heat input greater than 250 MMBtu/hr, and (2) fossil fuel-fired EGUs serving a generator with a nameplate capacity greater than 25 megawatt output. Maryland explains its intent that these definitions apply to non-EGUs and EGUs as defined for purposes of the NO_X SIP Call as amended.[3] In addition to the definitions of non-trading large NO_X unit, Maryland clarifies its intent by specifically listing in Regulation .02 all units in the State that currently meet the definitions. Regulation .01 also clarifies that non-EGUs subject to this rule are units that are not already subject to the CSAPR NO_X Ozone Season Group 2 Trading Program under 40 CFR part 97, subpart EEEEE.

Regulation .02 under COMAR 26.11.40 lists the currently affected non-EGUs meeting the definition of ''non-trading large NO_X unit'' (shown in the following table), and includes a provision that any new unit installed after May 1, 2018 or an existing unit that is modified such that it meets the definition of a large non-EGU will become subject to the requirements of COMAR 26.11.40. Regulation .03 under COMAR 26.11.40 establishes the NO_X annual tonnage caps for each source. The affected units and their NO_X ozone season caps are as follows:

Facility	Unit	NO_X ozone season cap (tons)
American Sugar Refining	C6	24
Dominion Energy Cove Point LNG	Frame 5–1 (Turbine S009), Frame 5–2 (Turbine S010), Frame 7–A, Frame 7–B, Aux. A, Aux B.	214
Luke Paper Mill	24, 25, and 26	656
National Institutes of Health	5–1156	23
New unit set-aside		96
Total		1,013

Regulation .03 also establishes a 96 ton set aside for new units or modified existing units. The total, 1,013 tons of NO_X, is consistent with the portion of the overall Maryland NO_X Budget Trading Program budget for large non-EGUs.[4] Regulation .03 stipulates that the combined NO_X ozone season emissions from units subject to COMAR 26.11.40 may not exceed 1,013 tons. Regulation .04 requires continuous emissions monitoring (CEM) of NO_X emissions at affected units in accordance with 40 CFR part 75, subpart H, as required by 40 CFR 51.121(i)(4),[5] maintenance of records and submittal of reports in accordance with 40 CFR part 75, and submittal of CEMs data to the State on a quarterly basis.

To meet NO_X SIP Call requirements and conform to COMAR 26.11.40, Maryland revised regulation .07A of COMAR 26.11.14 *Control of emissions from Kraft Pulp Mills* to remove the 947 ton ozone season NO_X cap that originally applied to the Luke Mill. A new provision in COMAR 26.11.14 establishes Luke's lower NO_X cap via a cross reference to Luke's 636 ton per year cap in COMAR 26.11.40.03. Regulation .07B removes the requirements for an owner or operator of a kraft pulp mill that exceeds the emission limit(s) specified in COMAR 26.11.14 to acquire one ozone season NO_X allowance for every ton of NO_X emissions over the limits to demonstrate compliance, and requires compliance instead to be demonstrated with the 636 ton per year cap via a CEMs meeting 40 CFR part 75. Maryland removed the provision for paper mills such as Luke Mill to acquire additional NO_X allowances in order for the sources in the State to remain under Maryland's total NO_X ozone season cap for the NO_X SIP Call.

Correspondingly, Maryland also revised a provision of COMAR 26.11.01—*General Administrative Provisions* to remove the definition for ''NO_X ozone season allowance'' which is no longer necessary because the revisions to COMAR 26.11.14 remove the requirement for fuel burning equipment at Luke to purchase NO_X ozone season allowances for any exceedance over its specified limits.

EPA finds that this May 2018 SIP submittal meets Maryland's NO_X SIP Call requirements (including requirements in CAA section 110 and 40 CFR 51.121) for non-EGUs through: (1) New regulation COMAR 24.11.40 which updates the State's requirements to include all currently applicable large non-EGUs and any new non-EGUs under the NO_X SIP Call; (2) the specified state-wide ozone season NO_X emissions cap of 1013 tons which is consistent with the portion of the overall Maryland NO_X emissions budget under the NO_X Budget Trading Program attributable to non-EGUs, and (3) through the 40 CFR part 75 monitoring, recordkeeping and reporting requirements which apply for the affected non-EGUs. In addition, the

[3] The definitions for non-EGUs and EGUs are set forth in the preamble to the April 2004 NO_X SIP Call amendments. *See* 69 FR 21604 and 21616, April 21, 2004.

[4] Maryland's NO_X Budget Trading Program regulations included an overall budget of 15,466 tons for EGUs and non-EGUs. *See, e.g.,* The NO_X Budget Trading Program: 2008 Highlights (October 2009) at 10, available at *https://www.epa.gov/airmarkets/nox-budget-trading-program-historical-reports.* While most of the overall budget was allocated directly to EGUs and non-EGUs (those shares were 13,793 tons and 947 tons, respectively), a 726-ton portion was not assigned to either sector, but instead was placed in set-asides. To identify the portion of the overall 15,466-ton budget attributable to non-EGUs that would be an appropriate cap for its replacement non-EGU rule, Maryland has therefore used the 1,013-ton non-EGU portion of the overall budget of 15,532 tons established for Maryland's EGUs and non-EGUs under a different federal rule promulgated contemporaneously with the NO_X SIP Call pursuant to CAA section 126. *See* 40 CFR part 97, subpart E, appendix C. In the absence of an express division of the State's overall NO_X Budget Trading Program budget between EGUs and non-EGUs, EPA believes the State's approach to identifying an appropriate cap for its replacement non-EGU rule is reasonable.

[5] EPA's regulations implementing the NO_X SIP Call are in 40 CFR 51.121.

revisions remove the ability of kraft pulp mills that exceed their NO_X limits and caps to comply by purchasing or otherwise acquiring NO_X allowances from EPA's ozone season NO_X trading program by removing these provisions in COMAR 26.11.14 and 26.11.01. The removal of the provisions allowing purchase of additional allowances removes the potential for increased local NO_X emissions.

The May 15, 2018 Maryland SIP submittal does not result in increased NO_X emissions, and therefore has no impact on any requirements related to attainment, reasonable further progress, or any other NAAQS requirements under the CAA. The submittal therefore meets section 110(l) of the CAA.

III. Proposed Action

EPA's review of this material indicates that Maryland's May 18, 2018 SIP revision submittal (Maryland SIP Revision #18–03) is approvable in accordance with CAA section 110. For the reasons noted previously, EPA is proposing to approve the Maryland SIP revision submitted on May 15, 2018. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

IV. Incorporation by Reference

In this proposed action, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference new Maryland regulation COMAR 26.11.40 and associated revisions to COMAR 26.11.01 and COMAR 26.11.14.07. EPA has made, and will continue to make, these materials generally available through *http://www.regulations.gov* and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

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

In addition, this action proposing approval of Maryland regulation COMAR 26.11.40 and associated revisions to other COMAR regulations does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: July 24, 2018.

Cecil Rodrigues,

Acting Regional Administrator, Region III.

[FR Doc. 2018–16778 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2016–0711; FRL–9981–91—Region 9]

Approval of California Air Plan Revision, South Coast Air Quality Management District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the South Coast Air Quality Management District (SCAQMD) portion of the California State Implementation Plan (SIP). This revision concerns emissions of volatile organic compounds (VOCs) from architectural coatings. We are proposing to approve a local rule to regulate emissions from architectural coatings under the Clean Air Act (CAA or the Act). We are taking comments on this proposal and plan to follow with a final action.

DATES: Any comments must arrive by September 7, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2016–0711 at *http://www.regulations.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia

submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Arnold Lazarus, EPA Region IX, (415) 972 3024, *Lazarus.Arnold@epa.gov.*

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

Table of Contents

I. The State's Submittal

A. What rule did the State submit?

Table 1 lists the rule addressed by this action with the date that it was adopted by the local air agency and submitted by the California Air Resources Board (CARB). On February 22, 2018, CARB requested the withdrawal from its earlier SIP submittal of one sentence from two definitions (''Bond Breakers'' and ''Form Release Compounds''), which exempted these materials from the rule, due to the adoption of a rule regulating these materials. Accordingly, our proposed approval of this rule does not include the two withdrawn sentences.

TABLE 1—SUBMITTED RULE

Local agency	Rule No.	Rule title	Amended	Submitted
SCAQMD	1113	Architectural Coatings	2/5/2016	8/22/2016

On September 27, 2016, the EPA determined that the submittal for SCAQMD Rule 1113 met the completeness criteria in 40 CFR part 51 Appendix V, which must be met before formal EPA review.

B. Are there other versions of this rule?

We approved an earlier version of SCAQMD Rule 1113 into the SIP on March 26, 2013 (78 FR 18244).

C. What is the purpose of the submitted rule revision?

VOCs contribute to the production of ground-level ozone, smog, and particulate matter, which harm human health and the environment. Section 110(a) of the CAA requires states to submit regulations that control VOC emissions. Architectural coatings are applied to stationary structures and their accessories. They include house paints, stains, industrial maintenance coatings, traffic coatings, and many other products. VOCs are emitted from the coatings during application and curing, and from the associated solvents used for thinning and clean-up. SCAQMD Rule 1113 controls VOC emissions by establishing VOC limits on architectural coatings. SCAQMD Rule 1113 was revised to increase stringency and reduce VOC emissions by updating VOC content limits, and restricting the small container exemption (less than 1 quart) for high-VOC coatings.

The EPA's technical support document (TSD) has more information about this rule.

II. The EPA's Evaluation and Action

A. How is the EPA evaluating the rule?

SIP rules must be enforceable (see CAA section 110(a)(2)), must not interfere with applicable requirements concerning attainment and reasonable further progress or other CAA requirements (see CAA section 110(l)), and must not modify certain SIP control requirements in nonattainment areas without ensuring equivalent or greater emissions reductions (see CAA section 193).

Generally, SIP rules must require Reasonably Available Control Technology (RACT) for each category of sources covered by a Control Techniques Guidelines (CTG) document as well as each major source of VOCs in ozone nonattainment areas classified as Moderate or above (see CAA section 182(b)(2)). The SCAQMD has been designated as Extreme nonattainment for the 2008 8-hour ozone NAAQS (40 CFR 81.305). As addressed further in the EPA's TSD for this rule, there are no relevant EPA CTG documents and architectural coatings are considered area sources. Therefore, architectural coating sources are not subject to RACT requirements.

Guidance and policy documents that we use to evaluate enforceability, revision/relaxation, and rule stringency include the following:

1. ''State Implementation Plans; General Preamble for the Implementation of Title I of the Clean Air Act Amendments of 1990,'' (57 FR 13498, April 16, 1992 and 57 FR 18070, April 28, 1992).

2. ''Issues Relating to VOC Regulation Cutpoints, Deficiencies, and Deviations'' (''the Bluebook,'' U.S. EPA, May 25, 1988; revised January 11, 1990).

3. ''Guidance Document for Correcting Common VOC & Other Rule Deficiencies'' (''the Little Bluebook'', EPA Region 9, August 21, 2001).

4. National Volatile Organic Compound Emission Standards for Architectural Coatings, 40 CFR 59.400, Subpart D, Table 1, VOC Content Limits for Architectural Coatings.

B. Does the rule meet the evaluation criteria?

We believe this rule is consistent with CAA requirements and relevant guidance regarding enforceability, stringency, and SIP revisions. The TSD has more information on our evaluation.

C. Public Comment and Proposed Action

As authorized in section 110(k)(3) of the Act, the EPA proposes to fully approve the submitted rule because we believe it fulfills all relevant requirements. We will accept comments from the public on this proposal until September 7, 2018. If we take final action to approve the submitted rule, our final action will incorporate this rule into the federally enforceable SIP.

III. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule, regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the SCAQMD rule described in Table 1 of this preamble. The EPA has made, and will continue to make, these materials available through *www.regulations.gov* and at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

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- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: July 24, 2018.

Michael Stoker,

Regional Administrator, Region IX.

[FR Doc. 2018–16795 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2018–0215; FRL–9981–75—Region 3]

Air Plan Approval; District of Columbia, Maryland, and Virginia; Maryland and Virginia Redesignation Requests and District of Columbia, Maryland, and Virginia Maintenance Plan for the Washington, DC-MD-VA 2008 Ozone Standard Nonattainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the requests from the State of Maryland (Maryland) and the Commonwealth of Virginia (Virginia) to redesignate to attainment their respective portions of the Washington, DC-MD-VA nonattainment area (hereafter ''the Washington Area'' or ''the Area'') for the 2008 8-hour ozone national ambient air quality standard (NAAQS or standard) (also referred to as the 2008 ozone NAAQS). EPA is not proposing to approve the redesignation request for the District of Columbia (the District) for its portion of the Area; EPA will address the District's redesignation request for its portion of the Area in a separate rulemaking action. EPA is also proposing to approve, as a revision to the District's, Maryland's, and Virginia's state implementation plans (SIPs), the joint maintenance plan submitted by the District, Maryland, and Virginia. The joint maintenance plan demonstrates maintenance of the 2008 ozone NAAQS through 2030 in the Washington Area. Approval of a maintenance plan is among the CAA criteria for redesignation to attainment, as discussed in more detail in this notice. The Washington Area maintenance plan includes motor vehicle emissions budgets (MVEBs) for the 2008 ozone NAAQS for nitrogen oxides (NO_X) and volatile organic compounds (VOCs), which are precursors to ozone. EPA has found the MVEBs adequate and is proposing to approve, as a SIP revision, these 2014, 2025, and 2030 NO_X and VOC MVEBs for the Washington Area.

DATES: Written comments must be received on or before September 7, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2018–0215 at *https://www.regulations.gov,* or via email to *spielberger.susan@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Sara Calcinore, (215) 814–2043, or by email at *calcinore.sara@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. What are the actions EPA is proposing?

On March 12, 2018, January 29, 2018, and January 3, 2018, the District, Maryland, and Virginia, respectively, formally submitted a request to redesignate their portions of the Washington Area from marginal nonattainment to attainment for the 2008 ozone NAAQS. Concurrently, the District, Maryland, and Virginia formally submitted, as a revision to their respective SIPs, a joint maintenance plan for the Washington Area to ensure continued attainment for at least 10 years following redesignation. The maintenance plan includes MVEBs for NO_X and VOC for the years 2014, 2025, and 2030. Pursuant to CAA section 107(d)(3), in this rulemaking action, EPA is proposing to approve the redesignation requests submitted by Maryland and Virginia for their portions of the Washington Area. EPA is not proposing to approve (at this time) the redesignation request from the District and will act on the District's redesignation request for its portion of the Area in a separate action. EPA is also proposing to approve, as revisions to the District's, Maryland's, and Virginia's SIPs, the joint maintenance plan submitted by the District, Maryland, and Virginia.

EPA is proposing to take several related actions. EPA is proposing to determine that Maryland and Virginia have met the requirements for redesignation for their respective portions of the Washington Area pursuant to section 107(d)(3)(E) of the CAA. EPA is therefore proposing to approve Maryland's and Virginia's redesignation requests and change the designation of their respective portions of the Washington Area from marginal nonattainment to attainment for the 2008 ozone NAAQS. EPA is also proposing to approve, as revisions to the District's, Maryland's, and Virginia's SIPs, the joint Washington Area maintenance plan that was prepared by the Metropolitan Washington Council of Governments (MWCOG) and jointly submitted by the District, Maryland, and Virginia. The maintenance plan is designed to ensure continued attainment in the Washington Area for the next ten years. Additionally, EPA has found the submitted MVEBs adequate and is proposing to approve, as revisions to the District's, Maryland's, and Virginia's SIPs, the 2014, 2025, and 2030 MVEBs for NO_X and VOC for the Washington Area that are identified in the Washington Area maintenance plan. The adequacy comment period for the MVEBs began on May 21, 2018, with EPA's posting of the availability of the District's, Maryland's, and Virginia's maintenance plan submittal on EPA's Adequacy website (at *https://www.epa.gov/state-and-local-transportation*). The adequacy comment period for these MVEBs ended on June 20, 2018. EPA did not receive any adverse comments on this submittal during the adequacy comment period. In letters dated July 24, 2018, EPA informed the District, Maryland, and Virginia that the 2014, 2025, and 2030 MVEBs are adequate for use in transportation conformity analyses.[1] Please see section V.B., ''What Is the Status of EPA's Adequacy Determination for the Proposed NO_X and VOC MVEBs for the Washington Area?'', of this rulemaking for further explanation of this process.

II. What is the background for these proposed actions?

Under the CAA, EPA establishes NAAQS for criteria pollutants in order to protect human health and the environment. In response to scientific evidence linking ozone exposure to adverse health effects, EPA promulgated the first ozone NAAQS, the 0.12 part per million (ppm) 1-hour ozone NAAQS, in 1979. *See* 44 FR 8202 (February 8, 1979). The CAA requires EPA to review and reevaluate the NAAQS every 5 years in order to consider updated information regarding the effects of the criteria pollutants on human health and the environment. On July 18, 1997, EPA promulgated a revised ozone NAAQS, referred to as the 1997 ozone NAAQS, of 0.08 ppm averaged over eight hours. 62 FR 38855. This 8-hour ozone NAAQS was determined to be more protective of public health than the previous 1979 1-hour ozone NAAQS. In 2008, EPA strengthened the 8-hour ozone NAAQS from 0.08 to 0.075 ppm. The 0.075 ppm standard is referred to as the 2008 ozone NAAQS. *See* 73 FR 16436 (March 27, 2008).

Upon promulgation of a new or revised NAAQS, section 107(d)(1)(B) of the CAA requires EPA to designate as nonattainment any areas that are violating the NAAQS based on the most recent three years of quality-assured ozone monitoring data. On May 21, 2012 and June 11, 2012, EPA designated nonattainment areas for the 2008 ozone NAAQS. 77 FR 30088 and 77 FR 34221. Effective July 20, 2012, the Washington Area was designated as marginal nonattainment for the 2008 ozone NAAQS. The Washington Area consists of the Counties of Calvert, Charles, Frederick, Montgomery, and Prince George's in Maryland, the Counties of Arlington, Fairfax, Loudoun, and Prince William and the Cities of Alexandria, Fairfax, Falls Church, Manassas, and Manassas Park Cities in Virginia, and the District of Columbia. *See* 40 CFR 81.309, 81.321, and 81.347.

As stated previously, on March 12, 2018, January 29, 2018, and January 3, 2018, the District, Maryland, and Virginia, respectively, formally submitted requests to redesignate their respective portions of the Washington Area from marginal nonattainment to attainment for the 2008 ozone NAAQS. The District, Maryland, and Virginia concurrently submitted, as revisions to their SIPs, a maintenance plan for the Washington Area to ensure continued attainment for at least 10 years following redesignation. In this rulemaking action, EPA is proposing to approve the redesignation requests submitted by Maryland and Virginia for their respective portions of the Area. EPA is not proposing to approve the redesignation request for the District for its portion and will act on the redesignation request for the District in a separate action. EPA is also proposing to approve, as revisions to the District's, Maryland's, and Virginia's SIPs, the maintenance plan jointly submitted by the District, Maryland, and Virginia.

[1] EPA originally informed the District, Maryland, and Virginia that the 2014, 2025, and 2030 MVEBs were adequate for use in transportation conformity analyses in letters dated July 18, 2018. EPA revised language in these letters and sent the revised letters to the District, Maryland, and Virginia on July 24, 2018. The original and revised letters are available online at *https://www.regulations.gov,* Docket ID: EPA–R03–OAR–2018–0215.

III. What are the criteria for redesignation?

Section 107(d)(3)(E) of the CAA allows redesignation of an area to attainment of the NAAQS provided that: (1) The Administrator (EPA) determines that the area has attained the applicable NAAQS; (2) the Administrator has fully approved the applicable implementation plan for the area under section 110(k) of the CAA; (3) the Administrator determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable SIP, applicable federal air pollutant control regulations, and other permanent and enforceable emission reductions; (4) the Administrator has fully approved a maintenance plan for the area as meeting the requirements of section 175A of the CAA; and (5) the State containing the area has met all requirements applicable to the area for purposes of redesignation under section 110 and part D of the CAA.

On April 16, 1992, EPA provided guidance on redesignations in the General Preamble for the Implementation of Title I of the CAA Amendments of 1990 (57 FR 13498) and supplemented this guidance on April 28, 1992 (57 FR 18070). EPA has provided further guidance on processing redesignation requests in the following documents:

1. ''Ozone and Carbon Monoxide Design Value Calculations,'' Memorandum from Bill Laxton, Director, Technical Support Division, June 18, 1990;
2. ''Maintenance Plans for Redesignation of Ozone and Carbon Monoxide Nonattainment Areas,'' Memorandum from G.T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, April 30, 1992;
3. ''Contingency Measures for Ozone and Carbon Monoxide (CO) Redesignations,'' Memorandum from G.T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, June 1, 1992;
4. ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (the ''Calcagni memorandum'');
5. ''State Implementation Plan (SIP) Actions Submitted in Response to Clean Air Act (CAA) Deadlines,'' Memorandum from John Calcagni, Director, Air Quality Management Division, October 28, 1992;
6. ''Technical Support Documents (TSDs) for Redesignation of Ozone and Carbon Monoxide (CO) Nonattainment Areas,'' Memorandum from G.T. Helms, Chief, Ozone/Carbon Monoxide Programs Branch, August 17, 1993;
7. ''State Implementation Plan (SIP) requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) National Ambient Air Quality Standards (NAAQS) On or After November 15, 1992,'' Memorandum from Michael H. Shapiro, Acting Assistant Administrator for Air and Radiation, September 17, 1993 (the ''Shapiro memorandum'');
8. ''Use of Actual Emissions in Maintenance Demonstrations for Ozone and CO Nonattainment Areas,'' Memorandum from D. Kent Berry, Acting Director, Air Quality Management Division, November 30, 1993;
9. ''Part D New Source Review (part D NSR) Requirements for Areas Requesting Redesignation to Attainment,'' Memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation, October 14, 1994; and
10. ''Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard,'' Memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, May 10, 1995.

IV. What is EPA's analysis of Maryland's and Virginia's redesignation requests for the Washington Area?

A. Has the Washington Area attained the 2008 ozone NAAQS?

For redesignation of a nonattainment area to attainment, the CAA requires EPA to determine that the area has attained the applicable NAAQS. *See* CAA section 107(d)(3)(E)(i). An area is attaining the 2008 ozone NAAQS if it meets the 2008 ozone NAAQS, as determined in accordance with 40 CFR 50.15 and appendix P of part 50, based on three complete, consecutive calendar years of quality-assured air quality data for all monitoring sites in the area. To attain the NAAQS, the three-year average of the annual fourth-highest daily maximum 8-hour average ozone concentrations, referred to as ozone design values, at each monitor must not exceed 0.075 ppm.[2] The air quality data must be collected and quality-assured in accordance with 40 CFR part 58 and recorded in EPA's Air Quality System (AQS). Ambient air quality monitoring data for the 3-year period must also meet data completeness requirements. An ozone design value is valid if daily maximum 8-hour average concentrations are available for at least 90 percent of the days within the ozone monitoring season,[3] on average, for the three-year period, with a minimum data completeness of 75 percent during the ozone monitoring season of any year during the three-year period. *See* section 2.3 of appendix P to 40 CFR part 50.

As part of the final rule, ''Implementation of the 2008 National Ambient Air Quality Standards for Ozone: State Implementation Plan (SIP) Requirements,'' for the 2008 ozone NAAQS (80 FR 12264, March 6, 2015) (hereinafter, SIP Requirements Rule), EPA modified the maximum attainment dates for all nonattainment areas for the 2008 ozone NAAQS to be consistent with the United States Court of Appeals for the District of Columbia Circuit's (D.C. Circuit) decision in *NRDC* v. *EPA,* 777 F .3d 456, 464–69 (D.C. Cir. 2014).[4] The SIP Requirements Rule established a maximum deadline for marginal nonattainment areas to attain the 2008 ozone NAAQS of three years from the effective date of designation, or July 20, 2015. *See* 80 FR at 12268; 40 CFR 51.1103.[5]

[2] The rounding convention under 40 CFR part 50, appendix P dictates that concentrations shall be reported in ppm to the third decimal place, with additional digits to the right of the third decimal place truncated. Thus, a computed three-year average ozone concentration of 0.0759 ppm or lower would meet the standard, but 0.0760 ppm or higher would be over the standard.

[3] The ozone season is defined by state in 40 CFR 58 appendix D. For the 2013–2015 time period, the ozone season was April–October for the states in the Area. Beginning in 2016, the ozone season is March–October for the states in the Washington Area. *See* 80 FR 65292, 65466–67 (October 26, 2015).

[4] In a final rule published on May 21, 2012 and effective July 20, 2012, EPA established the air quality thresholds that define the classification assigned to all nonattainment areas for the 2008 ozone NAAQS (the Classifications Rule). *See* 77 FR 30160. This rulemaking also established December 31 of each relevant calendar year as the attainment date for all nonattainment area classification categories. Section 181 of the CAA provides that the attainment deadline for ozone nonattainment area is ''as expeditiously as practicable'' but no later than the prescribed dates that are provided in Table 1 of that section. In the Classifications Rule, EPA translated the deadlines in Table 1 of CAA section 181 for purposes of the 2008 standard by measuring those deadlines from the effective date of the new designations, but extended those deadlines by several months to December 31 of the corresponding calendar year. Pursuant to a challenge of EPA's interpretation of the attainment deadlines, on December 23, 2014, the D.C. Circuit issued a decision rejecting, among other things, the Classifications Rule's attainment deadlines for the 2008 ozone nonattainment areas, finding that EPA did not have statutory authority under the CAA to extend those deadlines to the end of the calendar year. *NRDC* v. *EPA,* 777 F .3d 456, 464–69 (D.C. Cir. 2014).

[5] On February 16, 2018, the United States Court of Appeals for the District of Columbia Circuit (D.C. Cir. Court) issued an opinion on the SIP Requirements Rule. *South Coast Air Quality Mgmt. Dist.* v. *EPA,* No. 15–1115 (D.C. Cir. Feb. 16, 2018). The D.C. Cir. Court found certain provisions from the SIP Requirements Rule unreasonable including EPA's provision for a ''redesignation substitute.'' The D.C. Cir. Court vacated these provisions and found redesignations must comply with all required elements in CAA section 107(d)(3) and thus found the ''redesignation substitute'' which did not require all items in CAA section 107(d)(3)(E) violated the CAA and was thus unreasonable. The

Continued

In a final rulemaking action published on May 4, 2016, EPA determined that the Washington Area did not attain the 2008 ozone NAAQS by its July 20, 2015 attainment date, based on ambient air quality monitoring data for the 2012–2014 monitoring period. In that same action, EPA determined that the Washington Area qualified for a 1-year extension of its attainment date, as provided in section 181(a)(5) of the CAA and interpreted by regulation at 40 CFR 51.1107. With that final rulemaking action, the new attainment date for the Washington Area was July 20, 2016. *See* 81 FR 26697 (May 4, 2016).

On November 14, 2017 (82 FR 52651), in accordance with section 181(b)(2)(A) of the CAA and Provisions for Implementation of the 2008 Ozone NAAQS (40 CFR part 51, subpart AA), EPA made a determination that the Washington Area attained the 2008 ozone NAAQS by the July 20, 2016 attainment date. EPA's determination was based upon three years of complete, certified, and quality-assured data for the 2013–2015 monitoring period.

In addition, EPA has reviewed the most recent ambient air quality monitoring data for ozone in the Area, including preliminary 2017 design values, as submitted by the District, Maryland, and Virginia and recorded in EPA's AQS. The quality-assured, quality-controlled, and state-certified 2014 to 2016 ozone air quality data shows that the Washington Area continues to attain the 2008 ozone NAAQS. This data, as well as the preliminary design values for 2017, are summarized in Table 1 and are also included in the docket for this rulemaking available online at *http://www.regulations.gov,* Docket ID: EPA–R03–OAR–2018–0215.

TABLE 1—WASHINGTON AREA 2014–2016 AND PRELIMINARY 2015–2017 OZONE DESIGN VALUES

AQS Site ID	Site description	Jurisdiction	Annual 4th highest reading (ppm)				2014–2016 design value (ppm)	2015–2017 design value (ppm) [6]
			2014	2015	2016	2017		
11–001–0041 [7]	420 34th Street NE, Washington, DC 20019	District of Columbia	.....	.....	0.065	0.056	0.056	0.060
11–001–0043	2500 1st Street NW, Washington, DC	District of Columbia	0.068	0.072	0.072	0.071	0.070	0.071
11–001–0050	300 Van Buren Street NW, Washington, DC 20012	District of Columbia	0.069	0.72	0.071	0.067	0.070	0.070
24–009–0011	350 Stafford Road	Maryland	0.070	0.067	0.070	0.066	0.069	0.067
24–017–0010	14320 Oaks Road	Maryland	0.070	0.068	0.073	0.068	0.070	0.069
24–021–0037	Frederick County Airport	Maryland	0.063	0.070	0.070	0.067	0.067	0.069
24–031–3001	Lathrop E. Smith Environmental Education Center	Maryland	0.064	0.072	0.068	0.065	0.068	0.068
24–033–0030	Howard University's Beltsville Laboratory	Maryland	0.065	0.072	0.070	0.069	0.069	0.070
24–033–8003	PG County Equestrian Center	Maryland	0.069	0.069	0.073	0.072	0.070	0.071
24–033–9991	Powder Mill Rd., Laurel, MD 20708	Maryland	0.069	0.067	0.070	0.070	0.068	0.069
51–013–0020	S 18th and Hayes St.	Virginia	0.071	0.073	0.072	0.070	0.072	0.071
51–059–0030	STA. 46–B9, Lee Park, Telegraph Road	Virginia	0.065	0.072	0.073	0.068	0.070	0.071
51–107–1005	38–I, Broad Run High School, Ashburn	Virginia	0.063	0.071	0.068	0.066	0.067	0.068
51–153–0009	James S. Long Park	Virginia	0.062	0.067	0.067	0.065	0.065	0.066

The Washington Area's most recent monitoring data supports EPA's previous determination that the Area has attained, and continues to attain, the 2008 ozone NAAQS. In addition, as discussed subsequently with respect to the maintenance plan for the Washington Area, Maryland and Virginia have committed to continue monitoring ambient ozone concentrations in accordance with 40 CFR part 58. Therefore, EPA is proposing to determine that the Washington Area continues to attain the 2008 8-hour ozone NAAQS, which is required by CAA section 107(d)(3)(E)(i) for redesignation of a nonattainment area to attainment.

B. Have Maryland and Virginia met all applicable requirements of section 110 and part D of the CAA for the Washington Area and does the Washington Area have a fully approved SIP under section 110(k) of the CAA?

EPA has determined that Maryland and Virginia have met all SIP requirements applicable for purposes of this redesignation of the Maryland and Virginia portions of the Washington Area under section 110 of the CAA (General SIP Requirements) and that they have met all applicable SIP requirements under part D of Title I of the CAA, in accordance with section 107(d)(3)(E)(v). In addition, EPA has determined that the Maryland and Virginia SIPs are fully approved with respect to all requirements applicable for purposes of redesignation in accordance with section 107(d)(3)(E)(ii). In making these determinations, EPA ascertained what requirements are applicable to the Area and determined that the portions of the Maryland and Virginia SIPs meeting these requirements are fully approved under section 110(k) of the CAA. We note that SIPs must be fully approved only with respect to applicable requirements.

The September 4, 1992 Calcagni memorandum (''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992) describes EPA's interpretation of section 107(d)(3)(E) with respect to the timing of applicable requirements. Under this interpretation, to qualify for redesignation, states requesting redesignation to attainment must meet only the relevant CAA requirements that come due prior to the submittal of a complete redesignation request. *See also* Shapiro memorandum, September 17, 1993, and 60 FR 12459, 12465–12466, (March 7, 1995)

D.C. Cir. Court also vacated other provisions relating to anti-backsliding in the SIP Requirements Rule as the Court found them unreasonable. *Id.* The D.C. Circuit found other parts of the 2008 Ozone SIP Requirements Rule unrelated to anti-backsliding and this action reasonable and denied the petition for appeal on those. *Id.*

[6] As noted previously, the 2017 design values are preliminary.

[7] The 2014 and 2015 data at monitoring site 11–001–0041 (also referred to as ''the River Terrace monitor'') is incomplete. Therefore, the 2016 and 2017 design values are invalid. The River Terrace monitor was temporarily shut down in March 2014 due to renovations at the monitoring site. The River Terrace monitor was reinstated in 2016, and began operation in May 2016. The temporary shutdown of the River Terrace monitor is discussed in more detail in the TSD for this rulemaking action available online at *https://www.regulations.gov,* Docket ID: EPA–R03–OAR–2018–0215.

(redesignation of Detroit-Ann Arbor).[8] Applicable requirements of the CAA that come due subsequent to the area's submittal of a complete redesignation request remain applicable until a redesignation is approved, but are not required as a prerequisite to redesignation. Section 175A(c) of the CAA. *Sierra Club* v. *EPA,* 375 F .3d 537 (7th Cir. 2004). *See also* 68 FR 25424, 25427 (May 12, 2003) (redesignation of the St. Louis/East St. Louis area to attainment of the 1-hour ozone NAAQS).

1. Maryland and Virginia Have Met All Applicable Requirements of Section 110 and Part D of the CAA Applicable to the Washington Area for Purposes of Redesignation

a. Section 110 General Requirements for SIPs

Section 110(a)(2) of Title I of the CAA contains the general requirements for a SIP, which include enforceable emissions limitations and other control measures, means, or techniques, provisions for the establishment and operation of appropriate devices necessary to collect data on ambient air quality, and programs to enforce the limitations. The general SIP elements and requirements set forth in section 110(a)(2) include, but are not limited to, the following: (1) Submit a SIP that has been adopted by the state after reasonable public notice and hearing; (2) include enforceable emission limitations and other control measures, means, or techniques necessary to meet the requirements of the CAA; (3) provide for establishment and operation of appropriate devices, methods, systems and procedures necessary to monitor ambient air quality; (4) provide for implementation of a source permit program to regulate the modification and construction of stationary sources within the areas covered by the plan; (5) include provisions for the implementation of part C prevention of significant deterioration (PSD) and part D new source review (NSR) permit programs; (6) include provisions for stationary source emission control measures, monitoring, and reporting; (7) include provisions for air quality modeling; and, (8) provide for public and local agency participation in planning and emission control rule development.

Section 110(a)(2)(D) of the CAA requires SIPs to contain certain measures to prevent sources in a state from significantly contributing to air quality problems in another state. To implement this provision, EPA has required certain states to establish programs to address transport of air pollutants, in accordance with the NO_X SIP Call,[9] amendments to the NO_X SIP Call, May 14, 1999 (64 FR 26298), and March 2, 2000 (65 FR 11222), and the Cross-State Air Pollution Rule (CSAPR) Update, October 26, 2016 (81 FR 74504). However, the section 110(a)(2)(D) SIP requirements are not linked with a particular area's ozone designation and classification. EPA concludes that the SIP requirements linked with an area's ozone designation and classification are the relevant measures to evaluate when reviewing a redesignation request for the area. The section 110(a)(2)(D) requirements, where applicable, continue to apply to a state regardless of the designation (or redesignation) of any one particular area within the state. Thus, these requirements are not applicable requirements for purposes of redesignation. *See* 65 FR 37890 (June 15, 2000), 66 FR 50399 (October 19, 2001), and 68 FR 25418, 25426–25427 (May 13, 2003).

Similarly, other section 110 elements that are neither connected with attainment plan submissions nor linked with an area's ozone attainment status are not applicable requirements for purposes of redesignation. An area that is redesignated from nonattainment to attainment will remain subject to these statewide requirements after the area is redesignated to attainment of the 2008 ozone NAAQS. The section 110(a)(2) requirements, which are linked with a particular area's designation and classification, are the relevant measures to evaluate in reviewing a redesignation request. The section 110(a)(2) elements not linked to the area's nonattainment status are not applicable for purposes of redesignation. This approach is consistent with EPA's existing policy on applicability (*e.g.,* for redesignations) of conformity and oxygenated fuels requirements, as well as with section 184 ozone transport region (OTR) requirements. *See, e.g.,* Reading, Pennsylvania, proposed and final rulemakings for redesignation, 61 FR 53174–53176 (October 10, 1996) and 62 FR 24826 (May 7, 1997); Cleveland-Akron-Lorain, Ohio, final rulemaking for redesignation, 61 FR 20458 (May 7, 1996); and Tampa, Florida final rulemaking for redesignation, 60 FR 62748 (December 7, 1995). For further information and analysis, see the discussion of this issue in the Cincinnati, Ohio ozone redesignation (65 FR 37890, June 19, 2000), and the Pittsburgh, Pennsylvania ozone redesignation (66 FR 50399, October 19, 2001).

EPA has reviewed Maryland's and Virginia's SIPs and concludes that they meet the general SIP requirements under section 110 of the CAA, to the extent those requirements are applicable for purposes of redesignation. On November 17, 2014 (79 FR 62010) and March 27, 2014 (79 FR 17043), EPA approved elements of the SIPs submitted by Maryland and Virginia, respectively, which, with the exception of interstate transport, meet the requirements of CAA section 110(a)(2), for the 2008 ozone NAAQS. As explained previously, the general requirements of section 110(a)(2) are statewide requirements that are not linked to the 2008 8-hour ozone nonattainment status of the Washington Area and are therefore not ''applicable requirements'' for purpose of the review of Maryland's and Virginia's 2008 ozone NAAQS redesignation requests. Because Maryland's and Virginia's SIPs satisfy all of the general SIP elements and requirements set forth in CAA section 110(a)(2) applicable to and necessary for redesignation, EPA concludes that Maryland and Virginia have satisfied the criterion of section 107(d)(3)(E) regarding section 110 of the CAA.

b. Part D Requirements

Areas designated nonattainment for the ozone NAAQS are subject to the applicable nonattainment area and ozone-specific planning requirements of part D of the CAA. Sections 172–176 of the CAA, found in subpart 1 of part D, set forth the basic nonattainment requirements for all nonattainment areas. Section 172(c), under part D of the CAA, sets forth the basic requirements of air quality plans for states with nonattainment areas for all pollutants that are required to submit

[8] The Calcagni memorandum and Shapiro memorandum are included in the docket for this rulemaking available online at *http://www.regulations.gov,* Docket ID: EPA–R03–OAR–2018–0215.

[9] On October 27, 1998 (63 FR 57356), EPA finalized the ''Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone''—commonly called the NO_X SIP Call. The NO_X SIP call requires the District of Columbia and 22 states to reduce emissions of NO_X in order to reduce the transport of ozone and ozone precursors. EPA developed the NO_X Budget Trading Program, an allowance trading program that states could adopt to meet their obligations under the NO_X SIP Call. The NO_X Budget Trading Program allowed electric generating units (EGUs) greater than 25 megawatts and industrial non-electric generating units, such as boilers and turbines, with a rated heat input greater than 250 million British thermal units per hour (MMBtu/hr), referred to as ''large non-EGUs'', to participate in a regional NO_X cap and trade program. The NO_X SIP call also established reduction requirements for other non-EGUs, including cement kilns and stationary internal combustion (IC) engines.

plans pursuant to section 172(b). Section 182 of the CAA, found in subpart 2 of part D, establishes specific requirements for ozone nonattainment areas depending on the areas' nonattainment classifications.[10] The Washington Area was classified as marginal under subpart 2 of part D of the CAA for the 2008 ozone NAAQS. As such, the Area is subject to the subpart 1 requirements contained in CAA sections 172(c) and 176. The Area is also subject to the subpart 2 requirements contained in CAA section 182(a) (marginal nonattainment area requirements), which include, but are not limited to, submitting a baseline emissions inventory, adopting a SIP requiring emissions statements from stationary sources, and implementing a nonattainment NSR (NNSR) program for the relevant ozone standard. A thorough discussion of the requirements contained in CAA sections 172(c) and 182 can be found in the General Preamble for Implementation of Title I (57 FR 13498).

Additionally, states located in the OTR, which includes Maryland and portions of Virginia,[11] are also subject to the requirements of CAA section 184. All areas located in the OTR, both attainment and nonattainment, are subject to additional control requirements under section 184 for the purpose of reducing interstate transport of emissions that may contribute to downwind ozone nonattainment. The section 184 requirements include reasonably available control technology (RACT), NSR, enhanced vehicle inspection and maintenance (I/M), and Stage II vapor recovery or a comparable measure relating to gasoline dispensing facilities.

EPA has interpreted the section 184 OTR requirements, including the NSR program, as not being applicable for purposes of redesignation. The rationale for this is based on two considerations. First, the requirement to submit SIP revisions for the section 184 requirements continues to apply to areas in the OTR even after redesignation to attainment. Therefore, states remain obligated to have NSR, as well as RACT, and I/M programs, even after redesignation. Second, the section 184 control measures are region-wide requirements and do not apply to the area by virtue of the area's designation and classification, and thus are properly considered not relevant to an action changing an area's designation. *See* 61 FR 53174, 53175–53176 (October 10, 1996) and 62 FR 24826, 24830–24832 (May 7, 1997).

i. CAA Section 172 Requirements

As provided in CAA part D, subpart 2, for marginal ozone nonattainment areas such as the Washington Area, the ozone specific requirements of section 182(a) supersede (where overlapping) the attainment planning requirements that would otherwise apply under section 172(c), including the attainment demonstration and reasonably available control measures (RACM) under section 172(c)(1), reasonable further progress (RFP) under section 172(c)(2), and contingency measures under section 172(c)(9). 42 U.S.C. 7511a(a).

Section 172(c)(3) requires submission and approval of a comprehensive, accurate, and current inventory of actual emissions. This requirement is superseded by the inventory requirement in section 182(a)(1) discussed later in this notice.

Section 172(c)(4) requires the identification and quantification of allowable emissions for major new and modified sources in an area, and section 172(c)(5) requires source permits for the construction and operation of new and modified major stationary sources anywhere in the nonattainment area (NNSR). As explained previously, the Washington Area is included in the OTR established by Congress in section 184 of the CAA. Therefore, sources located in Maryland and the portions of Virginia included in the OTR will remain subject to the part D NNSR requirements even after the Washington Area is redesignated to attainment. Since the part D NNSR requirements apply to the Washington Area regardless of its attainment status, they are not considered to be relevant for purposes of redesignation. Regardless, Maryland and Virginia both have an approved NNSR program. *See* 82 FR 45475 (September 29, 2017) and 64 FR 51047 (September 21, 1999).

Section 172(c)(6) requires the SIP to contain control measures necessary to provide for attainment of the NAAQS. Because attainment has been reached in the Area, EPA finds no additional measures are needed in the SIPs to provide for attainment.

Section 172(c)(7) requires the SIP to meet the applicable provisions of section 110(a)(2). As noted previously, Maryland's and Virginia's SIPs meet the applicable requirements of section 110(a)(2) for purposes of redesignation.

ii. CAA Section 176 Conformity Requirements

Section 176(c) of the CAA requires states to establish criteria and procedures to ensure that federally supported or funded projects conform to the air quality planning goals in the applicable SIP. The requirement to determine conformity applies to transportation plans, programs, and projects that are developed, funded, or approved under title 23 of the United States Code (U.S.C.) and the Federal Transit Act (transportation conformity) as well as to all other federally supported or funded projects (general conformity). State transportation conformity SIP revisions must be consistent with federal conformity regulations relating to consultation, enforcement, and enforceability that EPA promulgated pursuant to its authority under the CAA.

EPA interprets the conformity SIP requirements[12] as not applicable for purposes of evaluating a redesignation request under section 107(d) because state conformity rules are still required after redesignation and federal conformity rules apply where state conformity rules have not been approved. *See Wall* v. *EPA,* 265 F .3d 426 (6th Cir. 2001) (upholding this interpretation); *see also* 60 FR 62748 (December 7, 1995) (redesignation of Tampa, Florida).

iii. Section 182 Requirements

Section 182(a)(1) requires states to submit a comprehensive, accurate, and current inventory of actual emissions from sources of NO_X and VOC emitted within the boundaries of the ozone nonattainment area. On July 17, 2014, the District and Virginia submitted a joint 2011 base year emissions inventory addressing NO_X and VOC emissions, as well as carbon monoxide (CO) emissions, for the Washington Area. On

[10] Ozone nonattainment areas are classified based on the severity of their ozone levels (as determined based on the area's ''design value,'' which represents air quality in the area for the most recent 3 years). The possible classifications for ozone nonattainment areas are Marginal, Moderate, Serious, Severe, and Extreme. *See* CAA section 181(a)(1).

[11] The OTR is comprised of the states of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, and the Consolidated Metropolitan Statistical Area, which includes the District of Columbia and portions of Virginia. The areas designated as in the Virginia portion of the OTR are as follows: Arlington County, Fairfax County, Loudoun County, Prince William County, Stafford County, Alexandria City, Fairfax City, Falls Church City, Manassas City, and Manassas Park City. *See, e.g.* ''Approval and Promulgation of Air Quality Implementation Plans; Virginia; NSR in the Ozone Transport Region'', 71 FR 39570 (July 13, 2006) and 71 FR 890 (January 6, 2006).

[12] CAA section 176(c)(4)(E) requires states to submit revisions to their SIPs to reflect certain federal criteria and procedures for determining transportation conformity. Transportation conformity SIPs are different from SIPs requiring the development of Motor Vehicle Emission Budgets (MVEBs), such as control strategy SIPs and maintenance plans.

August 4, 2014, Maryland submitted its 2011 base year emissions inventory for the Washington Area, which also addressed NO_X, VOC, and CO. EPA approved the District's, Maryland's, and Virginia's base year emissions inventories for NO_X and VOC for the 2008 ozone NAAQS on May 13, 2015 (80 FR 27255). On July 23, 2015 (80 FR 43625), EPA approved the District's, Maryland's, and Virginia's base year emission inventories for CO.

Under section 182(a)(2)(A), states with ozone nonattainment areas that were designated prior to the enactment of the 1990 CAA amendments were required to submit, within six months of classification, all rules and corrections to existing RACT rules that were required under section 172(b)(3) prior to the 1990 CAA amendments. EPA approved Maryland's and Virginia's SIP revisions satisfying the section 182(a)(2) RACT ''fix-up'' requirement on March 31, 1994 (59 FR 15117) and November 29, 1994 (59 FR 60908).

Section 182(c)(3) of the CAA requires areas classified as serious and above to adopt and implement an enhanced I/M program. The Washington Area was classified as severe for the 1979 1-hour ozone NAAQS, and therefore enhanced I/M was required. In addition, section 184(b)(1)(a) of the CAA requires areas located in the OTR that are a metropolitan statistical area, or part thereof, with a population of 100,000 or more to meet the enhanced I/M program requirements of CAA section 182(c)(3). EPA approved Maryland's enhanced I/M program into Maryland's SIP on October 29, 1999 (64 FR 58340). EPA approved Virginia's enhanced I/M program on September 1, 1999 (64 FR 47670), as revised April 22, 2008 (73 FR 21540).

CAA section 182(a)(2)(C) and section 182(a)(4) contain source permitting and offset requirements (known as NNSR). As discussed previously, part D NNSR will continue to apply to the Washington Area, regardless of attainment status, due to the Washington Area being part of the OTR. Therefore, EPA concludes that Maryland and Virginia need not have a fully approved part D NSR program prior to approval of the redesignation request. As stated previously, however, Maryland and Virginia both have an approved NNSR program. *See* 82 FR 45475 (September 29, 2017) for Maryland and 64 FR 51047 (September 21, 1999) for Virginia. On January 29, 2018 (83 FR 3982), EPA approved Maryland's May 8, 2017 SIP revision addressing the NNSR requirements for the 2008 ozone NAAQS and certifying that Maryland's existing NNSR program covering Maryland's portion of the Washington Area is at least as stringent as the requirements at 40 CFR 51.165, as amended by the SIP Requirements Rule. On May 11, 2017, Virginia formally submitted a SIP revision to address the specific NNSR requirements for the 2008 ozone NAAQS, located in 40 CFR 51.160–165. In Virginia's SIP revision, Virginia is certifying that its existing NNSR program covering Virginia's portion of the Washington Area is at least as stringent as the requirements at 40 CFR 51.165, as amended by the SIP Requirements Rule. EPA proposed approval of Virginia's May 11, 2017 SIP revision addressing the NNSR requirements for the 2008 ozone NAAQS on April 4, 2018 (83 FR 14386).[13]

Section 182(a)(3) requires states to submit periodic emission inventories and a revision to the SIP to require the owners or operators of stationary sources to annually submit emission statements documenting actual NO_X and VOC emissions. Maryland and Virginia submit periodic emission inventories as required by CAA section 182(a)(3). As stated above, EPA approved the District's, Maryland's, and Virginia's base year emissions inventories for NO_X and VOC for the 2008 ozone NAAQS on May 13, 2015 (80 FR 27255). With regard to stationary source emission statements, EPA approved Maryland's and Virginia's emission statement rules on October 12, 1994 (59 FR 51517) and May 2, 1995 (60 FR 21451), respectively, which satisfied the requirements of CAA section 182(a)(3)(B). Maryland's and Virginia's emission statement rules require certain sources in ozone nonattainment areas and the OTR to report annual NO_X and VOC emissions. EPA approved Maryland's and Virginia's emission statement certification SIPs (finding Maryland and Virginia had an emission statement program meeting section 182(a)(3) requirements for the 2008 ozone NAAQS) on July 16, 2018 (83 FR 32796) and June 1, 2018 (83 FR 25378), respectively.

Therefore, Maryland and Virginia have satisfied all applicable SIP requirements under section 110 and part D of title I of the CAA for purposes of redesignation of their respective portions of the Washington Area. As noted previously, EPA will act on the District's redesignation request for its portion of the Washington Area in a separate rulemaking.

[13] While not prejudging the outcome of EPA's rulemaking on Virginia's May 11, 2017 SIP revision, EPA expects to finalize rulemaking on that NNSR SIP revision before taking final action on this redesignation action.

2. Maryland and Virginia Have Fully Approved SIPs for Purposes of Redesignation Under Section 110(k) of the CAA

At various times, Maryland and Virginia have adopted and submitted, and EPA has approved, provisions addressing the various SIP elements applicable for the ozone NAAQS. As discussed previously, EPA has fully approved Maryland's and Virginia's SIPs for the Washington Area under section 110(k) for all requirements applicable for purposes of redesignation under the 2008 ozone NAAQS. EPA may rely on prior SIP approvals in approving a redesignation request (*see* the Calcagni memorandum at page 3; *Southwestern Pennsylvania Growth Alliance* v. *Browner,* 144 F.3d 984, 989–990 (6th Cir. 1998); *Wall* v. *EPA,* 265 F.3d 426), plus any additional measures it may approve in conjunction with a redesignation action (*see* 68 FR 25426 (May 12, 2003) and citations therein).

C. Are the air quality improvements in the Washington area due to permanent and enforceable emission reductions?

To redesignate an area from nonattainment to attainment, section 107(d)(3)(E)(iii) of the CAA requires EPA to determine that the air quality improvement in the area is due to permanent and enforceable reductions in emissions resulting from the implementation of the SIP and applicable federal air pollution control regulations and other permanent and enforceable emission reductions. Maryland and Virginia have demonstrated that the observed ozone air quality improvement in the Washington Area is due to permanent and enforceable reductions in NO_X and VOC emissions resulting from Maryland and Virginia measures approved as part of the SIP as well as federal measures.

In making this demonstration, Maryland and Virginia have calculated the change in emissions between 2011 and 2014. The change in emissions is shown in Table 2. Maryland and Virginia attribute the decrease in emissions and corresponding improvement in air quality during this time period to a number of regulatory control measures that have been implemented in the Washington Area and upwind areas in recent years. Based on the information summarized in the following sections, Maryland and Virginia have adequately demonstrated that the improvement in air quality is due to permanent and enforceable emissions reductions.

1. Permanent and Enforceable Emission Controls Implemented

a. Federal Emission Control Measures

A variety of federal and state control programs have contributed to reduced on-road, point source, and nonroad emissions of NO_X and VOC in the Washington Area, with additional emission reductions expected to occur in the future as older equipment and vehicles are replaced with newer, compliant models. Federal emission control measures include the following:

Tier 2 Motor Vehicle Emissions Standards and Gasoline Sulfur Control Requirements

On February 10, 2000 (65 FR 6698), EPA promulgated Tier 2 motor vehicle emission standards and gasoline sulfur control requirements. These emission control requirements result in lower NO_X and VOC emissions from new cars and light duty trucks, including sport utility vehicles. With respect to fuels, this rule required refiners and importers of gasoline to meet lower standards for sulfur in gasoline, which were phased in between 2004 and 2006. By 2006, refiners were required to meet a 30 ppm average sulfur level, with a maximum cap of 80 ppm. This reduction in fuel sulfur content ensures the effectiveness of low emission-control technologies. The Tier 2 tailpipe standards established in this rule were phased in for new vehicles between 2004 and 2009. EPA estimated in the final rule that this program will reduce annual NO_X emissions by about 2.2 million tons per year in 2020 and 2.8 million tons per year in 2030 after the program is fully implemented and non-compliant vehicles have all been retired.

Control of Emissions From Nonroad Spark-Ignition Engines and Equipment

On October 8, 2008 (73 FR 59034), EPA finalized emission standards for new nonroad spark-ignition engines. The exhaust emission standards applied beginning in 2010 for new marine spark-ignition engines and in 2011 and 2012 for different sizes of new land-based, spark-ignition engines at or below 19 kW (*i.e.* small engines used primarily in lawn and garden applications). In the October 8, 2008 final rule, EPA estimated that by 2030 the rule will result in annual nationwide reductions of 604,000 tons of volatile organic hydrocarbon emissions, 132,200 tons of NO_X emissions, and 5,500 tons of directly-emitted $PM_{2.5}$ emissions. These reductions correspond to significant reductions in the formation of ground-level ozone.

Nonroad Diesel Engines Tier 1 and Tier 2

On June 17, 1994 (59 FR 31306), EPA made an affirmative determination under section 213(a)(2) of the CAA that nonroad engines are significant contributors to ambient ozone or CO levels in more than one nonattainment area. In the same notice, EPA also made a determination under CAA section 213(a)(4) that other emissions from compression-ignition (CI) nonroad engines rated at or above 37 kilowatts (kW) cause or contribute to air pollution that may reasonably be anticipated to endanger public health or welfare. In the June 17, 1994 final rule, EPA set a first phase of emission standards (Tier 1 standards) for nonroad diesel engines rated 37 kW and above. These standards apply to nonroad, compression-ignition (*i.e.* diesel-powered) utility engines including, but not limited to, farm, construction, and industrial equipment, rated at or above 37 kW. On October 23, 1998 (63 FR 56968), EPA finalized a second phase of emission standards (Tier 2 standards) for nonroad diesel engines rated under 37 kW. These emission standards have resulted in a decrease in NO_X emissions from the combustion of diesel fuel used to power this equipment. The Tier 1 and Tier 2 standards for nonroad diesel engines will continue to result in emission reductions as older equipment is replaced with newer, compliant models.

Emissions Standards for Large Spark Ignition Engines

On November 8, 2002 (67 FR 68242), EPA established emission standards for large spark-ignition engines such as those used in forklifts and airport ground-service equipment; recreational vehicles using spark-ignition engines such as off-highway motorcycles, all-terrain vehicles, and snow mobiles; and recreational marine diesel engines. These emission standards were phased in from model year 2004 through 2012. When the emission standards are fully implemented in 2030, EPA expects a national 75 percent reduction in hydrocarbon (HC) emissions, 82 percent reduction in NO_X emissions, 61 percent reduction in CO emissions, and a 60 percent reduction in direct particulate matter (PM) emissions from these engines, equipment, and vehicles compared to projected emissions if the standards were not implemented.

Standards for Reformulated and Conventional Gasoline

On February 16, 1994 (59 FR 7716), EPA finalized regulations requiring that gasoline in certain areas be reformulated to reduce vehicle emissions of toxic and ozone-forming compounds, including NO_X and VOC. Reformulated gasoline (RFG) is required in the Washington Area. The first phase of the RFG program (Phase I) began in 1995 and the second phase (Phase II) began in 2000. These standards affect various gasoline-powered non-road mobile sources, such as lawn equipment, generators, and compressors. EPA estimates that Phase I of the RFG program resulted in a 2 percent and 17 percent annual reduction in NO_X, and VOCs, respectively, from 1995 emission levels and prevented 64,000 tons of smog-forming pollutants, including NO_X and VOC, from being emitted into the air from 1995 to 2000. Phase II of the RFG program, which began in 2000, was expected to reduce emissions of NO_X and VOC by 7 percent and 27 percent, respectively, from 1995 emission levels and reduce emissions of smog-forming pollutants by an additional 41,000 tons.[14] The RFG program continues to provide emission reductions in the Washington Area as the use of RFG results in less vehicle emissions of NO_X and VOC compared to the use of conventional gasoline.

Emission Standards for Locomotives and Locomotive Engines

On April 16, 1998 (63 FR 18978), EPA established emission standards for NO_X, HC, CO, PM, and smoke from newly manufactured and remanufactured diesel-powered locomotives and locomotive engines. These emission standards were effective in 2000 and are expected to result in a more than 60 percent reduction in NO_X emissions from locomotives by 2040 compared to 1995 baseline levels.

b. Control Measures Specific to the Washington Area

Maryland Healthy Air Act

In addition to the measures referenced previously, a reduction of emission of ozone precursors can also be attributed to the Maryland Healthy Air Act (Annotated Code of Maryland Environment Title 2 Ambient Air Quality Control Subtitle 10 Healthy Air Act Sections 2–1001 to 2–1005, with implementing regulations at COMAR 26.11.27 Emission Limitations for Power Plants). The Maryland Health Air Act (HAA) was effective on July 16, 2007 and approved by EPA on September 4, 2008 (73 FR 51599). The HAA established limits on the amount of NO_X and SO_2 emissions affected facilities in

[14] *See https://www.epa.gov/gasoline-standards/reformulated-gasoline* for more information on the RFG program.

Maryland could emit and required the installation of on-site pollution controls at 15 power plants in Maryland. The first phase of the HAA occurred between 2009 and 2010 and reduced NO_X emissions from affected sources by almost 70% compared to 2002 levels. The second phase of the HAA occurred between 2012 and 2013. Maryland estimates that the HAA will reduce NO_X emissions by approximately 75% from 2002 levels.

Closure of GenOn Potomac River LLC Facility

The decrease in emissions of ozone precursors is also attributable to the closure of the GenOn Potomac River plant located in Alexandria, Virginia. This 482-megawatt electrical generating facility consisted of five coal-fired boilers and emitted 557.7 tons of NO_X annually and 2.7 tons of NO_X per ozone season day (tpd) in 2011. The plant ceased operations and signed a mutual determination letter on December 21, 2012, agreeing to the permanent shutdown of the source and revoking all permits for the facility.[15] Therefore, this closure is permanent and federally enforceable.

2. Emission Reductions

Maryland and Virginia calculated the change in emissions between 2011 and 2014 throughout the entire Washington Area to demonstrate that air quality has improved. The change in emissions is shown in Table 2. Maryland and Virginia used the 2011 base year emissions inventory for the Washington Area as the nonattainment year inventory because 2011 was one of the three years used to designate the area nonattainment for the 2008 ozone NAAQS. EPA approved the Washington Area 2011 base year inventory as meeting the requirements of CAA section 182(a)(1) on May 13, 2015 (80 FR 27276) for NO_X and VOC emissions and July 23, 2015 (80 FR 43625) for CO emissions. As explained later in this notice, 2014 was used as the attainment year inventory.

TABLE 2—2011–2014 EMISSIONS REDUCTION FOR THE WASHINGTON, DC-MD-VA AREA

2011	2014	Δ 2011—2014	% Reduction from 2011
VOC Emissions (tpd)			
295.0	259.4	35.6	12.1
NO_X Emissions (tpd)			
436.5	296.9	139.6	32.0
CO Emissions (tpd)			
1,800.8	1,617.9	182.9	10.2

Note: 2011 emissions data is from the 2011 base year emissions inventory for the Washington, DC-MD-VA 2008 ozone NAAQS nonattainment area that was approved by EPA on May 13, 2015 (80 FR 27276) for NO_X and VOC emissions and July 23, 2015 (80 FR 43625) for CO emissions.

Table 2 shows that emissions of NO_X and VOC in the Washington area were reduced by 139.6 tpd and 35.6 tpd, respectively, between 2011 and 2014. As discussed previously, Maryland and Virginia identified several federal and state rules approved into Maryland's and Virginia's SIPs that resulted in the reduction of NO_X and VOC emissions from 2011 to 2014. Therefore, Maryland and Virginia have shown that the air quality improvements in the Washington Area are due to permanent and enforceable emission reductions.

D. Do the District, Maryland, and Virginia have fully approvable ozone maintenance plans for the Washington Area?

As one of the criteria for redesignation to attainment, section 107(d)(3)(E)(iv) of the CAA requires EPA to determine that the area has a fully approved maintenance plan pursuant to section 175A of the CAA. Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. Under CAA section 175A, the maintenance plan must demonstrate continued attainment of the NAAQS for at least 10 years after the Administrator approves a redesignation to attainment. Eight years after the redesignation, the state must submit a revised maintenance plan which demonstrates that attainment of the NAAQS will continue for an additional 10 years beyond the initial 10-year maintenance period. To address the possibility of future NAAQS violations, the maintenance plan must contain contingency measures, as EPA deems necessary, to assure prompt correction of the future NAAQS violation.

The Calcagni memorandum provides further guidance on the content of a maintenance plan, explaining that a maintenance plan should address five elements: (1) An attainment emission inventory; (2) a maintenance demonstration; (3) a commitment for continued air quality monitoring; (4) a process for verification of continued attainment; and (5) a contingency plan.

In conjunction with their requests to redesignate their respective portions of the Washington Area to attainment for the 2008 ozone NAAQS, the District, Maryland, and Virginia submitted, as a revision to their SIPs, a plan to provide for maintenance of the 2008 ozone NAAQS through 2030, which is more than 10 years after the expected effective date of the redesignation to attainment. EPA anticipates redesignating the entire Washington Area, including the District's portion, by 2019. As discussed in this notice, EPA is proposing to find that the District's, Maryland's, and Virginia's maintenance plan for the 2008 ozone NAAQS includes the necessary components per the CAA, including CAA section 175A and EPA guidance, and is proposing to approve the maintenance plan as revisions to the District's, Maryland's, and Virginia's SIPs.

[15] *See* Mutual Determination Letter from Virginia Department of Environmental Quality to Mr. William Lee Davis, President, GenOn Potomac River, LLC, Subject: Mutual Determination of Permanent Shutdown of the Potomac River Generating Station, December 20, 2012 included in the docket for this rulemaking available online at *http://www.regulations.gov,* Docket ID: EPA–R03–OAR–2018–0215.

1. Attainment Inventory

The Calcagni memorandum indicates that states requesting redesignation to attainment should develop an attainment emissions inventory in order to identify the level of emissions in the area which is sufficient to attain the NAAQS. The attainment inventory should be consistent with EPA's most recent guidance on emission inventories for nonattainment areas available at the time and should include the emissions during the time period associated with monitoring data showing attainment.

For the attainment inventory, the District, Maryland, and Virginia used the year 2014, which is one of the years during the three-year period associated with the monitoring data first showing attainment of the 2008 ozone NAAQS (*i.e.,* 2013 to 2015). As previously mentioned, on November 14, 2017, EPA determined that the Washington Area attained the 2008 ozone NAAQS by the attainment date, based on 2013 to 2015 data. *See* 82 FR 52651. The attainment year inventory is summarized in Table 3. A detailed evaluation of the methodology used to develop the attainment year inventory (and EPA's rationale to approve the attainment inventory) is provided in the Emission Inventory Technical Support Document (EI TSD), which is included in the docket for this rulemaking available online at *http://www.regulations.gov,* Docket ID: EPA–R03–OAR–2018–0215.

TABLE 3—2014 ATTAINMENT INVENTORY FOR THE WASHINGTON AREA

Source category	NO_X (tpd)	VOC (tpd)	CO (tpd)
Point	64.9	7.7	23.7
Non-Point (Area)	9.6	139.3	63.5
Marine, Air, Rail (MAR)	19.2	2.4	19.6
Nonroad Model	52	47.5	762.8
On-Road Mobile	136.8	61.3	744.1
Quasi-Point	14.4	1.2	4.2
Total	296.9	259.4	1617.9

2. Have the District, Maryland, and Virginia documented maintenance of the 2008 ozone NAAQS in the Washington Area?

a. Maintenance Emission Inventory for the Washington Area

The District, Maryland, and Virginia have demonstrated maintenance of the 2008 ozone standard through 2030 by the use of emission inventories showing that future emissions of NO_X and VOC for the Washington Area will remain at or below attainment year emission levels. A maintenance demonstration need not be based on modeling. *See Wall* v. *EPA,* 265 F.3d 426 (6th Cir. 2001), *Sierra Club* v. *EPA,* 375 F.3d 537 (7th Cir. 2004). *See also* 66 FR 53094, 53099–53100 (October 19, 2001) and 68 FR 25413, 25430–25432 (May 12, 2003).

The District, Maryland, and Virginia are using emissions inventories for the years 2025 and 2030 to demonstrate maintenance in the Washington Area. EPA anticipates redesignating the entire Washington Area, including the District's portion, in 2019. 2030 is more than 10 years after the expected effective date of the redesignation to attainment, and 2025 was selected to demonstrate that emissions are not expected to increase in the interim between the attainment year and the final maintenance year.

In order to develop the 2025 and 2030 inventories, the District, Maryland, and Virginia applied growth factors to the 2014 attainment year emissions inventory (shown in Table 3). A detailed evaluation of the methodology used to develop the maintenance inventory (and EPA's rational for approving the maintenance inventory as well as the growth factors used) is provided in EPA's EI TSD, which is included in the docket for this rulemaking available online at *http://www.regulations.gov,* Docket ID: EPA–R03–OAR–2018–0215.

The maintenance inventory, provided in Table 4, shows the projected emissions of NO_X, VOC, and CO in the Washington Area for 2014 (the attainment year), 2025, and 2030 and demonstrates that future emissions of NO_X, VOC, and CO will not exceed the levels of the 2014 attainment year inventory for the Washington area for a minimum of 10 years following redesignation.

TABLE 4—2014 TO 2030 NO_X, VOC, AND CO MAINTENANCE EMISSIONS INVENTORIES FOR THE WASHINGTON AREA

Source category	NO_X (tpd)			VOC (tpd)			CO (tpd)		
	2014	2025	2030	2014	2025	2030	2014	2025	2030
Point	64.9	66.0	68.5	7.7	8.8	9.4	23.7	25.1	26.2
Non-Point (Area)	9.6	9.9	10.0	139.3	153.7	160.3	63.6	64.9	65.5
Marine-Air-Rail (M–A–R)	19.2	21.4	22.4	2.4	2.6	2.6	19.6	19.9	20.7
Nonroad Mobile	52.0	29.6	27.8	47.5	44.9	47.2	762.8	845.8	898.8
On-Road Mobile	136.8	40.7	27.4	61.3	33.2	24.1	744.1	457.1	323.7
Quasi-Point	14.4	14.4	14.4	1.2	1.2	1.2	4.2	4.2	4.2
Total	296.9	182.0	170.5	259.4	244.4	244.8	1618.0	1417.0	1339.1
Δ 2014–2025	114.9			15.0			201.0		
Δ 2014–2030	126.4			14.6			278.9		

In summary, EPA finds the maintenance inventory for the Washington Area provided in Table 4 shows maintenance of the 2008 ozone NAAQS by providing emissions information and reasonable growth factors to support the demonstration that future emissions of NO_X and VOC will remain at or below 2014 emission levels (an inventory year showing attainment of NAAQS) when taking into account both future source growth and implementation of future controls. Table 4 shows that NO_X and VOC emissions are projected to decrease by 126.4 tpd and 14.6 tpd, respectively, between 2014 and 2030. EPA finds that the District, Maryland, and Virginia have demonstrated maintenance of the 2008 ozone standard in the Washington Area through 2030.

b. Control Measures for Maintenance of Air Quality in the Washington Area

The point, nonroad, and on-road emission projections for 2025 and 2030 include a variety of control strategies that will reduce emissions of NO_X and VOC in future years.

i. Point Sector Controls

COMAR 26.11.38 Control of NO_X Emissions From Coal-Fired Electric Generating Units

COMAR 26.11.38 (also referred to as the Maryland NO_X Rule) established new NO_X emission standards and additional monitoring and reporting requirements for coal-fired EGUs in Maryland. COMAR 26.11.38 was approved by EPA into the SIP on May 30, 2017 (82 FR 24546). The coal-fired EGUs included in this rule account for more than 80 percent of the State of Maryland's NO_X emissions from power plants. These new NO_X emission standards have resulted in reductions in NO_X emissions.

ii. Nonroad Emission Controls

As discussed previously, a variety of federal and state control programs have contributed to reduced on-road, point source, and nonroad emissions of NO_X and VOC in the Washington Area, with additional emission reductions expected to occur in the future. These Federal measures include the following and are discussed in more detail in section IV.C.1.b. of this rulemaking: (1) Control of Emissions from Nonroad Spark-Ignition Engines and Equipment; (2) Nonroad Diesel Engines Tier 1 and Tier 2; (3) Emissions Standards for Large Spark Ignition Engines; (4) Standards for Reformulated and Conventional Gasoline; and, (5) Emission Standards for Locomotives and Locomotive Engines.

iii. On-Road Emission Controls

Tier 3 Vehicle Emissions and Fuel Standards Program

On April 28, 2014 (79 FR 23414), EPA established more stringent vehicle emissions standards. The vehicle emissions standards will reduce both tailpipe and evaporative emissions of the ozone precursors NO_X and VOC from passenger cars, light-duty trucks, medium-duty passenger vehicles, and some heavy-duty vehicles. These standards will result in significant reductions in ozone concentrations due to the decrease in NO_X and VOC emissions. The Tier 3 standards include new light- and heavy-duty vehicle emission standards for exhaust emissions of VOC, NO_X, and PM, as well as new evaporative emissions standards. In the final rule, EPA estimates that in 2030, when Tier 3 vehicles will make up the majority of the fleet as well as vehicle miles traveled, NO_X and VOC emissions from on-highway vehicles will be reduced by about 21 percent compared to projected emission levels if the Tier 3 standards were not implemented.

Transportation Emission Reduction Measures

The National Capital Region Transportation Planning Board (TPB) [16] utilizes many strategies to reduce emissions from mobile sources by reducing the number of vehicle trips and/or vehicle miles traveled. Such strategies include, but are not limited to, ridesharing programs, telecommuting programs, improved transit and bicycling facilities, and clean fuel vehicle programs. A summary of these measures is provided by TPB in their transportation conformity analyses. The emission reductions from these strategies were not included in the 2025 and 2030 maintenance emissions inventories.

Inspection and Maintenance (I/M) Programs

The District, Maryland, and Virginia operate enhanced I/M programs to ensure that motorists are driving vehicles that meet federal emission requirements. Owners of vehicles that do not meet requirements, based on tail pipe or On-Board Diagnostic (OBD) testing, must repair the vehicles or show that the total costs of repair are more than waiver limitations. As noted previously, EPA approved Maryland's and Virginia's enhanced I/M program into Maryland's and Virginia's SIPs on October 29, 1999 (64 FR 58340) and September 1, 1999 (64 FR 47670), as revised April 22, 2008 (73 FR 21540), respectively. EPA approved the District's enhanced I/M program into the District's SIP on June 11, 1999 (64 FR 31498).

3. Continued Air Quality Monitoring

The District, Maryland, and Virginia have committed, in their joint maintenance plan for the Washington Area, to continue to operate an appropriate air quality monitoring network in accordance with 40 CFR part 58. The District, Maryland, and Virginia also committed, in their redesignation requests, to continue to monitor ozone concentrations in the Washington Area in accordance with 40 CFR part 58 and EPA-approved annual monitoring plans, to quality-assure the monitoring data in accordance with 40 CFR part 58, and to enter all data into AQS in a timely fashion.

4. Verification of Continued Attainment

The District, Maryland, and Virginia state in their maintenance plan submittal that they have the legal authority to develop, implement, and enforce regulations regarding air pollution, including the requirements of the maintenance plan for the Washington Area. The District, Maryland, and Virginia cite the regulations and statutory provisions included in Table 5 below as providing them with the authority to develop, implement, and enforce the requirements of the maintenance plan for the Washington Area.

[16] The National Capital Region Transportation Planning Board (TPB) is the federally designated metropolitan planning organization (MPO) for metropolitan Washington.

TABLE 5—MEASURES CITED AS PROVIDING THE DISTRICT, MARYLAND, AND VIRGINIA WITH THE AUTHORITY TO DEVELOP, IMPLEMENT, AND ENFORCE THE REQUIREMENTS OF THE MAINTENANCE PLAN FOR THE WASHINGTON AREA

State	Citation	Description
Virginia	Section 10.1–1308 of the Virginia Air Pollution Control Law (Title 10.1, Chapter 13 of the Code of Virginia).	Authorizes the State Air Pollution Control Board to promulgate regulations abating, controlling, and prohibiting air pollution in order to protect public health and welfare.
Maryland	Annotated Code of Maryland, Section 2–103	Legal authority to implement and enforce.
Maryland	Annotated Code of Maryland, Environment Article, Section 2–302(a)–(d).	Authority for MDE to set emission standards and ambient air quality standards for each air quality control area in the state.
Maryland	Annotated Code of Maryland, Environment Article, Section 2–601–614.	Authority for MDE to enforce the standards and impose penalties.
District of Columbia	Air Pollution Control Act of 1984, as amended (D.C. Official Code Section 8–101.05–101.06).	Provides authority to ''develop a comprehensive program for the control and prevention of air pollution in the District that provides for the administration and enforcement of the requirements of [the Act] and the regulations promulgated pursuant to [the Act].''
District of Columbia	20 DCMR Sections 101, 102, and 105	Authority for inspection, order for compliance, and penalty, respectively.

In their joint maintenance plan submittal, the District, Maryland, and Virginia also referenced several regulatory elements that each state will retain in order to maintain attainment of the 2008 ozone NAAQS. These regulatory elements are summarized in Table 6.

TABLE 6—REGULATORY MEASURES CITED FOR CONTINUED ATTAINMENT

State	Citation	Description
District of Columbia	20 DCMR 202 and 20 DCMR 303.8	Shutdown requirements.
District of Columbia	20 DCMR Chapter 2 (General and Non-Attainment Area Permits) and 20 DCMR Chapter 3 (Operating Permits and Acid Rain Programs).	Permitting requirements.
District of Columbia	20 DCMR 804, 805, 899 (NO_X), 20 DCMR Chapter 10 (NO_X Emissions Budget), and 20 DCMR Chapter 7 (Volatile Organic Compounds).	Regulatory requirements.
District of Columbia	18 DCMR Chapters 4, 6, 7, 11, 26, and 99	I/M program requirements.
District of Columbia	20 DCMR Chapter 5	Emission statement requirements.
Maryland	COMAR 26.11.01.05–1	Emission statement requirements.
Maryland	COMAR 11.14.08	I/M program requirements.
Maryland	COMAR 26.11.02 and COMAR 26.11.03	Permitting requirements.
Virginia	9VAC5–20–220	Shutdown requirements.
Virginia	9VAC5–80	Permits for stationary sources.
Virginia	9VAC5–91	I/M program requirements for Northern Virginia.
Virginia	9VAC5–20–160.B	Emission statement requirements.

Verification of continued attainment is accomplished through operation of the ambient ozone monitoring network and the periodic update of the area's emissions inventory. As stated above, the District, Maryland, and Virginia have committed, in their joint maintenance plan for the Washington Area, to continue to operate an appropriate air quality monitoring network in accordance with 40 CFR part 58. The District, Maryland, and Virginia also committed, in their redesignation requests, to continue to monitor ozone concentrations in the Washington Area in accordance with 40 CFR part 58 and EPA-approved annual monitoring plans, to quality-assure the monitoring data in accordance with 40 CFR part 58, and to enter all data into AQS in a timely fashion. The District, Maryland, and Virginia state in their joint maintenance plan that they will track attainment and maintenance using ambient and source emission data.

In addition, to track the progress of the maintenance demonstration, the District, Maryland, and Virginia state in their joint maintenance plan submittal that they will periodically update the emissions inventory. The District, Maryland, and Virginia also commit to an annual evaluation consisting of a comparison of key emissions trend indicators, such as the annual emissions update of stationary sources and the Highway Performance Monitoring System (HPMS) vehicle miles traveled data reported to the Federal Highway Administration (FHWA), to the growth assumptions used in the plan. The District, Maryland, and Virginia also commit in their maintenance plan submittal to developing and submitting to EPA ''comprehensive tracking inventories every three years or as required by federal regulation during the maintenance plan period.'' EPA notes that point source facilities covered by the District's, Maryland's, and Virginia's emission statement rules are required to submit NO_X and VOC emissions on an annual basis to address CAA requirements in CAA section 182.[17]

[17] In the District's May 25, 2018 emission statement certification SIP submittal for the 2008 ozone NAAQS, the District cites to section 20–500.9 of the District of Columbia Municipal Regulations (DCMR) (20 DCMR 500.9) as containing the District's emission statement rules. However, the District's emission statement rules were SIP-approved as 20 DCMR 500.7 (60 FR 27889, May 26, 1995). A recodification of 20 DCMR 500 caused the

5. What is the contingency plan for the Washington Area?

Section 175A of the CAA requires that the state must adopt a maintenance plan, as a SIP revision, that includes such contingency measures as EPA deems necessary to assure that the state will promptly correct a violation of the NAAQS that occurs after a redesignation of the area to attainment of the NAAQS. The maintenance plan must identify the contingency measures to be considered and, if needed for maintenance, adopted and implemented; a schedule and procedure for adoption and implementation; and, a time limit for action by the state. The state should also identify specific indicators to be used to determine when the contingency measures need to be considered, adopted, and implemented.

As required by section 175A of the CAA, the District, Maryland, and Virginia have adopted a contingency plan for the Washington Area to address possible future ozone air quality problems as described herein and in the TSD for this rulemaking available online at *http://www.regulations.gov,* Docket ID: EPA–R03–OAR–2018–0215. EPA's analysis of the contingency plan as addressing requirements in CAA section 175A is also in the TSD.

a. Contingency Measures

The District, Maryland, and Virginia included several measures as contingency measures in their joint maintenance plan submittal that EPA found to not be appropriate for use as contingency measures as discussed in detail in the TSD for this rulemaking. However, since emission reductions from these measures were not accounted for in the maintenance inventory or the MVEBs, it is expected that these measures will provide more emission reductions than what was projected in the maintenance inventory or the MVEBs. Thus, these measures will provide additional assurance that the 2008 ozone standard will be maintained in the Washington Area. A description of the District's, Maryland's, and Virginia's submitted contingency measures as well as EPA's evaluation of these measures and the contingency plan as a whole can be found in the TSD for this rulemaking available online at *http://www.regulations.gov,* Docket ID: EPA–R03–OAR–2018–0215. Table 7 lists the measures that EPA finds appropriate to use as contingency measures for the Washington Area.

TABLE 7—MEASURES FOUND TO BE APPROPRIATE TO USE AS CONTINGENCY MEASURES FOR THE WASHINGTON AREA

Measure	State
Ozone Transport Commission (OTC) 2009–2014 model rule for VOC for consumer products [18].	Virginia.
OTC 2009–2014 model rule for VOC for architectural and industrial maintenance coatings [19].	Virginia.
Additional contingency measures as needed	District of Columbia, Maryland, and/or Virginia.

b. Indicators

The District, Maryland, and Virginia include specific indicators, or ''triggers'', to be used to determine when the contingency measures need to be considered, adopted, and implemented. In the contingency measure implementation schedule included in the maintenance plan and discussed later in this notice, the District, Maryland, and Virginia state that the ''schedule onset'' for the implementation of any contingency measure will begin three months after quality assured data determine that an exceedance or violation of the 2008 ozone NAAQS occurred within the previous year or upon notification from EPA that a contingency measure must be implemented. Another trigger is if any future year emissions inventory indicates that the Washington Area's total emissions of NO_X or VOC exceeded the levels in the attainment year inventory. If an audit of the attainment year and future year inventories does not reconcile the original estimated emissions with the exceedances, then the District, Maryland, and Virginia commit to implementing one or more of the contingency measures to ensure that future total emissions of NO_X and VOC in the Washington Area do not exceed the levels in the attainment year inventory.

c. Schedule and Procedure for Adoption and Implementation of Contingency Measures

The District, Maryland, and Virginia have committed to implementing any contingency measure according to the following schedule: (1) Schedule onset: Notification received from EPA that a contingency measure must be implemented or three months after quality assured data determine that an exceedance or violation occurred within the previous year; (2) applicable regulation or program will be adopted six months following the schedule onset; (3) applicable regulation or program will be implemented six months following adoption; and, (4) compliance with regulation, or full program implementation, to be achieved within twelve months of adoption.

The District and Metropolitan Washington Air Quality Committee (MWAQC) will use their regional coordination process to determine the contingency measure to be implemented.

d. EPA's Evaluation of the Contingency Plan for the Washington Area

Based on EPA's evaluation of the District's, Maryland's, and Virginia's contingency plan for the Washington Area, which is provided in the TSD for this rulemaking available online at *http://www.regulations.gov,* Docket ID: EPA–R03–OAR–2018–0215, EPA finds that the contingency plan includes the required elements for CAA section 175A and relevant EPA guidance and will promptly correct any violation of the

emission statement rules under 20 DCMR 500.7 to move to 20 DCMR 500.9. Despite the recodification, the District's emission statement rules continue to require applicable point sources in the District to submit information on NO_X and VOC emissions on an annual basis. EPA intends to propose conditional approval of the District's emission statement certification SIP for the 2008 ozone NAAQS, contingent on the District's submittal of a SIP revision updating the District's SIP to reflect the recodification of 20 DCMR 500.

[18] The Model Rule for Consumer Products was developed by the OTC and establishes limits on VOC emissions from consumer products including, but not limited to, adhesives, air fresheners, general purpose cleaners, and hairsprays. *See* ''2013 Consumer Product Update'', May 21, 3013, available at *https://otcair.org/document.asp?Fview=modelrules.*

[19] The Model Rule for Architectural and Industrial Maintenance (AIM) Coatings was developed by the OTC and establishes limits on VOC emissions from AIM coatings, including, but not limited to concrete/masonry sealer, driveway sealers, and wood coatings. *See* ''Model Rule 2009–2014—Architectural & Industrial Maintenance (AIM) Coatings'', Updated October 13, 2014, available at *https://otcair.org/document.asp?Fview=modelrules.*

NAAQS that occurs after the redesignation of the Washington Area.

EPA has concluded that the District's, Maryland's, and Virginia's joint maintenance plan adequately addresses the five basic components of a maintenance plan: Attainment inventory, maintenance demonstration, monitoring network, verification of continued attainment, and a contingency plan. Therefore, EPA concludes that the maintenance plan SIP revisions submitted by the District, Maryland, and Virginia meet the requirements of CAA section 175A. EPA is proposing to approve the maintenance plan as a revision to the District's, Maryland's, and Virginia's SIPs.

V. Have the District, Maryland, and Virginia adopted approvable MVEBs?

A. What are the MVEBs?

Under section 176(c) of the CAA, new transportation plans, programs, or projects that receive federal funding or support, such as the construction of new highways, must ''conform'' (*i.e.,* be consistent with) the SIP. Conformity to the SIP means that transportation activities will not cause new air quality violations, worsen existing air quality problems, or delay timely attainment of the NAAQS or interim air quality milestones. Regulations at 40 CFR part 93 set forth EPA policy, criteria, and procedures for demonstrating and assuring conformity of transportation activities to a SIP. Transportation conformity is a requirement for nonattainment and maintenance areas.[20]

Under the CAA, states are required to submit, at various times, control strategy SIPs for nonattainment areas and maintenance plans for areas seeking redesignations to attainment of the ozone standard and maintenance areas. *See* the SIP Requirements Rule. These control strategy SIPs (including reasonable further progress plans and attainment plans) and maintenance plans must include MVEBs for criteria pollutants, including ozone, and their precursor pollutants (NO_X and VOC for ozone) to address pollution from on-road transportation sources. The MVEBs are the portion of the total allowable emissions that are allocated to highway and transit vehicle use that, together with emissions from other sources in the area, will provide for attainment or maintenance of the NAAQS. *See* 40 CFR 93.101.

Under 40 CFR part 93, a MVEB for an area seeking redesignation to attainment must be established, at minimum, for the last year of the maintenance plan. A state may adopt MVEBs for other years as well. The MVEB serves as a ceiling on emissions from an area's planned transportation system. The MVEB concept is further explained in the preamble to the November 24, 1993 Transportation Conformity Rule (58 FR 62188). The preamble also describes how to establish the MVEB in the SIP and how to revise the MVEB, if needed, subsequent to initially establishing a MVEB in the SIP. The most recently approved MVEBs for the Washington Area originate from the attainment plan for the 1997 ozone NAAQS, which EPA found adequate on February 7, 2013 (78 FR 9044).

B. What is the status of EPA's adequacy determination for the proposed 2025 and 2030 VOC and NO_X MVEBs for the Washington Area?

When reviewing submitted control strategy SIPs or maintenance plans containing MVEBs, EPA must affirmatively find that the MVEBs contained therein are adequate for use in determining transportation conformity. Once EPA affirmatively finds that the submitted MVEBs are adequate for transportation purposes, the MVEBs must be used by state and federal agencies in determining whether proposed transportation projects conform to the SIP as required by section 176(c) of the CAA.

EPA's substantive criteria for determining adequacy of a MVEB are set out in 40 CFR 93.118(e)(4). The process for determining adequacy consists of three basic steps: (1) Public notification of a SIP submission, (2) provision for a public comment period, and (3) EPA's adequacy determination. This process for determining the adequacy of submitted MVEBs for transportation conformity purposes was initially outlined in EPA's May 14, 1999 guidance, ''Conformity Guidance on Implementation of March 2, 1999, Conformity Court Decision.'' EPA adopted regulations to codify the adequacy process in the Transportation Conformity Rule Amendments for the ''New 8-Hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards and Miscellaneous Revisions for Existing Areas; Transportation Conformity Rule Amendments—Response to Court Decision and Additional Rule Change,'' on July 1, 2004 (69 FR 40004). Additional information on the adequacy process for transportation conformity purposes is available in the proposed rule titled, ''Transportation Conformity Rule Amendments: Response to Court Decision and Additional Rule Changes,'' 68 FR 38974, 38984 (June 30, 2003).

The District's, Maryland's, and Virginia's maintenance plan includes NO_X and VOC MVEBs for the Washington Area for 2014 (the attainment year), 2025 (the intermediate year), and 2030 (the last year of the maintenance period). The District's, Maryland's, and Virginia's maintenance plan SIP submission, including the NO_X and VOC MVEBs for the Washington Area, was available for public comment on EPA's adequacy website on May 21, 2018 at *https://www.epa.gov/state-and-local-transportation.* The EPA public comment period on adequacy of the 2014, 2025, and 2030 MVEBs for the Washington Area closed on June 20, 2018. No comments on the submittal were received during the adequacy comment period. EPA reviewed the NO_X and VOC MVEBs in accordance with the adequacy process in 40 CFR part 93 and found the MVEBs adequate. EPA anticipates it will publish a notice of adequacy for the 2014, 2025, and 2030 MVEBs for the Washington Area before taking final action on this redesignation of the Washington Area. In letters dated July 24, 2018, EPA informed the District, Maryland, and Virginia that the 2014, 2025, and 2030 MVEBs are adequate for use in transportation conformity analyses.[21] EPA's analysis of the MVEBs is included in the Notice of Adequacy TSD, which is included in the docket for this rulemaking available online at *http://www.regulations.gov,* Docket ID: EPA–R03–OAR–2018–0215.

The MVEBs were calculated using the most current USEPA Motor Vehicle Emissions Simulator (MOVES) model (MOVES2014a) and regional travel demand forecasting model at the time of the submittal. These MVEBs, when considered together with all other emissions sources, are consistent with maintenance of the 2008 ozone standard. The MVEBs are shown in Table 8.

[20] Maintenance areas are areas that were previously nonattainment for a particular NAAQS, but have been redesignated to attainment with an approved maintenance plan for the NAAQS.

[21] As stated previously, EPA originally informed the District, Maryland, and Virginia that the 2014, 2025, and 2030 MVEBs were adequate for use in transportation conformity analyses in letters dated July 18, 2018. EPA revised language in these letters and sent the revised letters to the District, Maryland, and Virginia on July 24, 2018. The original and revised letters are available online at *http://www.regulations.gov,* Docket ID: EPA–R03–OAR–2018–0215.

TABLE 8—WASHINGTON, DC-MD-VA MAINTENANCE PLAN ON-ROAD MOBILE SOURCE EMISSIONS BUDGETS

Year	NO_X on-road emissions (tpd)	VOC on-road emissions (tpd)
Attainment Year 2014 Emission and Budget	136.8	61.3
Intermediate Year 2025 Emission and Budget	40.7	33.2
Final Year 2030 Emission and Budget	27.4	24.1

C. What is a safety margin and how was it allocated?

EPA's transportation conformity regulations allow for the use of a safety margin, also referred to as a ''transportation buffer'', in the development of MVEBs for maintenance plans. A ''safety margin'' is the difference between the attainment level of emissions (from all sources) and the projected level of emissions (from all sources) in the maintenance plan. All or a portion of these transportation buffers can be allotted to mobile source inventories to develop MVEBs.

Table 4 shows the difference in total emissions for NO_X and VOC from all sources between the attainment year (2014) and the intermediate year (2025) as well as the attainment year (2014) and the final maintenance year (2030). These differences in emissions provide estimates of the total available transportation buffers for NO_X and VOC in 2025 and 2030. The total available transportation buffers for NO_X is 114.9 tpd in 2025 and 126.4 tpd in 2030 and for VOC the total available transportation buffer is 15.0 tpd in 2025 and 14.6 tpd in 2030. The District, Maryland, and Virginia used 20% of the total available transportation buffer to develop the second set of mobile budgets for 2025 and 2030 in the maintenance plan. The transportation buffers add 8.1 tpd of NO_X and 6.6 tpd of VOC to the 2025 emission inventories, and 5.5 tpd of NO_X and 4.8 tpd of VOC to the 2030 emission inventories. The MVEBs with the transportation buffers described previously for the Washington Area are shown in Table 9.

TABLE 9—WASHINGTON, DC-MD-VA MAINTENANCE PLAN ON-ROAD MOBILE SOURCE EMISSIONS BUDGETS WITH TRANSPORTATION BUFFERS

Year	NO_X on-road emissions (tpd)	VOC on-road emissions (tpd)
Attainment Year 2014 Emissions & Budget	136.8	61.3
Predicted 2025 Emission	40.7	33.2
Transportation Buffer	8.1	6.6
Intermediate Year 2025 Budget	48.8	39.8
Predicted 2030 Emission	27.4	24.1
Transportation Buffer	5.5	4.8
Final Year 2030 Budget	32.9	28.9

These two sets of MVEBs (with and without transportation buffers) have been developed for both milestone years (2025 and 2030). As can be seen in Table 10, the MVEBs that include the transportation buffer (Table 9), remain below the emission levels of the maintenance inventory.

TABLE 10—MAINTENANCE INVENTORY: NO_X AND VOC EMISSIONS IN THE WASHINGTON AREA, INCLUDING MVEBS WITH TRANSPORTATION BUFFER, 2014 TO 2030

Source category	NO_X (tpd)			VOC (tpd)		
	2014	2025	2030	2014	2025	2030
Point	64.9	66.0	68.5	7.7	8.8	9.4
Non-Point (Area)	9.6	9.9	10.0	139.3	153.7	160.3
M–A–R	19.2	21.4	22.4	2.4	2.6	2.6
Nonroad Mobile	52.0	29.6	27.8	47.5	44.9	47.2
On-Road Mobile	136.8	48.8	32.9	61.3	39.8	28.9
Quasi-Point	14.4	14.4	14.4	1.2	1.2	1.2
Total	296.9	190.1	176.0	259.4	251.0	249.6
Δ 2014–2025	106.8			8.4		
Δ 2014–2030	120.9			9.8		

The District, Maryland, and Virginia will only use the MVEBs with transportation buffers, shown in Table 9, as needed in situations where the conformity analysis must be based on different data, models, or planning assumptions, including, but not limited to, updates to demographic, land use, or project-related assumptions, than were

used to create the first set of MVEBs in the maintenance plan. The technical analyses used to demonstrate compliance with the MVEBs and the need, if any, to use transportation buffers will be fully documented in the conformity analysis and follow the Transportation Planning Board's (TPB) interagency consultation procedures. Regulations governing the interagency consultation process adopted by the District, Maryland, Virginia, and the TPB are as follows:

1. District of Columbia: Title 20 Environment, Chapter 20–15 General and Transportation Conformity, Rule Numbers 20–1503, 20–1504, 20–1505, 20–1506, 20–1507
2. Maryland: Title 26 Department of Environment, Subtitle 11 Air Quality, Chapter 26 Conformity, Regulation Numbers 26.11.26.04, 26.11.26.05, 26.11.26.06, 26.11.26.07, 26.11.26.08
3. Virginia: 9VAC5 Chapter 151 Regulation for Transportation Conformity Section 70 Consultation (9VAC5–151–70)
4. Transportation Planning Board: Report titled ''Transportation Planning Board Consultation Procedures with respect to Transportation Conformity Regulations Governing TPB Plans and Programs,'' May 20, 1998

EPA finds that the District, Maryland, and Virginia continue to demonstrate maintenance of the 2008 ozone standard with both sets of MVEBs, including the MVEBs with the transportation buffers. Therefore, EPA is proposing to approve, as revisions to the District's, Maryland's, and Virginia's SIPs, the MVEBs contained in this maintenance plan for the Washington Area.

VI. Proposed Action

EPA is proposing to approve the requests from Maryland and Virginia to redesignate to attainment their respective portions of the Washington Area for the 2008 ozone NAAQS. EPA is not proposing to approve the redesignation request from the District and will address the District's redesignation request in a separate rulemaking action. EPA is also proposing to approve, as a revision to the District's, Maryland's, and Virginia's SIPs, the joint maintenance plan submitted by the District, Maryland, and Virginia. The joint maintenance plan demonstrates maintenance of the 2008 ozone NAAQS through 2030 in the Washington Area and includes 2014, 2025, and 2030 MVEBs for NO_X and VOCs for the 2008 ozone NAAQS. Finally, EPA has found adequate and is proposing to approve these 2014, 2025, and 2030 NO_X and VOC MVEBs for the Washington Area. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

VII. General Information Pertaining to SIP Submittals From the Commonwealth of Virginia

In 1995, Virginia adopted legislation that provides, subject to certain conditions, for an environmental assessment (audit) ''privilege'' for voluntary compliance evaluations performed by a regulated entity. The legislation further addresses the relative burden of proof for parties either asserting the privilege or seeking disclosure of documents for which the privilege is claimed. Virginia's legislation also provides, subject to certain conditions, for a penalty waiver for violations of environmental laws when a regulated entity discovers such violations pursuant to a voluntary compliance evaluation and voluntarily discloses such violations to the Commonwealth and takes prompt and appropriate measures to remedy the violations. Virginia's Voluntary Environmental Assessment Privilege Law, Va. Code Sec. 10.1–1198, provides a privilege that protects from disclosure documents and information about the content of those documents that are the product of a voluntary environmental assessment. The Privilege Law does not extend to documents or information that: (1) Are generated or developed before the commencement of a voluntary environmental assessment; (2) are prepared independently of the assessment process; (3) demonstrate a clear, imminent and substantial danger to the public health or environment; or (4) are required by law.

On January 12, 1998, the Commonwealth of Virginia Office of the Attorney General provided a legal opinion that states that the Privilege law, Va. Code Sec. 10.1–1198, precludes granting a privilege to documents and information ''required by law,'' including documents and information ''required by federal law to maintain program delegation, authorization or approval,'' since Virginia must ''enforce federally authorized environmental programs in a manner that is no less stringent than their federal counterparts. . . .'' The opinion concludes that ''[r]egarding § 10.1–1198, therefore, documents or other information needed for civil or criminal enforcement under one of these programs could not be privileged because such documents and information are essential to pursuing enforcement in a manner required by federal law to maintain program delegation, authorization or approval.''

Virginia's Immunity law, Va. Code Sec. 10.1–1199, provides that ''[t]o the extent consistent with requirements imposed by federal law,'' any person making a voluntary disclosure of information to a state agency regarding a violation of an environmental statute, regulation, permit, or administrative order is granted immunity from administrative or civil penalty. The Attorney General's January 12, 1998 opinion states that the quoted language renders this statute inapplicable to enforcement of any federally authorized programs, since ''no immunity could be afforded from administrative, civil, or criminal penalties because granting such immunity would not be consistent with federal law, which is one of the criteria for immunity.''

Therefore, EPA has determined that Virginia's Privilege and Immunity statutes will not preclude the Commonwealth from enforcing its program consistent with the federal requirements. In any event, because EPA has also determined that a state audit privilege and immunity law can affect only state enforcement and cannot have any impact on federal enforcement authorities, EPA may at any time invoke its authority under the CAA, including, for example, sections 113, 167, 205, 211 or 213, to enforce the requirements or prohibitions of the state plan, independently of any state enforcement effort. In addition, citizen enforcement under section 304 of the CAA is likewise unaffected by this, or any, state audit privilege or immunity law.

VIII. Statutory and Executive Order Reviews

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

provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

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

The action approving Maryland's and Virginia's redesignation request for their respective portions of the Washington Area for the 2008 ozone NAAQS as well as the District's, Maryland's, and Virginia's maintenance plan for the Washington Area, is not approved to apply on any Indian reservation land as defined in 18 U.S.C. 1151 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).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: July 24, 2018.

Cosmo Servidio,

Regional Administrator, Region III.

[FR Doc. 2018–16882 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2017–0699; FRL–9981–42—Region 6]

Air Plan Approval; Arkansas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Pursuant to the Federal Clean Air Act (CAA or the Act), the Environmental Protection Agency (EPA) is proposing to approve portions of the revisions to the Arkansas State Implementation Plan (SIP) submitted by the Arkansas Department of Environmental Quality (ADEQ) on March 24, 2017. Most of the revisions are administrative in nature and make the SIP current with Federal rules. The EPA is also proposing to make ministerial changes to the Code of **Federal Register** (CFR) to reflect SIP actions pertaining to the Arkansas Prevention of Significant Deterioration (PSD) program.

DATES: Written comments should be received on or before September 7, 2018.

ADDRESSES: Submit your comments, identified by EPA–R06–OAR–2017–0699, at *http://www.regulations.gov* or via email to *paige.carrie@epa.gov.* For additional information on how to submit comments see the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this issue of the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Paige, (214) 665–6521, *paige.carrie@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of this issue of the **Federal Register**, the EPA is approving the State's SIP submittal as a direct rule without prior proposal because the Agency views this as noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action no further activity is contemplated. If the EPA receives relevant 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. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time.

For additional information, see the direct final rule, which is located in the rules section of this issue of the **Federal Register**.

Dated: July 31, 2018.

Anne Idsal,

Regional Administrator, Region 6.

[FR Doc. 2018–16905 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2013–0492; FRL–9981–67—Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Delaware; Interstate Transport Requirements for the 2010 1-Hour Sulfur Dioxide Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve portions of a state implementation plan (SIP) revision submittal from the State of Delaware. This revision addresses the infrastructure requirement for interstate transport of pollution with respect to the 2010 1-hour sulfur dioxide (SO_2) national ambient air quality standard (NAAQS). This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 7, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2013–0492 at *http://www.regulations.gov,* or via email to *spielberger.susan@epa.gov.* For

comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Joseph Schulingkamp, (215) 814–2021, or by email at *schulingkamp.joseph@epa.gov.*

SUPPLEMENTARY INFORMATION: On May 29, 2013, the State of Delaware, through the Delaware Department of Natural Resources and Environmental Control (DNREC) submitted a SIP revision addressing the infrastructure requirements under section 110(a)(2) of the CAA for the 2010 1-hour SO_2 NAAQS.

I. Background

A. General

On June 2, 2010, the EPA promulgated a revised primary SO_2 standard, establishing a new 1-hour primary standard at the level of 75 parts per billion (ppb), based on the 3-year average of the annual 99th percentile of 1-hour daily maximum concentrations (hereafter ''the 2010 1-hour SO_2 NAAQS''). At the same time, the EPA also revoked the previous 24-hour and annual primary SO_2 standards. *See* 75 FR 35520 (June 22, 2010). *See* 40 CFR 50.11. The previous SO_2 air quality standards were set in 1971, including a 24-hour average primary standard at 140 ppb and an annual average primary standard at 30 ppb. *See* 36 FR 8186 (April 30, 1971).

Current scientific evidence links short-term exposures to SO_2, ranging from five minutes to 24 hours, with an array of adverse respiratory effects including bronchoconstriction and increased asthma symptoms. These effects are particularly important for asthmatics at elevated ventilation rates (*e.g.,* while exercising or playing). Studies also show a connection between short-term exposure and increased visits to emergency departments and hospital admissions for respiratory illnesses, particularly in at-risk populations including children, the elderly, and asthmatics.

B. EPA's Infrastructure Requirements

Pursuant to section 110(a)(1) of the CAA, states are required to submit a SIP revision to address the applicable requirements of section 110(a)(2) within three years after promulgation of a new or revised NAAQS or within such shorter period as EPA may prescribe. Section 110(a)(2) requires states to address basic SIP elements to assure attainment and maintenance of the NAAQS—such as requirements for monitoring, basic program requirements, and legal authority. Section 110(a) imposes the obligation upon states to make a SIP submission to EPA for a new or revised NAAQS, but the contents of that submission may vary depending upon the facts and circumstances of each NAAQS and what is in each state's existing SIP. In particular, the data and analytical tools available at the time the state develops and submits the SIP revision for a new or revised NAAQS affect the content of the submission. The content of such SIP submission may also vary depending upon what provisions the state's existing SIP already contains.

Specifically, section 110(a)(1) provides the procedural and timing requirements for SIP submissions. Section 110(a)(2) lists specific elements that states must meet for infrastructure SIP requirements related to a newly established or revised NAAQS such as requirements for monitoring, basic program requirements, and legal authority that are designed to assure attainment and maintenance of the NAAQS.

C. Interstate Pollution Transport Requirements

Section 110(a)(2)(D)(i)(I) of the CAA requires a state's SIP to include adequate provisions prohibiting any emissions activity in one state that contributes significantly to nonattainment, or interferes with maintenance, of the NAAQS in any downwind state. The EPA sometimes refers to these requirements as prong 1 (significant contribution to nonattainment) and prong 2 (interference with maintenance), or jointly as the ''good neighbor'' provision of the CAA. Further information can be found in the Technical Support Document (TSD) for this rulemaking action, which is available online at *www.regulations.gov,* Docket number EPA–R03–OAR–2013–0492.

II. Summary of SIP Revision and EPA Analysis

On May 29, 2013, Delaware submitted, through DNREC, a revision to its SIP to satisfy the infrastructure requirements of section 110(a)(2) of the CAA for the 2010 1-hour SO_2 NAAQS, including the interstate transport requirements of section 110(a)(2)(D)(i)(I). On January 22, 2014 (79 FR 3506), the EPA approved Delaware's infrastructure SIP submittal for the 2010 1-hour SO_2 NAAQS for all applicable elements of section 110(a)(2) with the exception of 110(a)(2)(D)(i)(I). This proposed rulemaking action is addressing the portions of Delaware's infrastructure submittal for the 2010 1-hour SO_2 NAAQS that pertain to transport requirements.[1] [2]

The portions of Delaware's May 29, 2013 SIP submittal addressing interstate transport (for section 110(a)(2)(D)(i)(I)) discuss how Delaware does not significantly contribute with respect to the 2010 1-hour SO_2 NAAQS to nonattainment in, or interfere with maintenance in, any other state and discusses prevailing wind direction in the region. Additionally, Delaware described in its submittal several existing SIP-approved measures and other federally enforceable source-specific measures, pursuant to permitting requirements under the CAA, that apply to SO_2 sources within the state.

Based on EPA's analysis, EPA agrees with Delaware's general conclusion that

[1] For the EPA's explanation of its ability to act on discrete elements of section 110(a)(2), *see* 80 FR 2865 (Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; Infrastructure Requirements for the 2008 Ozone, 2010 Nitrogen Dioxide, and 2010 Sulfur Dioxide National Ambient Air Quality Standards; Approval of Air Pollution Emergency Episode Plan (January 21, 2015)).

[2] This proposed approval action is based on the information contained in the administrative record for this action, and does not prejudge any other future EPA action that may make other determinations regarding any of the subject state's air quality status. Any such future actions, such as area designations under any NAAQS, will be based on their own administrative records and the EPA's analyses of information that becomes available at those times. Future available information may include, and is not limited to, monitoring data and modeling analyses conducted pursuant to the EPA's SO_2 Data Requirements Rule (80 FR 51052, August 21, 2015) and information submitted to the EPA by states, air agencies, and third-party stakeholders such as citizen groups and industry representatives.

the existing Delaware SIP is adequate to prevent sources in Delaware from significantly contributing to nonattainment or interfering with maintenance in another state with respect to the 2010 1-hour SO_2 NAAQS. A detailed summary of EPA's review and rationale for proposed approval of this SIP revision as meeting CAA section 110(a)(2)(D)(i)(I) for the 2010 1-hour SO_2 NAAQS may be found in the TSD.

III. Proposed Action

EPA is proposing to approve the portions of Delaware's May 29, 2013 SIP revision addressing interstate transport for the 2010 1-hr SO_2 NAAQS as these portions meet the requirements in section 110(a)(2)(D)(i)(I) of the CAA. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

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 proposed action:

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

In addition, this proposed rule, addressing Delaware's interstate transport requirements for the 2010 1-hour SO_2 NAAQS, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Reporting and recordkeeping requirements, Sulfur oxides.

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

Dated: July 12, 2018.

Cosmo Servidio,

Regional Administrator, Region III.

[FR Doc. 2018–16796 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

[Docket No. 180208146–8690–01]

RIN 0648–XG025

Pacific Island Pelagic Fisheries; 2018 U.S. Territorial Longline Bigeye Tuna Catch Limits

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

ACTION: Proposed specifications; request for comments.

SUMMARY: NMFS proposes a 2018 limit of 2,000 metric tons (t) of longline-caught bigeye tuna for each U.S. Pacific territory (American Samoa, Guam, and the Commonwealth of the Northern Mariana Islands (CNMI)). NMFS would allow each territory to allocate up to 1,000 t each year to U.S. longline fishing vessels in a specified fishing agreement that meets established criteria. As an accountability measure, NMFS would monitor, attribute, and restrict (if necessary) catches of longline-caught bigeye tuna, including catches made under a specified fishing agreement. The proposed catch limits and accountability measures would support the long-term sustainability of fishery resources of the U.S. Pacific Islands.

DATES: NMFS must receive comments by August 23, 2018.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2018–0026, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0026,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Send written comments to Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Region (PIR), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *http://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Rebecca Walker, NMFS PIRO Sustainable Fisheries, 808–725–5184.

SUPPLEMENTARY INFORMATION: NMFS proposes to specify a 2018 catch limit of 2,000 t of longline-caught bigeye tuna for each U.S. Pacific territory. NMFS would also authorize each U.S. Pacific territory to allocate up to 1,000 t of its 2,000 t bigeye tuna limit to U.S. longline fishing vessels that are permitted to fish under the Fishery Ecosystem Plan for Pacific Fisheries of the Western Pacific (FEP). Those vessels must be identified in a specified fishing agreement with

the applicable territory. The Western Pacific Fishery Management Council recommended these specifications. The proposed catch and allocation limits and accountability measures are identical to those specified for U.S. territories in each year since 2014 (for the most recent example, see 82 FR 47642, October 13, 2017).

NMFS will monitor catches of longline-caught bigeye tuna by the longline fisheries of each U.S Pacific territory, including catches made by U.S. longline vessels operating under specified fishing agreements. The criteria that a specified fishing agreement must meet, and the process for attributing longline-caught bigeye tuna, will follow the procedures in 50 CFR 665.819. When NMFS projects that a territorial catch or allocation limit will be reached, NMFS would, as an accountability measure, prohibit the catch and retention of longline-caught bigeye tuna by vessels in the applicable territory (if the territorial catch limit is projected to be reached), and/or vessels in a specified fishing agreement (if the allocation limit is projected to be reached).

NMFS will consider public comments on the proposed action and will announce the final specifications in the **Federal Register**. On March 20, 2017, in *Territory of American Samoa* v. *NMFS, et al.* (16–cv–95, D. Haw), a federal judge set aside a NMFS rule that amended the American Samoa Large Vessel Prohibited Area (LVPA) for eligible longliners because it did not consider under the Deeds of Cession the protection of cultural fishing in American Samoa. NMFS is appealing this decision. However, NMFS invites public comments that address the impact of this proposed rule on cultural fishing in American Samoa. NMFS must receive any comments on this rule by the date provided in the **DATES** heading. NMFS may not consider any comments not postmarked or otherwise transmitted by that date. Regardless of the final specifications, all other existing management measures will continue to apply in the longline fishery.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator for Fisheries has determined that this proposed specification is consistent with the FEP, other provisions of the Magnuson-Stevens Act, and other applicable laws, subject to further consideration after public comment.

Certification of Finding of No Significant Impact on Substantial Number of Small Entities

The Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that these proposed specifications, if adopted, would not have a significant economic impact on a substantial number of small entities.

The proposed action would specify a 2018 limit of 2,000 t of longline-caught bigeye tuna for American Samoa, Guam, and the CNMI. NMFS would also allow each territory to allocate up to 1,000 t of its 2,000 t limit to U.S. longline fishing vessels in a specified fishing agreement that meets established criteria set forth in 50 CFR 665.819. As an accountability measure, NMFS would monitor, attribute, and restrict (if necessary) catches of longline-caught bigeye tuna by vessels in the applicable U.S. territory (if the territorial catch limit is projected to be reached), or by vessels operating under the applicable specified fishing agreement (if the allocation limit is projected to be reached). Payments under the specified fishing agreements support fisheries development in the U.S. Pacific territories and the long-term sustainability of fishery resources of the U.S. Pacific Islands.

This proposed action would directly apply to longline vessels federally permitted under the FEP, specifically Hawaii, American Samoa, and Western Pacific longline permit holders. As of May 2018, 145 vessels had Hawaii permits and 47 had American Samoa permits. No Western Pacific general permit has been issued since 2011.

Based on dealer data collected by the State of Hawaii, Hawaii longline vessels landed approximately 32.75 million pounds (lb) of pelagic fish valued at $101.6 million in 2017. With 145 vessels making either a deep- or shallow-set trip in 2017, the ex-vessel value of pelagic fish caught by Hawaii-based longline fisheries averaged almost $701,000 per vessel. In 2016, American Samoa-based longline vessels landed approximately 4.5 million lb of pelagic fish valued at $4.7 million, where albacore made up the largest proportion of pelagic longline commercial landings at 3.35 million lb. With 18 active longline vessels in 2016, the ex-vessel value of pelagic fish caught by American Samoa fishery averaged about $261,111 per vessel.

NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide. Based on available information, NMFS has determined that all vessels permitted federally under the FEP are small entities, *i.e.,* they are engaged in the business of fish harvesting (NAICS 114111), are independently owned or operated, are not dominant in their field of operation, and have annual gross receipts not in excess of $11 million. Even though this proposed action would apply to a substantial number of vessels, the implementation of this action would not result in significant adverse economic impact to individual vessels. The proposed action would potentially benefit the Hawaii longline fishermen by allowing them to fish under specified fishing agreements with a territory, which could extend fishing effort for bigeye tuna in the western Pacific and provide more bigeye tuna for markets in Hawaii and elsewhere.

In accordance with Federal regulations at 50 CFR part 300, subpart O, vessels that possess both an American Samoa and Hawaii longline permit are not subject to the U.S bigeye tuna limit. Therefore, these vessels may retain bigeye tuna and land fish in Hawaii after the date NMFS projects the fishery would reach that limit. Further, catches of bigeye tuna made by such vessels are attributed to American Samoa, provided the fish was not caught in the U.S. EEZ around Hawaii. In 2017, all dual American Samoa/Hawaii longline permitted vessels were included in the fishing agreement with the CNMI and American Samoa. Therefore, NMFS attributed bigeye catches by those vessels to the two territories.

The 2018 U.S. bigeye tuna catch limit is 3,554 t, which is the same limit in place for 2016 and higher than the limit for 2017. NMFS established this limit through a separate action (83 FR 33851, July 17, 2018). Based on preliminary logbook data, NMFS expects the fishery to reach this limit by mid-October 2018.

Through this action, Hawaii-based longline vessels could potentially enter into one or more fishing agreements with participating territories. This would enhance the ability of these vessels to extend fishing effort in the western and central Pacific Ocean after reaching the 2018 U.S. limit and provide more bigeye tuna for markets in Hawaii. Providing opportunity to land

bigeye tuna in Hawaii in the last quarter of the year when market demand is high will result in positive economic benefits for fishery participants and net benefits to the nation. Allowing participating territories to enter into specified fishing agreements under this action provides benefits to the territories by providing funds for territorial fisheries development projects. Establishing a 2,000 t longline limit for bigeye tuna where territories are not subject to Western and Central Pacific Fisheries Commission longline limits is not expected to adversely affect vessels based in the territories.

Historical catch of bigeye tuna by the American Samoa longline fleet has been less than 2,000 t, even including the catch of vessels based in American Samoa, catch by dual permitted vessels that land their catch in Hawaii, and catch attributed to American Samoa from U.S. vessels under specified fishing agreements. With regard to Guam and the CNMI, no longline fishing has occurred since 2011.

Under the proposed action, longline fisheries managed under the FEP are not expected to expand substantially nor change the manner in which they are currently conducted, (*i.e.,* area fished, number of vessels longline fishing, number of trips taken per year, number of hooks set per vessel during a trip, depth of hooks, or deployment techniques in setting longline gear), due to existing operational constraints in the fleet, the limited entry permit programs, and protected species mitigation requirements. The proposed rule does not duplicate, overlap, or conflict with other Federal rules and is not expected to have significant impact on small organizations or government jurisdictions. Furthermore, there would be little, if any, disproportionate adverse economic impacts from the proposed rule based on gear type, or relative vessel size. The proposed rule also will not place a substantial number of small entities, or any segment of small entities, at a significant competitive disadvantage to large entities.

For the reasons above, NMFS does not expect the proposed action to have a significant economic impact on a substantial number of small entities. As such, an initial regulatory flexibility analysis is not required and none has been prepared.

This action is exempt from review under E.O. 12866.

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

Dated: August 2, 2018.

Samuel D. Rauch III,

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

[FR Doc. 2018–16883 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 665

RIN 0648–BH63

Pacific Island Fisheries; Ecosystem Component Species

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

ACTION: Notice of availability of fishery ecosystem plan amendments; request for comments.

SUMMARY: NMFS announces that the Western Pacific Fishery Management Council (Council) proposes to amend the Fishery Ecosystem Plans (FEP) for American Samoa, the Mariana Archipelago, and Hawaii. Amendment 4 to the American Samoa FEP, Amendment 5 to the Marianas FEP, and Amendment 5 to the Hawaii FEP would reclassify certain management unit species as ecosystem component species. The intent of these amendments is to focus management efforts on species that are in need of conservation and management, and improve efficiency of fishery management in the region.

DATES: NMFS must receive comments on the proposed amendments by October 9, 2018.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2018–0021, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2018-0021,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Send written comments to Michael D. Tosatto, Regional Administrator, NMFS Pacific Islands Region (PIR), 1845 Wasp Blvd., Bldg. 176, Honolulu, HI 96818.

Instructions: NMFS may not consider comments sent by any other method, to any other address or individual, or received after the end of the comment period. All comments received are a part of the public record, and NMFS will generally post them 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).

The Council prepared Amendment 4 to the American Samoa FEP, Amendment 5 to the Marianas FEP, and Amendment 5 to the Hawaii FEP. Those amendments, available as a single document, include an environmental assessment (EA). Copies of the amendments and EA, and other supporting documents are available at *https://www.regulations.gov* or the Council, 1164 Bishop St., Suite 1400, Honolulu, HI 96813, tel 808–522–8220, fax 808–522–8226, *www.wpcouncil.org.*

FOR FURTHER INFORMATION CONTACT: Sarah Ellgen, Sustainable Fisheries, NMFS PIR, 808–725–5173.

SUPPLEMENTARY INFORMATION: The Council established the FEPs for American Samoa, the Mariana Archipelago, and Hawaii to conserve and manage fisheries in the US Exclusive Economic Zone (Federal waters) in the Pacific Islands. The Council developed the FEPs, and NMFS implemented the associated regulations, under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Under the National Standard guidelines (50 CFR 600.305 and 600.310) for the Magnuson-Stevens Act, the Council and NMFS manage any fish species or stock that generally is a target of a Federal fishery and caught predominantly in Federal waters. Councils develop fishery management plans for these species (known as management unit species (MUS) that describe the fisheries, essential fish habitat (EFH), the scientific data required for effective implementation of the plan, the data that should be collected from the fisheries, and other required elements. The FEPs specify maximum sustainable yield, optimum yield, and status determination criteria so that overfishing and overfished determinations can be made. The Council and NMFS are also required to set annual catch limits (ACL) and accountability measures (AM) for all MUS, and the FEPs describe the process for specifying ACLs and AMs.

The FEPs have documented that the Council would use the system for classifying certain stocks as ecosystem component species (ECS), based on the criteria outlined in National Standard 1. National Standard 1 describes ECS as stocks that are included in an FEP to achieve ecosystem management objectives, but do not require conservation and management. Once reclassified as ECS, the number of MUS would be reduced from 205 species or families to 11 species in the American Samoa FEP, from 227 species or families to 13 species in the Marianas FEP, and from 173 species or families to 20 species in the Hawaii FEP. Appendix B in the amendment document list the proposed ECS for each area.

For a detailed description of the methods that the Council and NMFS used to identify the species to reclassify from MUS to ECS, please refer to Section 2 of the EA (see **ADDRESSES**).

The proposed action would change the definitions of MUS and ECS in the FEPs to reflect the Council's recommendations. It would also replace the FEP definitions of Currently Harvested Coral Reef Taxa (CHCRT) and Potentially Harvested Coral Reef Taxa (PHCRT) with Coral Reef ECS. All management measures that allow for the collection of data on EC species and protect the associated role of ECS in the ecosystem, and/or address other ecosystem issues, would be retained. These include permits and fees, reporting and recordkeeping requirements, prohibitions, allowable gear and gear restrictions, notifications, at-sea observer coverage, vessel marking and gear identification, area closures, and quotas, seasons, and minimum sizes for American Samoa and Mariana precious coral ECS. The management measures unique to the CHCRT and PHCRT would be carried forward to the coral reef ECS.

Finally, the proposed action would result in revision or removal of those sections of the FEPs that are not required for ECS, including EFH designations for ECS. The effects of this change on the environment would be minor, however, because the total area designated as EFH would change only for the deep (400–700 m) benthic substrates near Guam, the CNMI, and American Samoa, and reclassification would not change any fishery activities.

NMFS must receive comments on the proposed amendments by October 9, 2018 for consideration in the decision to approve, partially approve, or disapprove the amendments.

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

Dated: August 3, 2018.

Margo B. Schulze-Haugen,

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

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Notices

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

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2018–0013]

Trade and Foreign Agriculture Affairs; Codex Alimentarius Commission: International Standard-Setting Activities

AGENCY: Office of Trade and Foreign Agriculture Affairs (TFAA), USDA.

ACTION: Notice.

SUMMARY: This notice informs the public of the sanitary and phytosanitary standard-setting activities of the Codex Alimentarius Commission (Codex), in accordance with section 491 of the Trade Agreements Act of 1979, as amended, and the Uruguay Round Agreements Act. This notice also provides a list of other standard-setting activities of Codex, including commodity standards, guidelines, codes of practice, and revised texts. This notice, which covers Codex activities during the time periods from June 1, 2016, to May 31, 2017, and June 1, 2017, to July 20, 2018, seeks comments on standards under consideration and recommendations for new standards.

ADDRESSES: The U.S. Codex Office invites interested persons to submit their comments on this notice. Comments may be submitted by one of the following methods:

- *Federal e-Rulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at the website for submitting comments.
- *Mail, including CD–ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250–3700.
- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

Instructions: All items submitted by mail or email are to include the Agency name and docket number FSIS–2018–0013. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information to *http://www.regulations.gov.*

Please state that your comments refer to Codex and, if your comments relate to specific Codex committees, please identify the committee(s) in your comments and submit a copy of your comments to the delegate from that particular committee.

Docket: For access to background documents or comments received, call (202) 720–5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Mary Frances Lowe, United States Manager for Codex Alimentarius, U.S. Department of Agriculture, Office of Food Safety, South Agriculture Building, 1400 Independence Avenue SW, Room 4861, Washington, DC 20250–3700; Telephone: (202) 205–7760; Fax: (202) 720–3157; Email: *USCodex@fsis.usda.gov.*

For information pertaining to particular committees, contact the delegate of that committee. A complete list of U.S. delegates and alternate delegates can be found in Attachment 2 of this notice. Documents pertaining to Codex and specific committee agendas are accessible via the internet at *http://www.codexalimentarius.org/meetings-reports/en/.* The U.S. Codex Office also maintains a website at *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius.*

SUPPLEMENTARY INFORMATION:

Background

The World Trade Organization (WTO) was established on January 1, 1995, as the common international institutional framework for the conduct of trade relations among its members in matters related to the Uruguay Round Trade Agreements. The WTO is the successor organization to the General Agreement on Tariffs and Trade (GATT). United States membership in the WTO was approved and the Uruguay Round Agreements Act (Uruguay Round Agreements) was signed into law by the President on December 8, 1994, Public Law 103–465, 108 Stat. 4809. The Uruguay Round Agreements became effective, with respect to the United States, on January 1, 1995. The Uruguay Round Agreements amended the Trade Agreements Act of 1979. Pursuant to section 491 of the Trade Agreements Act of 1979, as amended, the President is required to designate an agency to be ''responsible for informing the public of the sanitary and phytosanitary (SPS) standard-setting activities of each international standard-setting organization'' (19 U.S.C. 2578). The main international standard-setting organizations are Codex, the World Organisation for Animal Health, and the International Plant Protection Convention. The President, pursuant to Proclamation No. 6780 of March 23, 1995, (60 FR 15845), designated the U.S. Department of Agriculture as the agency responsible for informing the public of the SPS standard-setting activities of each international standard-setting organization. The Secretary of Agriculture has delegated to the Office of Trade and Foreign Agricultural Affairs the responsibility to inform the public of the SPS standard-setting activities of Codex. The Office of Trade and Foreign Agricultural Affairs has, in turn, assigned the responsibility for informing the public of the SPS standard-setting activities of Codex to the U.S. Codex Office (USCO).

Codex was created in 1963 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Codex is the principal international organization for establishing standards for food. Through adoption of food standards, codes of practice, and other guidelines developed by its committees and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers, ensure fair practices in the food trade, and promote coordination of food standards work undertaken by international governmental and nongovernmental organizations. In the United States, U.S. Codex activities are managed and carried out by the United States Department of Agriculture (USDA); the Food and Drug

Administration (FDA), Department of Health and Human Services (HHS); the National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC); and the Environmental Protection Agency (EPA).

As the agency responsible for informing the public of the SPS standard-setting activities of Codex, the U.S. Codex Office publishes this notice in the **Federal Register** annually. Attachment 1 (Sanitary and Phytosanitary Activities of Codex) sets forth the following information:

1. The SPS standards under consideration or planned for consideration; and

2. For each SPS standard specified:

a. A description of the consideration or planned consideration of the standard;

b. Whether the United States is participating or plans to participate in the consideration of the standard;

c. The agenda for United States participation, if any; and

d. The agency responsible for representing the United States with respect to the standard.

TO OBTAIN COPIES OF THE STANDARDS LISTED IN ATTACHMENT 1, PLEASE CONTACT THE CODEX DELEGATE OR THE U.S. CODEX OFFICE.

This notice also solicits public comment on standards that are currently under consideration or planned for consideration and recommendations for new standards. The delegate, in conjunction with the responsible agency, will take the comments received into account in participating in the consideration of the standards and in proposing matters to be considered by Codex.

The U.S. delegate will facilitate public participation in the United States Government's activities relating to Codex. The U.S. delegate will maintain a list of individuals, groups, and organizations that have expressed an interest in the activities of the Codex Committees and will disseminate information regarding U.S. delegation activities to interested parties. This information will include the status of each agenda item; the U.S. Government's position or preliminary position on the agenda items; and the time and place of planning meetings and debriefing meetings following the Codex committee sessions. In addition, the U.S. Codex Office makes much of the same information available through its web page at *http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius.* If you would like to access or receive information about specific committees, please visit the web page or notify the appropriate U.S. delegate or the U.S. Codex Office, Room 4861, South Agriculture Building, 1400 Independence Avenue SW, Washington, DC 20250–3700 (*uscodex@fsis.usda.gov*).

The information provided in Attachment 1 describes the status of Codex standard-setting activities by the Codex Committees for the time periods from June 1, 2016, to May 31, 2017, and June 1, 2017, to July 20, 2018. Attachment 2 provides a list of U.S. Codex Officials (including U.S. delegates and alternate delegates). A list of forthcoming Codex sessions may be found at: *http://www.fao.org/fao-who-codexalimentarius/meetings/en/.*

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *http://www.fsis.usda.gov/federal-register.*

Done at Washington, DC.

Mary Frances Lowe,

U.S. Manager for Codex Alimentarius.

Attachment 1

Sanitary and Phytosanitary Activities of Codex

Codex Alimentarius Commission and Executive Committee

The Codex Alimentarius Commission convened for its 41st Session July 2–6, 2018, in Rome, Italy. At that time, the Commission adopted standards recommended by Committees at Step at 8 or Step 5/8 (final adoption), and it advanced the work of Committees by adopting draft standards at Step 5 (for further comment and consideration by the relevant committee). The Commission also considered proposals for new work; discontinuation of work; amendments to Codex standards and related texts; matters arising from the reports of the Commission, the Executive Committee and subsidiary bodies; committees working by correspondence and a possible pilot for a committee on standards advancement; regular review of Codex work management; Codex budgetary and financial matters for 2020–2021; FAO/WHO Scientific Support for Codex activities; matters arising from FAO and WHO; reports on side events on FAO and WHO capacity development activities, the Codex Trust Fund, and discussion panels with International Government Organizations and Non-Governmental Organizations; election of the chairperson and vice-chairpersons of Codex; and other business.

Before the Commission meeting, the Executive Committee met for its 75th Session from June 26 to 29, 2018. It is composed of the chairperson and vice-chairpersons of the CAC; seven members elected by the Commission from each of the following geographic regions: Africa, Asia, Europe, Latin America and the Caribbean, Near East, North America, and South-West Pacific; and regional coordinators from the six regional committees. The United States participated as the member elected on a geographic basis for North America. The Executive Committee conducted a critical review of the elaboration of Codex standards; reviewed the implementation status of the 2014–2019 Strategic Plan and preparation of the 2020–2025 Strategic Plan; and considered the work of committees working by correspondence and the possibility of a pilot for a committee on standards advancement, FAO/WHO Scientific Support for Codex work, other matters arising from FAO and WHO, and financial and budgetary issues.

Responsible Agency: USDA/TFAA/USCO.

U.S. Participation: Yes.

Codex Committee on Residues of Veterinary Drugs in Foods

The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) determines priorities for the consideration of residues of veterinary drugs in foods and recommends Maximum Residue Limits (MRLs) for veterinary drugs. The Committee also develops codes of practice, as may be required, and considers methods of sampling and analysis for the determination of veterinary drug residues in food. A veterinary drug is defined as any substance applied or administered to any food producing animal such as meat or milk producing animals, poultry, fish, or bees, whether used for therapeutic, prophylactic or diagnostic purposes, or for modification of physiological functions or behavior.

A Codex MRL for residues of veterinary drugs is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or ug/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be permitted or recognized as acceptable in or on a food. Residues of a veterinary drug include the parent compounds or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the veterinary drug concerned. An MRL is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI) or on the basis of a temporary ADI that utilizes an additional safety factor. When establishing an MRL, consideration is also given to residues that occur in food of plant origin or the environment. Furthermore, the MRL may be reduced to be consistent with official recommended or authorized usage, approved by national authorities, of the veterinary drugs under practical conditions.

An ADI is an estimate made by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) of the amount of a veterinary drug, expressed on a body weight basis, which can be ingested daily in food over a lifetime without appreciable health risk.

The Committee convened for its 24th Session (CCRVDF24) in Chicago, Illinois, April 23–27, 2018. The relevant document is REP18/RVDF. The following items were

adopted by the 41st Session of the Commission in July 2018:

Adopted at Step 5/8:

• Proposed draft MRLs for amoxicillin (finfish fillet, muscle); ampicillin (finfish fillet, muscle; lufenuron (salmon and trout fillet); monepantel (cattle fat, kidney, liver, muscle).

Adopted at Step 8:

• Draft Risk Management Recommendation for gentian violet.

Adopted at Step 5:

• Proposed draft MRL for flumethrin (honey).

The Commission also adopted the proposed amendment to the Risk Analysis Principles Applied by CCRVDF in the Codex *Procedural Manual,* and approved new work on the priority list of veterinary drugs for evaluation by the Joint Expert Committee on Food Additives, as recommended by CCRVDF24.

The Committee will continue working on the following items:

• Proposed draft MRLs for zilpaterol hydrochloride (cattle fat, kidney, liver, muscle);

• Draft Priority List of veterinary drugs requiring approval by CAC;

• Discussion paper on extrapolation of MRLs to one or more species (including a pilot on extrapolation of MRLs identified in Part D of the Priority List);

• Coordination with the Codex Committee on Pesticide Residues/Electronic Working Group on the revision of the Classification of Food and Feed for the development of a harmonized definition for edible offal/animal tissues for the establishment of MRLs;

• Database on countries needs for MRLs; and

• Discussion paper on advantages and disadvantages of a parallel approach to compound evaluation.

The following items were discontinued:

• Discussion paper on the revision of the criteria for the use of multi-residue analytical methods for the determination and identification of veterinary drugs in foods in the Guidelines for the design and implementation of national regulatory food safety assurance programs associated with the use of veterinary drugs in food producing animals; and

• Discussion paper on MRLs for groups of fish species.

Responsible Agencies: HHS/FDA/Center for Veterinary Medicine; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Contaminants in Foods

The Codex Committee on Contaminants in Foods (CCCF) establishes or endorses permitted maximum levels (MLs), as necessary, revises existing guideline levels (GLs) for contaminants and naturally occurring toxicants in food and feed; prepares priority lists of contaminants and naturally occurring toxicants for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA); considers and elaborates methods of analysis and sampling for the determination of contaminants and naturally occurring toxicants in food and feed; considers and elaborates on standards or codes of practice (COPs) for related subjects; and considers other matters assigned to it by the Commission in relation to contaminants and naturally occurring toxicants in food and feed.

The Committee convened for its 12th Session (CCCF12) in Utrecht, the Netherlands, March 12–16, 2018. The relevant document is REP18/CF. The following standards were forwarded to the CAC for consideration and adopted by the 41st Session of the Commission in July 2018:

Adopted at Step 5/8:

• MLs for lead in selected commodities (revision of MLs and consequential revocation of corresponding MLs/amendments to MLs in the General Standard for Contaminants and Toxins in Food and Feed (GSCTFF) (CXS 193–1995));

• MLs for cadmium in chocolate containing or declaring ≥50% to <70% total cocoa solids on a dry matter basis; and chocolate containing or declaring ≥70% total cocoa solids on a dry matter basis;

• MLs for methylmercury in tuna, alfonsino, marlin and shark, and revocation of the GLs for methylmercury in predatory and non-predatory fish;

• Amendment to the note for the ML on inorganic arsenic in rice (consequential amendment); and

• COP for the prevention and reduction of dioxins, dioxin-like PCBs and non-dioxin-like polychlorinated biphenyls (PCB) contamination in food and feed.

Adopted at Step 5:

• COP for the reduction of 3–MCPDE and GE in refined oils and products made with refined oils; and

• Guidelines for risk analysis of instances of contaminants in food where there is no regulatory level or risk management framework established.

The Commission also approved discontinuation of work on the following items, as recommended by CCCF12:

• Establishment of MLs for cadmium in dry mixtures of cocoa and sugars sold for final consumption; and

• Establishment of MLs for methylmercury in amberjack and swordfish.

The Committee suspended working on the following items:

• Establishment of MLs for total aflatoxins in ready-to-eat peanuts; and

• Establishment of MLs for total aflatoxins and ochratoxin A in nutmeg, chili and paprika, ginger, pepper and turmeric.

The Committee will continue working on the following items:

• MLs for lead in wine and edible offals;

• MLs for cadmium in chocolate and cocoa-derived products (category of chocolate and chocolate products containing or declaring (1) <30% and (2) ≥30% to <50% total cocoa solids on a dry matter basis;

• Discussion paper on establishment of MLs for hydrocyanic acid (HCN) in cassava and cassava-based products and occurrence of mycotoxins in these products;

• Discussion paper on structured approach to prioritize commodities for which new MLs for lead could be established for inclusion in the General Standard for Contaminants and Toxins in Food and Feed;

• Discussion paper on aflatoxins in cereals (establishment of MLs for total aflatoxins in wheat, maize, sorghum and rice (specifying the categories));

• Discussion paper on development of a COP for the prevention and reduction of cadmium contamination in cocoa;

• Discussion paper on forward workplan for CCCF; and

• Priority list of contaminants and naturally occurring toxicants for evaluation by JECFA.

The Committee also agreed to start discussion on the following items:

• Discussion paper on lead and cadmium in quinoa;

• Discussion paper on general guidance on data analysis for ML development; and

• Discussion paper, including a project document, for a proposal for new work on the revision of the COP for prevention and reduction of lead contamination in foods (CXC 56–2004).

Responsible Agencies: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Food Additives

The Codex Committee on Food Additives (CCFA) establishes or endorses acceptable maximum levels (MLs) for individual food additives; prepares a priority list of food additives for risk assessment by the Joint FAO/WHO Expert Committee on Food Additives (JECFA); assigns functional classes to individual food additives; recommends specifications of identity and purity for food additives for adoption by the Codex Alimentarius Commission; considers methods of analysis for the determination of additives in food; and considers and elaborates standards or codes of practice for related subjects such as the labeling of food additives when sold as such. The 50th Session of the Committee (CCFA50) convened in Xiamen, China, March 26–30, 2018. The relevant document is REP18/FA. Immediately prior to the Plenary Session, there was a two-day physical Working Group (PWG) on the General Standard for Food Additives (GSFA) chaired by the United States.

The following items were recommended by CCFA50 and considered by the 41st Session of the Commission in July 2018:

Adopted at Step 5/8:

• Proposed draft specifications for the identity and purity of food additives; and

• Proposed draft amendments to the *Class Names and International Numbering System (INS) for Food Additives* (CAC/GL 36–1989).

Adopted at Step 8 and 5/8:

• Draft and proposed draft food additive provisions of the GSFA.

Adopted:

• Replacement of the name ''sodium aluminosilicate'' with ''sodium aluminum silicate'' in the *GSFA* (CXS 192–1995); *Class Names and the INS for Food Additives* (CXG 36–1989); *Standard for Milk Powders and Cream Powder* (CXS 207–1999); *Standard for a Blend of Skimmed Milk and Vegetable Fat in Powdered Form* (CXS 251–2006); and *Standard for Edible Casein Products* (CXS 290–1995);

• Revised food additive provisions of the GSFA related to the alignment of the annexes of the Standard for Certain Canned Fruits

(CXS 319–2015) and to the alignment of 14 standards for fish and fish products; and

• Revised food additive sections of 14 standards for fish and fish products and the *Standard for Certain Canned Fruits* (CXS 319–2015).

Revoked:

• Food additive provisions of the GSFA;

• Food-additive provisions for specific malates and/or tartrates from the Standards for *Mozzarella* (CXS 262–2006), *Cottage Cheese* (CXS 273–1968), *Cream Cheese* (CXS 275–1973), *Fermented Milks* (CXS 243–2003), and *Dairy Fat Spreads* (CXS 253–2006) due to a lack of JECFA specifications for these additives; and

• Food-additive provisions for sodium sorbate (INS 201) from the Standards for *Instant Noodles* (CXS 249–2006), *Fermented Milks* (CXS 243–2003), *Dairy Fat Spreads* (CXS 253–2006), *Cottage Cheese* (CXS 273–1968), *Cream Cheese* (CXS 275–1973), the *General Standard for Cheese* (CXS 283–197), and 11 standards for named cheeses due to a lack of JECFA specifications for the additive.

The Committee will continue working on:

• Draft and proposed draft food additive provisions of the GSFA, and technological justification for the use of preservatives and anticaking agents for surface treatment of mozzarella with high moisture content covered by *Standard for Mozzarella* (CXS 262–2006) (EWG led by the United States);

• Proposals for additions and changes to the *Priority List of Substances Proposed for Evaluation by JECFA* (PWG led by Canada);

• Alignment of the food additive provisions of commodity standards and relevant provisions of the GSFA; consider revisions to the ''References to Commodity Standard for GSFA Table 3 Additives'' section of Table 3; proposed revisions to food-additive provisions in Food Categories 13.1.1, 13.1.2, and 13.1.3 for ascorbyl palmitate (INS 304) and ascorbyl stearate (INS 305) (EWG led by Australia, Japan and the United States);

• Revision of the Class Names and the INS for Food additives (EWG led by Iran and Belgium);

• New or revised provisions of the GSFA (PWG led by the United States);

• Clarification of the appropriate descriptors for Food Categories 14.1.4.2 and 14.1.5 for ready-to-drink coffee and tea beverages (Codex Secretariat);

• Review of all group food additives in the GSFA to determine if all food-additives in the group share a Group Acceptable Daily Intake (Codex Secretariat in consultation with JECFA Secretariat);

• Development of an inventory of data available on the use of nitrates (INS 251, 252) and nitrites (INS 249, 250) with a view to consulting with JECFA and CCFA regarding next steps (eWG led by the European Union and the Netherlands);

• Development of an alternative to Note 161 relating to the use of sweeteners and, subject to agreement on the wording of an alternative, review of recommendations in CX FA 14/47/13 in the context of pending and adopted provisions (EWG led by United States and the European Union); and

• Preparation of a discussion paper on the use of the terms ''fresh'', ''plain'', ''unprocessed'' and ''untreated'' in existing Codex texts (Russian Federation).

The Committee also agreed to hold a one and one-half day PWG on the GSFA immediately preceding the 51st Session of the CCFA, to be chaired by the United States. That group will discuss the recommendations of the EWG on the GSFA, new proposals and proposed revisions of food additive provisions in the GSFA.

The Committee also agreed to hold a half day PWG on the GSFA immediately preceding the 51st Session of the CCFA to be chaired by Australia. That group will discuss the recommendations of the PWG on alignment.

Responsible Agency: HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Pesticide Residues

The Codex Committee on Pesticide Residues (CCPR) is responsible for establishing MRLs for pesticide residues in specific food items or in groups of food; establishing MRLs for pesticide residues in certain animal feeding stuffs moving in international trade where this is justified for reasons of protection of human health; preparing priority lists of pesticides for evaluation by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR); considering methods of sampling and analysis for the determination of pesticide residues in food and feed; considering other matters in relation to the safety of food and feed containing pesticide residues; and establishing maximum limits for environmental and industrial contaminants showing chemical or other similarity to pesticides in specific food items or groups of food.

The 50th Session of the Committee (CCPR50) met in Haikou, China, April 9–14, 2018. The relevant document is REP18/PR. The following items were considered at the 41st Session of the Codex Alimentarius Commission in July 2018:

Adopted at Step 8 and 5/8:

• Three hundred eighty-six (386) MRLs for different pesticide residues.

• Revisions of the Classification: Class A—Primary Commodities of Plant Origin—Type 04 Nuts, Seeds, and SAPs (Step 8 and 5/8);

• Revision of the Classification: Class A-Primary Commodities of Plant Origin—Type 05 Herbs and Spices (Step 8).

Adopted at Step 5/8:

• Tables with Examples of Representative Commodities for Commodity Groups in Type 04 and Type 05 (For inclusion in the Principles and Guidance for the Selection of Representative Commodities for the Extrapolation of Maximum Residue Limits for Pesticides for Commodity Groups).

The Commission also discontinued work, approved new work, and revoked existing MRLs as recommended by CCPR50.

The Committee will continue working on the following items:

• Revision of the Classification: Impact of the Revised Commodity Groups and Subgroups in Type 03, Type 04 and Type 05 on the CXLs adopted by the Codex Alimentarius Commission;

• Draft and proposed draft Revision of the Classification of Food and Feed;

• Development of a system within the classification of food and feed to provide codes for commodities not meeting the criteria for crop grouping;

• Discussion Paper on the review of the International Estimated Short-term Intake Equations (IESTI);

• Discussion paper on management of unsupported compounds;

• Discussion paper on biopesticides;

• Discussion paper on the revision of the guidelines on the use of mass spectrometry for the identification, confirmation and quantitative determination of residues;

• Discussion paper on the opportunities and challenges related to the participation of JMPR in an international joint review of a new compounds;

• National Registration Database of Pesticides; and

• Establishment of Codex Schedules and Priority Lists of Pesticides.

Responsible Agencies: EPA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Food Import and Export Inspection and Certification Systems

The Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) is responsible for developing principles and guidelines for food import and export inspection and certification systems, with a view to harmonizing methods and procedures that protect the health of consumers, ensure fair trading practices, and facilitate international trade in foodstuffs; developing principles and guidelines for the application of measures by the competent authorities of exporting and importing countries to provide assurance, where necessary, that foodstuffs comply with requirements, especially statutory health requirements; developing guidelines for the utilization, as and when appropriate, of quality assurance systems to ensure that foodstuffs conform with requirements and promote the recognition of these systems in facilitating trade in food products under bilateral/multilateral arrangements by countries; developing guidelines and criteria with respect to format, declarations, and language of such official certificates as countries may require with a view towards international harmonization; making recommendations for information exchange in relation to food import/export control; consulting as necessary with other international groups working on matters related to food inspection and certification systems; and considering other matters assigned to it by the Commission in relation to food inspection and certification systems. The 24th Session of the Committee will convene in Brisbane, Australia, October 22–26, 2018.

The Committee will continue working on the following items:

• Project document for new work on guidance on paperless use of electronic certificates (*Revision of Guidelines for Design, Production, Issuance and Use of Generic Official Certificates*);

• Project document for new work on guidance on regulatory approaches to third party assurance schemes in food safety and fair practices in the food trade;

• Discussion paper on food integrity and food authenticity;
• Discussion paper on consideration of emerging issues and future directions for the work of the Codex Committee on Food Import and Export Inspection and Certification Systems;
• Framework for the preliminary assessment and identification of priority areas for CCFICs; and
• Inter-sessional physical working groups: trial.

Responsible Agencies: USDA/FSIS; HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Methods of Analysis and Sampling

The Codex Committee on Methods of Analysis and Sampling (CCMAS) defines the criteria appropriate to Codex Methods of Analysis and Sampling; serves as a coordinating body for Codex with other international groups working on methods of analysis and sampling and quality assurance systems for laboratories; specifies, on the basis of final recommendations submitted to it by the bodies referred to above, reference methods of analysis and sampling appropriate to Codex standards which are generally applicable to a number of foods; considers, amends if necessary, and endorses as appropriate, methods of analysis and sampling proposed by Codex commodity committees, except for methods of analysis and sampling for residues of pesticides or veterinary drugs in food, the assessment of microbiological quality and safety in food, and the assessment of specifications for food additives; elaborates sampling plans and procedures, as may be required; considers specific sampling and analysis problems submitted to it by the Commission or any of its Committees; and defines procedures, protocols, guidelines or related texts for the assessment of food laboratory proficiency, as well as quality assurance systems for laboratories.

The 39th Session of the Committee (CCMAS39) met in Budapest, Hungary, May 7–11, 2018. The relevant document is REP18/MAS.

At its 41st Session in July 2018, the Commission adopted, amended and revoked methods of analysis and sampling as recommended by CCMAS39. The Commission also approved new work as proposed by CCMAS:

• Revision of the Guidelines on Measurement Uncertainty (CXG 54–2004); and
• Project plan and amendment of the General Guidelines on Sampling (CXG 50–2004).

The Committee will continue working on the following item:

• Review/Revision of the General Standard for Methods of Analysis and Sampling (CSX 234.

At CCMAS 39, the Committee agreed to discontinue work on criteria for endorsement of biological methods to detect chemicals of concern.

Responsible Agencies: HHS/FDA; USDA/AMS.

U.S. Participation: Yes.

Codex Committee on Food Labelling

The Codex Committee on Food Labelling (CCFL) drafts provisions on labeling applicable to all foods; considers, amends, and endorses draft specific provisions on labeling prepared by the Codex Committees drafting standards, codes of practice, guidelines; and studies specific labeling problems assigned by the Codex Alimentarius Commission. The Committee also studies problems associated with the advertisement of food with particular reference to claims and misleading descriptions.

The Committee convened its 44th Session (CCFL44) in Asuncion, Paraguay, October 16–20, 2017. The relevant document is REP18/FL. The following item was adopted by the Commission at its 41st Session in July 2018, as recommended by CCFL44:

Adopted at Step 8:

• Draft Revision of the General Standard for the Labelling of Prepackaged Foods: Date marking.

The Committee will continue working on the following items:

• Proposed draft Guidance for the Labelling of Non-Retail Containers;
• Proposed draft Guidelines on Front of Pack Nutrition Labelling;
• Discussion paper on internet sales/e-commerce;
• Discussion paper on allergen labelling;
• Discussion paper on innovation—use of technology in food labelling;
• Discussion paper on labelling of alcoholic beverages;
• Discussion paper on criteria for the definition of ''high in'' nutritional descriptors for fats, sugars and sodium;
• Discussion paper on labelling of foods in joint presentation and multipack formats; and
• Discussion paper on future work and direction of CCFL (update).

Responsible Agencies: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Food Hygiene

The Codex Committee on Food Hygiene (CCFH):

• Develops basic provisions on food hygiene, applicable to all food or to specific food types;
• Considers and amends or endorses provisions on food hygiene contained in Codex commodity standards and codes of practice developed by Codex commodity committees;
• Considers specific food hygiene problems assigned to it by the Commission;
• Suggests and prioritizes areas where there is a need for microbiological risk assessment at the international level and develops questions to be addressed by the risk assessors; and
• Considers microbiological risk management matters in relation to food hygiene and in relation to the FAO/WHO risk assessments.

The Committee convened for its 49th Session (CCFH49) in Chicago, Illinois, November 13–17, 2017. The relevant document is REP 18/FH. The following item was adopted by the 41st Session of the Commission in July 2018, as recommended by CCFH49:

Adopted at Step 5/8:

• Proposed draft Revision of the *Code of Practice (COP) for Fish and Fishery Products (Guidance for histamine control),* with minor amendment accepted to section 13.1.2.

The Commission also approved new work as recommended by CCFH49:

• Code of Practice on food allergen management for food business operators; and
• Guidance for the management of (micro)biological foodborne crises/outbreaks.

The Committee will continue working on the following items:

• Proposed draft Revision of the *General Principles of Food Hygiene* and its HACCP Annex;
• The placement for the guidance on histamine control in CXC 52–2003, the amendments of other sections of CXC 52–3002, and the revision of the section on sampling, examination and analyses in standards for fish and fishery products related to histamine food safety;
• Discussion paper on future work on Shiga toxin-producing *Escherichia coli* (STEC); and
• New work proposals/Forward Workplan.

Responsible Agencies: HHS/FDA; USDA/FSIS.

U.S. Participation: Yes.

Codex Committee on Fresh Fruits and Vegetables

The Codex Committee on Fresh Fruits and Vegetables (CCFFV) is responsible for elaborating worldwide standards and codes of practice, as may be appropriate, for fresh fruits and vegetables, consulting as necessary, with other international organizations in the standards development process to avoid duplication.

The 20th Session of the Committee (CCFFV20) met in Kampala, Uganda, October 2–6, 2017. The relevant document is REP 18/FFV.

The following items were considered by the Commission at its 40th Session in July 2018, and the Commission took action as recommended by CCFFV20:

Adopted at Step 8:

• Draft Standard for Aubergines.

Adopted at Step 5:

• Draft Standard for Ware Potatoes.

Approved new work:

• Standards for yam, onions and shallots, and berry fruits.

The Committee will continue working on the following items:

• Proposed Layout for Standards for Fresh Fruits and Vegetables;
• Draft Standard for Garlic;
• Draft Standard for Kiwifruit;
• Draft Standard for Ware Potatoes;
• Proposed Draft Standard for Fresh Dates;
• Discussion paper on glossary of terms used in the layout for Codex standards for fresh fruits and vegetables; and
• Recommendation on the inclusion of mono and di-glycerides of fatty acids and salts of myristic, palmitic and stearic acids with ammonia, calcium, potassium and sodium in the GSFA under the food categories ''surface-treated fresh fruits'' and ''surface treated fresh vegetables.''

Responsible Agencies: USDA/Agricultural Marketing Service (AMS); HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Nutrition and Foods for Special Dietary Uses

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) is responsible for studying nutrition issues referred to it by the Codex Alimentarius Commission. The Committee also drafts general provisions, as appropriate, on nutritional aspects of all foods and develops standards, guidelines, and related texts for foods for special dietary uses, in cooperation with other committees where necessary; considers, amends if necessary, and endorses provisions on nutritional aspects proposed for inclusion in Codex standards, guidelines, and related texts.

The Committee convened for its 39th Session (CCNFSDU) in Berlin, Germany, December 4–8, 2017. The reference document is REP 18/NFSDU. The following item was adopted by the Commission at its 41st Session in July 2–6, 2018, as recommended by CCNFSDU39.

Adopted at Step 5:

• Review of the *Standard for Follow-up Formula:* Proposed ''Essential composition requirements for older infants and young children.''

The Committee will continue working on the following items:

• Proposed draft Claim for ''free of'' trans fatty acids;

• Discussion of biological methods used to detect chemicals of concern;

• Review of the Standard for Follow-up Formula: Scope, product definition, labelling;

• Proposed draft definition for biofortification;

• Proposed draft Nutrient Reference Values—Noncommunicable Disease (NRV–NCD) for EPA and DHA;

• Proposed draft guideline for ready to use therapeutic foods;

• Nutrient Reference Values—Requirements (NRV–R) for older infants and young children;

• Mechanism/framework for considering the technological justification of food additives;

• Discussion paper on harmonized probiotic guidelines for use in foods and dietary supplements; and

• General guidelines to establish nutritional profiles.

Responsible Agencies: HHS/FDA; USDA/Agricultural Research Service (ARS).

U.S. Participation: Yes.

Ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance (re-activated in 2016).

The Ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) is responsible for (1) reviewing and revising, as appropriate, the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CAC/RCP 61–2005) to address the entire food chain, in line with the mandate of Codex; and (2) considering the development of *Guidance on Integrated Surveillance of Antimicrobial Resistance,* taking into account the guidance developed by the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) and relevant World Organisation for Animal Health (OIE) documents. The objective of the Task Force is to develop science-based guidance on the management of foodborne antimicrobial resistance, taking full account of the WHO *Global Action Plan on Antimicrobial Resistance,* in particular objectives 3 and 4, the work and standards of relevant international organizations, such as FAO, WHO, and OIE, and the One-Health approach, to ensure members have the necessary guidance to enable coherent management of antimicrobial resistance along the food chain. The Task Force is expected to complete its work within three (or a maximum of four) sessions.

The Task Force will convene for its 6th Session (the 2nd Session since reactivation in 2016) in the Republic of Korea, December 10–14, 2018.

The Committee will continue to discuss:

• The Proposed draft Revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance;

• Proposed draft Guidelines on Integrated surveillance of Antimicrobial Resistance; and

• Request for Scientific Advice from Food and Agriculture Organization (FAO) and World Health Organization (WHO) in collaboration with OIE.

Responsible Agencies: FDA/USDA.

U.S. Participation: Yes.

Codex Committee on Fats and Oils

The Codex Committee on Fats and Oils (CCFO) is responsible for elaborating worldwide standards for fats and oils of animal, vegetable, and marine origin, including margarine and olive oil.

The Committee will convene in 2019 for its 26th Session.

The Committee will continue working on the following items:

• Revision of the *Standard for Named Vegetable Oils:* Essential composition of sunflower seed oils;

• Revision of the *Standard for Named Vegetable Oils:* Inclusion of walnut oil, almond oil, hazelnut oil, pistachio oil, flaxseed oil, and avocado oil;

• Revision of the *Standard for Named Vegetable Oils:* Replacement of acid value with free fatty acids for virgin palm oil and inclusion of free fatty acids for crude palm kernel oil; and

• Revision of the *Standard for Olive Oils and Pomace Olive Oils* (Codex Stan 33–1981).

• Gathering information on technical difficulties in the implementation of the fish oil standard, specifically on monitoring its application with respect to the conformity of named fish oils with the requirements (especially the fatty acid profile), and its effect on trade;

• Alignment of food additives provisions in standards for fats and oils (except fish oils) and technological justification for use of emulsifiers;

• Proposals for new substances to be added to the list of acceptable previous cargoes;

• Provision of relevant information (if available from Member countries) to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) on the 23 substances on the list of acceptable previous cargoes currently on the list; and

• Discussion paper on the applicability of the fatty acid composition of all oils listed in Table 1 in relation to the fatty acid composition of corresponding crude (unrefined) forms in the *Standard for Named Vegetable Oils.*

Responsible Agencies: HHS/FDA; USDA/Agricultural Research Service (ARS).

U.S. Participation: Yes.

Codex Committee on Processed Fruits and Vegetables

The Codex Committee on Processed Fruits and Vegetables (CCPFV) is responsible for elaborating worldwide standards and related texts for all types of processed fruits and vegetables including, but not limited to canned, dried, and frozen products, as well as fruit and vegetable juices and nectars. Proposals for new work were received by Executive Committee of the Codex Alimentarius Commission (CCEXEC) and approved by CAC40 (July 17–22, 2017) for cashew kernels, chili sauce, mango chutney, dried sweet potato, gochujang, dried fruits, and canned mixed fruits.

The Commission authorized CCPFV to work by correspondence until CAC 41 (2018) to prioritize the proposals for new work, prepare a work plan, and prepare recommendations on the establishment of electronic working groups. The Commission at its 41st Session in July 2018 endorsed the CCPFV Chairperson's proposed work plan and recommendations (1) to establish 7 EWGS to prepare proposed drafts for comments and consideration by the CCPFV, and (2) to schedule a physical meeting of the Committee at an appropriate time.

Responsible Agencies: USDA/Agricultural Marketing Service; HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Sugars

The Codex Committee on Sugars (CCS) elaborates worldwide standards for all types of sugars and sugar products.

The Committee has been re-activated to work by correspondence on a draft *Standard for Non-Centrifuged Dehydrated Sugar Cane Juice.* The work is behind schedule. The Commission at its 41st Session in July 2018 agreed to extend the work by correspondence by one year, reporting back to the Commission at its 42nd session, and noted the possibility that a physical meeting could be convened.

Responsible Agencies: HHS/FDA.

U.S. Participation: Yes.

Codex Committee on Cereals, Pulses and Legumes

The Codex Committee on Cereals, Pulses and Legumes (CCCPL) elaborates worldwide standards and/or codes of practice, as appropriate, for cereals, pulses and legumes and their products.

The Committee has been reactivated to work by correspondence to draft an international Codex Standard for quinoa. The following item was considered by the Commission at its 41st Session in July 2018:

• Standard for Quinoa

The Commission agreed to adopt, subject to the endorsement of the labelling

provisions by CCFL45, the draft standard for quinoa at Step 8, except for the provisions for moisture content and grain size, which were returned to Step 6. The Commission also established an EWG, chaired by Costa Rica and co-chaired by Chile and the United States of America, to continue the work on the provisions for moisture content and grain size. The Commission further encouraged members to identify a validated method of analysis for saponins to allow for full implementation of the standard.

Responsible Agencies: HHS/FDA.

U.S. Participation: Yes.

Certain Codex Commodity Committees

Several Codex Alimentarius Commodity Committees have adjourned *sine die.* The following Committees fall into this category:

• Cocoa Products and Chocolate—adjourned 2001.

Responsible Agency: HHS/FDA; DCO/NOAA.

U.S. Participation: Yes.

• Fish and Fishery Products—adjourned 2016.

Responsible Agency: HHS/FDA/NOAA.

U.S. Participation: Yes.

• Meat Hygiene—adjourned 2003.

Responsible Agency: USDA/FSIS.

U.S. Participation: Yes.

• Milk and Milk Products—adjourned 2017.

Responsible Agency: USDA/AMS; HHS/FDA.

U.S. Participation: Yes.

• Natural Mineral Waters—adjourned 2008.

Responsible Agency: HHS/FDA.

U.S. Participation: Yes.

• Vegetable Proteins—adjourned 1989.

Responsible Agency: USDA/ARS.

U.S. Participation: Yes.

FAO/WHO Regional Coordinating Committees

The FAO/WHO Regional Coordinating Committees define the problems and needs of the regions concerning food standards and food control; promote within the Committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from food control and stimulate the strengthening of food control infrastructures; recommend to the Commission the development of worldwide standards for products of interest to the region, including products considered by the Committees to have an international market potential in the future; develop regional standards for food products moving exclusively or almost exclusively in intra-regional trade; draw the attention of the Commission to any aspects of the Commission's work of particular significance to the region; promote coordination of all regional food standards work undertaken by international governmental and non-governmental organizations within each region; exercise a general coordinating role for the region and such other functions as may be entrusted to them by the Commission; and promote the use of Codex standards and related texts by members.

There are six regional coordinating committees:

Coordinating Committee for Africa

Coordinating Committee for Asia

Coordinating Committee for Europe

Coordinating Committee for Latin America and the Caribbean

Coordinating Committee for the Near East

Coordinating Committee for North America and the South West Pacific

Coordinating Committee for Africa

The Committee (CCAFRICA) will convene its 23rd Session in 2019.

The Committee will continue to work on the following items:

• Proposed draft Regional Standard for Unrefined Shea Butter;

• Proposed draft Regional Standard for Fermented Cooked Cassava Based Products;

• Proposed draft Regional Standard for Gnetum Spp leaves;

• Priority Setting criteria for the establishment of work priorities as laid down in the Codex *Procedural Manual;*

• Comments on the preparation of the new global Codex Strategic Plan;

• Food quality and safety situation in countries of the Region (on-line platform, prioritization of needs in the region and comments for future consideration);

• Use of Codex Standards in the Region;

• Proposed draft Standard on Dried Meat;

• Discussion paper and project document on a Harmonized Food Law; and

• Discussion paper/project on a Regional Standard for a Fermented Non-Alcoholic Cereal Based Drink (Mahewu).

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: Yes (as observer).

Coordinating Committee for Asia

The Committee (CCASIA) will convene its 21st Session in 2019.

The Committee will continue to work on the following items:

• Report on the status of the Implementation of the Activities of the Strategic Plan Relevant to CCASIA;

• Discussion paper and project document on the Development of a Regional Standard for Rice Based Low Alcohol Beverages (cloudy types);

• Discussion paper and project document on the Development of a Regional Standard for Soybean Products Fermented with the Bacterium Bacillus Subtilis;

• Discussion paper and project document on the Development of a Regional Standard for Quick Frozen Dumpling (Jiaozi);

• Discussion paper and the project document on the Development of a Regional Standard/Code of Practice for Zongzi;

• Emerging Issues as priorities for the CCASIA region; and

• Information sharing on the Food Safety Control Systems.

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: Yes (as observer).

Coordinating Committee for Europe

The Committee (CCEUROPE) will convene its 31st Session in 2019.

The Committee will continue to work on the following items:

• Survey of critical and emerging issues;

• On-line Platform and information sharing on the Food Safety Control Systems;

• Survey on the use of Codex Standards;

• Relevant languages of the Codex Alimentarius Commission in the work of CCEUROPE; and

• Funding translation and interpretation services into Russian for the effective operation of CCEUROPE.

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: Yes (as observer).

Coordinating Committee for Latin America and the Caribbean

The Coordinating Committee for Latin America and the Caribbean (CCLAC) will convene its 21st in 2019.

The Committee will continue to work on the following items:

• Monitoring of the Strategic Plan for CCLAC;

• Critical and Emerging Issues and prioritization of CCLAC issues within the framework of Codex;

• Comments on the Food Safety Control Systems Platform;

• Cross-cutting topics for the region, proposed draft standards and seeking regional support; and

• Proposal for the Development of a Standard for Yams.

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: Yes (as observer).

Coordinating Committee for the Near East

The Coordinating Committee for the Near East (CCNEA) will convene its 10th Session in 2019.

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: No.

Coordinating Committee for North America and the South West Pacific (CCNASWP)

The Committee (CCNASWP) will convene its 15th Session in 2019.

The Committee will continue to work on the following items:

• New work on the development of a Regional Standard for Kava as a beverage when mixed with cold water;

• Recommendation that Vanuatu be re-appointed as Coordinator for North America and the South West Pacific;

• Proposed draft Regional Standard for Fermented Noni-Juice; and

• Development of on-line platform for information on sharing food quality and safety systems.

Responsible Agency: USDA/FSIS/USCO.

U.S. Participation: Yes.

Contact: U.S. Codex Office, United States Department of Agriculture, Room 4861, South Agriculture Building, 1400 Independence Avenue SW, Washington, DC 20250–3700, Phone: (202) 205–7760, Fax: (202) 720–3157, Email: *uscodex@fsis.usda.gov*.

Attachment 2

U.S. Codex Alimentarius Officials

Codex Chairpersons From the United States

Codex Committee on Food Hygiene

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Codex Committee on Processed Fruits and Vegetables

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Codex Committee on Residues of Veterinary Drugs in Foods

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U.S. Delegates and Alternate Delegates

Worldwide General Codex Subject Committees

Contaminants in Foods

(Host Government—The Netherlands)

U.S. Delegate

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Alternate Delegate

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Food Additives

(Host Government—China)

U.S. Delegate

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Alternate Delegate

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Food Hygiene

(Host Government—United States)

U.S. Delegate

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Food Import and Export Certification and Inspection Systems

(Host Government—Australia)

U.S. Delegate

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Food Labelling

(Host Government—Canada)

U.S. Delegate

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Alternate Delegate

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General Principles

(Host Government—France)

Delegate Note: A member of the Steering Committee heads the delegation to meetings of the General Principles Committee.

Methods of Analysis and Sampling

(Host Government—Hungary)

U.S. Delegate

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Nutrition and Foods for Special Dietary Uses

(Host Government—Germany)

U.S. Delegate

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Alternate Delegate

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Pesticide Residues

(Host Government—China)

U.S. Delegate

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Alternate Delegate

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Residues of Veterinary Drugs in Foods

(Host Government—United States)

U.S. Delegate

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Alternate Delegate

Vacant

Worldwide Commodity Codex Committees (Active)

Cereals, Pulses and Legumes

(Host Government—United States)

U.S. Delegate

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Fats and Oils

(Host Government—Malaysia)

U.S. Delegate

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Alternate Delegate

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Fresh Fruits and Vegetables

(Host Government—Mexico)

U.S. Delegate

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Processed Fruits and Vegetables

(Host Government—United States)

U.S. Delegate

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Spices and Culinary Herbs

(Host Government—India)

U.S. Delegate

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Alternate Delegate

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Sugars

(Host Government—United Kingdom)

U.S. Delegate

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Worldwide Ad Hoc Codex Task Forces (Active)

Antimicrobial Resistance (Reactivated 2016)

(Host Government—Republic of Korea)

U.S. Delegate

Donald A. Prater, DVM, Assistant Commissioner for Food Safety Integration, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993, Phone: +1–301–348–3007, *Donald.Prater@fda.hhs.gov*.

Alternate Delegate

Neena Anandaraman, DVM, MPH, Veterinary Science Policy Advisor, Office of Chief Scientist, U.S. Department of Agriculture, Jamie L. Whitten Building, Room 339A, 1200 Independence Avenue SW, Washington, DC 20024, Phone: +1 (202) 260–8789, *Neena.Anandaraman@osec.usda.gov*.

Worldwide Commodity Codex Committees (Adjourned)

Cocoa Products and Chocolate (adjourned *sine die* 2001)

(Host Government—Switzerland)

U.S. Delegate

Michelle Smith, Ph.D., Senior Policy Analyst, Office of Food Safety, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration (HFS–317), Harvey W. Wiley Federal Building, 5001 Campus Drive, College Park, MD 20740–3835, Phone: +1 (240) 402–2024, Fax: +1 (301) 436–2632, *Michelle.Smith@fda.hhs.gov*.

Fish and Fishery Products (adjourned *sine die* 2016)

(Host Government—Norway)

U.S. Delegate

Dr. William R. Jones, Deputy Director, Office of Food Safety (HFS–300), U.S. Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, Phone: +1 (240) 402–2300, Fax: +1 (301) 436–2601, *William.Jones@fda.hhs.gov*.

Alternate Delegate

Steven Wilson, Deputy Director, Office of International Affairs and Seafood Inspection, National Marine Fisheries Service, NOAA, U.S. Department of Commerce, 1315 East-West Highway, Silver Spring, Maryland 20910, Phone: +1 (301) 427–8312 *Steven.Wilson@noaa.gov*.

Meat Hygiene (adjourned *sine die* 2003)

(Host Government—New Zealand)

U.S. Delegate

Vacant

Milk and Milk Products (adjourned *sine die* 2017)

(Host Government—New Zealand)

U.S. Delegate

Christopher Thompson, Dairy Standardization Branch, Mail Stop 0230, Room 2756, Agricultural Marketing Service, U.S. Department of Agriculture, 1400 Independence Avenue SW, Washington, DC 20250, Phone: +1 (202) 720–9382, Fax: +1 (844) 804–4701, *Christopher.D.Thompson@ams.usda.gov*.

Alternate Delegate

John F. Sheehan, Director, Division of Dairy, Egg and Meat Product Safety, Office of Food Safety, Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration (HFS–315), Harvey W. Wiley Federal Building, 5001 Campus Drive, College Park, MD 20740, Phone: +1 (240) 402–1488, Fax: +1 (301) 436–2632, *John.Sheehan@fda.hhs.gov*.

Natural Mineral Waters (adjourned *sine die* 2008)

(Host Government—Switzerland)

U.S. Delegate

Dr. Yinqing Ma, Branch Chief, Beverages Branch, Division of Plant Products and Beverages, Office of Food Safety (HFS–317), Center for Food Safety and Applied Nutrition, U.S. Food and Drug

Administration, 5001 Campus Drive, College Park, MD 20740, Phone: +1 (240) 402–2479, Fax: +1 (301) 436–2632, *Yinqing.Ma@fda.hhs.gov.*

Vegetable Proteins (adjourned *sine die* 1989)

(Host Government—Canada)

U.S. Delegate

Vacant

Ad Hoc Intergovernmental Task Forces (Dissolved)

Animal Feeding (Dissolved 2013)

(Host government—Switzerland)

U.S. Delegate

Vacant

[FR Doc. 2018–16944 Filed 8–7–18; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Tongass National Forest; Ketchikan Misty Fjords Ranger District; Alaska; South Revillagigedo Integrated Resource Project Environmental Impact Statement

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Forest Service will prepare an Environmental Impact Statement (EIS) for the South Revillagigedo Integrated Resource Project (South Revilla IRP) which proposes to harvest timber, restore watershed function, enhance or restore fish and wildlife habitat, and develop recreation opportunities using an integrated approach in the Shelter Cove, Shoal Cove, and Thorne Arm areas within the Ketchikan Misty Fjords Ranger District, Tongass National Forest. The Proposed Action would harvest about 60 million board feet of timber from up to 6,000 acres over the course of 15 years. In addition, transportation management activities such as road construction, reconstruction, maintenance, and decommissioning are proposed. At the same time that it would approve the proposed project, the Forest Service may approve a project-specific Forest Plan amendment to ensure the project is consistent with the Plan.

DATES: Comments concerning the scope of the analysis must be received by September 7, 2018. Designated opportunities for additional comments will be provided. The draft EIS, is expected to be published July 2019. A final EIS is expected July, 2020.

ADDRESSES: Send or hand-deliver specific written comments to the Ketchikan Misty Fjords Ranger District, Attn: South Revilla IRP, 3031 Tongass Avenue, Ketchikan, Alaska 99901; telephone (907) 225–2148. The FAX number is (907) 225–8738. Comments may be emailed to: *comments-alaska-tongass-ketchikan-mistyfiord@fs.fed.us* with South Revilla IRP in the subject line. In all correspondence, include your name, address, and organization name if you are commenting as a representative of an organization.

FOR FURTHER INFORMATION CONTACT: Susan Howle, District Ranger, Ketchikan Misty Fjords Ranger District, 3031 Tongass Avenue, Ketchikan, Alaska 99901; Daryl Bingham, Planning Staff, (907) 228–4114, or Damien Zona, Interdisciplinary Team Leader, (907) 228–4126. Individuals who use telecommunication devices for the deaf may call the Federal Information Relay Service at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: This EIS will tier to and incorporate by reference the 2016 Tongass Land and Resource Management Plan Final EIS. The project area is located on Revillagigedo Island, approximately 17 miles northeast of Ketchikan, Alaska, within the Ketchikan Misty Fjords Ranger District, Tongass National Forest and encompasses about 58,159 acres of National Forest System lands.

Purpose and Need for Action

The purpose of the South Revilla IRP is to implement the 2016 Tongass Land and Resource Management Plan (Forest Plan) direction to move the project area toward the desired future conditions described in that plan. More specifically, the purpose is to manage the timber resource for production of sawtimber and other wood products, improve ecosystem and watershed health, and provide a range of recreation opportunities to meet public and tourism business demand through an integrated approach to meet multiple resource objectives. Maintaining existing, and expanding opportunities for the recreation and tourism sector would contribute to the local economy.

There is a need to provide a sustainable level of forest products to contribute to the economic sustainability of the region. Providing old-growth timber would preserve a viable timber industry during the transition to young-growth management and would provide jobs and opportunities for Southeast Alaska residents. Past management activities have affected watershed function in the project area. There is a need to improve and restore the natural range of habitat conditions in the project area to support viable wildlife, fish, and plant populations and to sustain diversity and production. Restoration would contribute to traditional, cultural, and subsistence uses by residents of Southeast Alaska. There is a need to provide sustainable recreation opportunities to a diverse and growing group of forest users. A sustainable recreation program in terms of operations and maintenance is needed to maintain infrastructure at an acceptable level.

Proposed Action

The Forest Service proposes to harvest timber, construct and reconstruct roads, restore watershed function, enhance or restore fish and wildlife habitat, and develop recreation opportunities in the Shelter Cove, Shoal Cove and Thorne Arm areas within the Ketchikan Misty Fjords Ranger District, Tongass National Forest. The project area includes the following land use designations (LUDs): Wilderness, Semi-remote Recreation, Old-growth Habitat, Special Interest Area, Scenic River, Modified Landscape, and Timber Production (Forest Plan, Chapter 3). Proposed activities will be consistent with Forest Plan direction. A proposed action map and information on the 2018 Shelter Cove and Saddle Lakes Recreation Area Master Plan is provided on the project web page at: *https://www.fs.usda.gov/project/?project=53477.*

Forest and Transportation Management

The Forest Service proposes to harvest about 60 million board feet of old-growth timber from up to 6,000 acres of forested land in the Modified Landscape and Timber Production LUDs using one or more timber sales, with activities that would occur over the course of 15 years. The Proposed Action would construct about 30 miles of new National Forest System road and reconstruct about 104 miles of existing roads. Temporary road construction would include about 105 miles. Existing rock quarries would be used as available or new quarries would be developed as necessary to provide raw materials for road construction. Existing log transfer facilities at Shelter Cove and Shoal Cove could be used. Young-growth harvest may be considered during this planning phase if it meets the purpose and need of the Proposed Action.

Watershed and Wildlife Habitat Management

Watershed enhancement and restoration activities would include instream and floodplain wood

placement, riparian thinning, blasting of a partial fish barrier, invasive plant management and culvert replacement/removal. Wildlife habitat treatments would move habitat toward favorable wildlife conditions and will be planned based on project design and identified needs.

Recreation Management

Recreation opportunities will be developed using the 2018 Shelter Cove and Saddle Lakes Recreation Area Master Plan and ongoing public input. The Proposed Action will be refined through public involvement to meet the Purpose and Need for the project and consistency with the Forest Plan. The 2008 Access and Travel Management Plan and its associated Motor Vehicle Use map would be reviewed and updated as needed.

Proposed Forest Plan Amendment

The 2012 Planning Rule (36 CFR 219.13(b)(2)) requires the Responsible Official to identify which substantive requirements of the Rule are likely to be directly related to a proposed land management plan amendment (36 CFR 219.13(b)(5) and 36 CFR 219.8 through 219.11) in the initial notice for the amendment (36 CFR 219.16(a)(1)). At this time, the Responsible Official believes that a modification to Scenic Integrity Objectives in the Forest Plan may be necessary for this project (see Possible Alternatives section.)

Possible Alternatives

Scoping comments will be used to develop a range of alternatives to the Proposed Action in response to significant issues that are identified. A No-action Alternative will be analyzed as the baseline for comparison of action alternatives. Other alternative(s) may include a project-specific Tongass Forest Plan amendment to lower the Scenic Integrity Objectives (Forest Plan, p. 4–54 to 4–56), if needed, on portions of timber analysis areas in the project area to meet the Purpose and Need. If included in the South Revilla IRP, this plan amendment would only apply to the commercial timber sales undertaken as part of this specific project only; therefore, the notification requirements and objection procedures of 36 CFR 218, subparts A and B, apply rather than the notification requirements of 36 CFR 219. The 2012 Planning Rule (36 CFR 219.13(b)(2)) requires the Responsible Official to identify which substantive requirements of the Rule are likely to be directly related to the a proposed land management plan amendment. At this time, the Responsible Official believes the following requirements of the Rule are likely to apply to an amendment that would modify the Scenic Integrity Objectives of the Forest Plan for this project: 36 CFR 219.8(b)(2); 36 CFR 219.10(a)(1); and 36 CFR 219.10(b)(1)(i).

Lead and Cooperating Agencies

The Forest Service will be the lead agency for this project. Invited cooperating agencies include: Ketchikan Indian Community, Organized Village of Saxman, Metlakatla Indian Community, State of Alaska Department of Fish and Game, State of Alaska Department of Forestry, and Ketchikan Gateway Borough.

Responsible Official

The Responsible Official for this project is M. Earl Stewart, Forest Supervisor, Tongass National Forest.

Nature of Decision To Be Made

Given the Purpose and Need, the Forest Supervisor will review alternatives, and consider the environmental consequences to make decisions including: (1) Whether to select the Proposed Action or another alternative; (2) the locations, design, and scheduling of restoration activities, habitat improvements, road construction and reconstruction, and recreation development or decommissioning opportunities; (3) mitigation measures and monitoring; (4) whether there may be a significant restriction to subsistence resources; and (5) whether a project-specific Forest Plan amendment to lower Scenic Integrity Objectives (Forest Plan, p. 4–54 to 4–57) is necessary.

Preliminary Issues

Preliminary concerns identified by the interdisciplinary team include: (1) Designing an economical timber sale(s) that meets market demand; (2) effects of Forest Plan scenery direction on the ability to design an economical timber sale; (3) effects of timber harvest and road construction on wildlife habitat and travel corridors; (4) effects of timber harvest and road construction on watershed condition; (5) effects of timber harvest and road construction to rare and sensitive plants; and (6) effects of herbicide use on other resources.

Permits or Licenses Required

All necessary permits will be obtained prior to project implementation.

Scoping Process

This Notice of Intent initiates the scoping process, which guides the development of the EIS. To help determine the location and types of activities, and how they will occur across the landscape, the Forest Service is seeking information, comments, and assistance from Tribal Governments; Federal, State, and local agencies; stakeholders, individuals and organizations interested in or affected by the proposed activities. In addition, a legal notice will be published in the *Ketchikan Daily News,* the newspaper of record for this project. A scoping document has been prepared and will be distributed to interested parties who have subscribed through an electronic mailing list to receive project information. Individuals and organizations wishing to subscribe may do so at *https://public.govdelivery.com/accounts/USDAFS/subscriber/new?preferences=true.*

Additionally, there will be in-person opportunities for involvement including open houses and subsistence hearings held in Ketchikan, Alaska. Project information, meeting announcements, legal notices, and documents will be provided on the project web page at: *https://www.fs.usda.gov/project/?project=53477.*

Forest Service regulations at 36 CFR part 218, subparts A and B (78 FR 18481–18504) regarding the project-level predecisional administrative review process applies to projects and activities implementing land management plans that are not authorized under the Healthy Forests Restoration Act. The South Revilla IRP is an activity implementing the Forest Plan and is subject to 36 CFR 218.

Only individuals or entities who submit timely and specific written comments concerning this project during this or another public comment period established by the Responsible Official will be eligible to file an objection. It is important that reviewers provide their comments at such times and in such manner that they are useful to the agency's preparation of the EIS. Therefore, comments should be provided prior to the close of the comment period and should clearly articulate the reviewer's concerns and contentions.

Comments received in response to this solicitation, including names and addresses of those who comment, will be part of the public record for this proposed action. Comments submitted anonymously will be accepted and considered. Anonymous commenters will not gain standing to object as defined in 36 CFR 218.2.

Dated: July 26, 2018.

Chris French,

Associate Deputy Chief, National Forest System.

[FR Doc. 2018–16884 Filed 8–7–18; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

Agency: U.S. Census Bureau.

Title: Business and Professional Classification Report.

OMB Control Number: 0607–0189.

Form Number(s): SQ–CLASS.

Type of Request: Extension of a currently approved collection.

Number of Respondents: 57,000.

Average Hours per Response: 13 minutes.

Burden Hours: 12,350.

Needs and Uses: This request is for continued clearance of the Business and Professional Classification Report (SQ–CLASS). The primary purpose of SQ–CLASS Report is to meet the ongoing sample needs of the Census Bureau's various surveys of the retail trade, wholesale trade, and services portions of the economy (our current business surveys) as defined by the North American Industry Classification System (NAICS). The data collected by the SQ–CLASS report are used to update the samples in our current business surveys to reflect newly opened establishments. Additionally, establishments in the five-year economic census will receive data collection instruments specifically tailored to their industry based on the classification information obtained by the SQ–CLASS report.

To keep current with rapid changes in the marketplace caused by new businesses (a.k.a. births) the Census Bureau samples newly assigned Employer Identification Numbers (EINs) obtained from the Internal Revenue Service. Each EIN can only be selected once for the SQ–CLASS report. Companies are selected for the SQ–CLASS sample based on the presence of a newly filed application for an EIN. Companies in the sample are asked to provide data about the establishment(s) associated with the new EIN including a more reliable measure of size, consisting of sales in two recent months, company affiliation information, a new or more detailed industry classification code, and other key information needed to maintain proper coverage of the business universe on the Business Register for the current business surveys.

Based on information collected on the SQ–CLASS form, EINs meeting the criteria for inclusion in the Census Bureau's current business surveys may be eligible for a second phase of sampling. Companies with new EINs selected in this second sampling are asked to report annually on the annual retail, wholesale, and service surveys. A subsample of the wholesale and retail EINs also may be added to the monthly retail and wholesale surveys. Similarly, a subsample of companies with new EINs in the service industries are asked to report in the quarterly services surveys.

The Economic Census and the current business surveys represent the primary source of facts about the structure and function of the U.S. economy, providing essential information to government and the business community in making sound decisions. This information helps build the foundation for the calculation of Gross Domestic Product (GDP) and other economic indicators. Crucial to its success are the accuracy and reliability of the Business Register, which provides the Economic Census and current business surveys with their establishment lists. Critical to the quality of information housed in the Business Register is that each of the statistical units has an accurate industry classification, measure of size, activity status, and physical address assigned to it. The vital information obtained from the SQ–CLASS report is fed back to the Business Register to represent changes in industries and confirm coverage between the years of the Economic Census.

We are not proposing any major changes to the collection. Minimal changes are being made to the economic activity descriptions in the primary business activity question on the SQ–CLASS report. These changes include providing additional examples of activities included in a specific economic sector. Respondents will continue to choose the economic sector of their business and then select their type of business from a list of business activities based on their response to the question about their economic sector. These selections correspond to NAICS codes, which are then assigned to each business establishment. If the respondents do not see their business activity listed, then they will provide a brief description of their business activity. The response is then assigned a NAICS code by an analyst using an automated coding tool. This is the same methodology that the Census Bureau uses in the Economic Census to assign industry classification.

Affected Public: Business or other for-profit; not-for-profit institutions.

Frequency: One time.

Respondent's Obligation: Mandatory.

Legal Authority: The Census Bureau conducts this survey under the authority of Title 13, U.S.C., Sections 131, 182, and 193. This collection is made mandatory under the provisions of Title 13 U.S.C., Sections 224 and 225.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Sheleen Dumas,

Departmental Lead PRA Officer, Office of the Chief Information Officer.

[FR Doc. 2018–16915 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[07/18/2018 through 07/31/2018]

Firm name	Firm address	Date accepted for investigation	Product(s)
Ashland Foundry & Machine Works, LLC.	500 East Centre Street, Ashland, PA 17921.	7/24/2018	The firm manufactures ferrous and non-ferrous cast parts, primarily for pumps, including pump impellers, stuffing boxes, and suction covers.
Crestwood Pools, Inc	220 Stage Road, Vestal, NY 13850.	7/26/2018	The firm manufactures above-ground wood-wall pools, spas, exercise tanks, and related components.
T.A. Pelsue Company d/b/a Pelsue Equipment Company, Inc.	2500 South Tejon Street, Englewood, CO 80110.	7/26/2018	The firm manufactures custom vehicles and trailers for the communications industry, as well as related equipment including work tents, portable ventilators, and manhole equipment.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Irette Patterson,

Program Analyst.

[FR Doc. 2018–16892 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

First Responder Network Authority Combined Committee and Board Meeting

AGENCY: First Responder Network Authority (''FirstNet Authority''), U.S. Department of Commerce.

ACTION: Notice of open public meetings.

SUMMARY: The Board of the First Responder Network Authority (''FirstNet Authority Board'') will convene a meeting of the FirstNet Authority Board and the Committees of the FirstNet Authority Board (''Board Committees'') that will be open to the public via teleconference and WebEx on August 13, 2018.

DATES: A combined meeting of the Board Committees and the FirstNet Authority Board will be held on August 13, 2018, between 11:00 a.m. and 12:00 p.m., Eastern Daylight Time (EDT). The meeting of the FirstNet Authority Board and the Governance and Personnel, Technology, Public Safety Advocacy, and Finance Committees will be open to the public via teleconference and WebEx only from 11:00 a.m. to 12:00 p.m. EDT.

ADDRESSES: The combined meeting of the FirstNet Authority Board and Board Committees will be conducted via teleconference and WebEx only. Members of the public may listen to the meeting by dialing toll free 1–877–917–6910 and using passcode 3324054. To view the slide presentation, the public may visit the URL: *https://www.mymeetings.com/nc/join/* and enter Conference Number: PWXW7911812 and Audience Passcode: 3324054. Alternatively, members of the public may view the slide presentation by directly visiting the URL: *https://www.mymeetings.com/nc/join.php?i=PWXW7911812&p=3324054&t=c.*

FOR FURTHER INFORMATION CONTACT: Karen Miller-Kuwana, Board Secretary, FirstNet Authority, 12201 Sunrise Valley Drive, M/S 243, Reston, VA 20192; telephone: (571) 665–6177; email: *Karen.Miller-Kuwana@firstnet.gov*. Please direct media inquiries to Ryan Oremland at (571) 665–6186.

SUPPLEMENTARY INFORMATION: This notice informs the public that the FirstNet Authority Board and Board Committees will convene a combined meeting open to the public via teleconference and WebEx only on August 13, 2018.

Background: The Middle Class Tax Relief and Job Creation Act of 2012 (47 U.S.C. 1401 *et seq.*)) (''the Act'') established the FirstNet Authority as an independent authority within the National Telecommunications and Information Administration that is headed by a Board. The Act directs the FirstNet Authority to ensure the building, deployment, and operation of a nationwide, interoperable public safety broadband network. The FirstNet Authority Board is responsible for making strategic decisions regarding the FirstNet Authority's operations. The FirstNet Authority Board held its first public meeting on September 25, 2012.

Matters to be Considered: The FirstNet Authority will post a detailed agenda for the combined meeting of the Board Committees and FirstNet Authority Board meeting on its website, *http://www.firstnet.gov,* prior to the meetings. The agenda topics are subject to change. Please note that the subjects that will be discussed by the Board Committees and the FirstNet Authority Board may involve commercial or financial information that is privileged or confidential or other legal matters affecting the FirstNet Authority. As such, the Board Committee Chairs and

Board Chair may call for a vote to close the meetings only for the time necessary to preserve the confidentiality of such information, pursuant to 47 U.S.C. 1424(e)(2).

Times and Dates of Meeting: A combined meeting of the FirstNet Authority Board and Board Committees will be held on August 13, 2018, between 11:00 a.m. and 12:00 p.m., Eastern Daylight Time (EDT). The meeting of the FirstNet Authority Board and Board Committees will be open to the public via teleconference and WebEx from 11:00 a.m. to 12:00 p.m. EDT. The times listed above are subject to change. Please refer to FirstNet's website at *www.firstnet.gov* for the most up-to-date information.

Place: The combined meeting of the FirstNet Authority Board and Board Committees will be conducted via teleconference and WebEx.

Other Information: The combined meeting of the FirstNet Authority Board and Board Committees is open to the public via teleconference and WebEx only. On the date and time of the meeting, members of the public may listen to the meeting by dialing toll free 1–877–917–6910 and using passcode 3324054. To view the slide presentation, the public may visit the URL: *https://www.mymeetings.com/nc/join/* and enter Conference Number: PWXW7911812 and Audience Passcode: 3324054. Alternatively, members of the public may view the slide presentation by directly visiting the URL: *https://www.mymeetings.com/nc/join.php?i=PWXW7911812&p=3324054&t=c*.

If you experience technical difficulty, please contact the Conferencing Center customer service at 1–866–900–1011. Public access will be limited to listen-only. Due to the limited number of ports, attendance via teleconference will be on a first-come, first-served basis.

The FirstNet Authority Board and Combined Committee Meeting is accessible to people with disabilities. Individuals requiring accommodations are asked to notify Ms. Miller-Kuwana by telephone (571) 665–6177 or email at *Karen.Miller-Kuwana@firstnet.gov* at least five (5) business days before the applicable meeting.

Records: The FirstNet Authority maintains records of all FirstNet Authority Board proceedings. Minutes of the FirstNet Authority Board Meeting and the Board Committee Meetings will be available at *www.firstnet.gov.*

Dated: August 2, 2018.

Karen Miller-Kuwana,

Board Secretary, First Responder Network Authority.

[FR Doc. 2018–16912 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–TL–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Emerging Technology Technical Advisory Committee (ETTAC); Notice of Recruitment of Private-Sector Members

The Bureau of Industry and Security (BIS) is announcing a recruitment for new candidates to serve on the Emerging Technology Technical Advisory Committee (ETTAC) to advise the Department of Commerce and other agency officials on emerging technologies with potential dual-use applications. This advice will include: (a) The identification of such technologies as early as possible in their developmental stages both within the United States and abroad; (b) assessing and providing information on emerging technologies, potential ''chokepoint technologies'' (for example, technologies that, if developed by an adversary prior to development by the United States, could present grave threats to United States national and/or economic security) and trends in technologies of particular interest to BIS; (c) assessing the potential impact of the Export Administration Regulations (EAR) on research activities, including technical and policy issues relating to controls under the EAR, revisions of the Commerce Control List, including proposed revisions of multilateral controls in which the United States participates, and the issuance of regulations; and (d) any other matters relating to actions designed to carry out the policy set forth in Section 3(2)(A) of the Export Administration Act of 1979 as well as the directives contained in Section 1758 of H.R. 5515, the John S. McCain National Defense Authorization Act for Fiscal Year 2019. In its work, the Committee will be forward leaning—focusing both on the current state of emerging technologies and projecting their likely effects five to ten years in the future on national security, the U.S. defense industrial base, and the overall health and competitiveness of the U.S. economy.

The ETTAC will consist of experts drawn from academia, industry, federal laboratories, and pertinent U.S. Government departments and agencies who are engaged in developing and producing cutting edge technology in areas key to maintaining a U.S. forward leaning presence in the world economy. ETTAC members are appointed by the Secretary of Commerce and serve terms of two years, and may not serve more than four consecutive years. The membership term limit reflects the Department's commitment to attaining balance and diversity. As a general rule members will be highly ranked, accomplished and recognized leaders, engineers, and scientists working in their disciplines as researchers and/or program managers. All members must be able to qualify for a Secret security clearance or a security clearance at a level sufficient to perform their work for the committee. The ETTAC will also reach out to other government and non-government experts to ensure a broad and thorough review of the issues. The ETTAC meets approximately four times per year. Members of the Committee will not be compensated for their services.

To respond to this recruitment notice, please send a copy of your resume to Ms. Yvette Springer at *Yvette.Springer@bis.doc.gov*.

Deadline: This Notice of Recruitment will close 30 days from its date of publication in the **Federal Register**.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2018–16893 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–878]

Certain Corrosion-Resistant Steel Products From the Republic of Korea: Notice of Court Decision Not in Harmony With Final Determination of Investigation and Notice of Amended Final Results

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On June 22, 2018, the United States Court of International Trade (the CIT) entered final judgment sustaining the Department of Commerce's (Commerce) remand results pertaining to the final determination in the antidumping duty (AD) investigation on certain corrosion-resistant steel products (CORE) from the Republic of Korea (Korea) for Hyundai Steel Company (Hyundai). Commerce is notifying the public that the final judgment in this case is not in harmony with the final determination, and that

Commerce has determined a dumping margin of 7.89 percent *ad valorem* for Hyundai. We have also revised the ''all others'' rate to 8.32 percent *ad valorem.*

DATES: June 22, 2018.

FOR FURTHER INFORMATION CONTACT: Chloee Sagmoe or Elfi Blum, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2273 and (202) 482–0197, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 2, 2016, Commerce published the *Final Determination* for the AD investigation of CORE from Korea pertaining to mandatory respondents Hyundai and Dongkuk Steel Mill Co., Ltd/Union Steel Manufacturing Co., Ltd. (Dongkuk). The period of investigation (POI) is April 1, 2014, through March 31, 2015.[1] In the *Final Determination,* Commerce calculated weighted-average dumping margins for Hyundai and Dongkuk that were above *de minimis* and which were not based on total facts available. Commerce calculated the ''all-others'' rate using a simple average of dumping margins calculated for the mandatory respondents.[2] Commerce determined a weighted-average dumping rate of 8.75 percent for Dongkuk, 47.80 percent for Hyundai, and 31.73 for all-others.[3]

On January 10, 2018, the CIT remanded for Commerce to provide Hyundai with an opportunity to remedy the deficiencies at issue for its further manufactured sales of skelp, sheet, and blanks (SSBs), and to recalculate Hyundai's overall margin.[4] Commerce determined in the AD investigation that the application of facts available, with an adverse inference, pursuant to sections 776(a)(1), 776(a)(2), and 776(b) of the Act, was warranted for Hyundai's U.S. sales of tailor welded blanks (TWBs), auto parts, and SSBs because: (1) Certain information was not available on the record; (2) Hyundai's December 29, 2015 data submissions were untimely; and (3) Hyundai significantly impeded the proceeding through delays and the provision of unusable information. As stated above, the CIT remanded to Commerce, instructing Commerce to provide Hyundai with an opportunity to remedy its deficiencies with respect to its sales and costs of SSBs, holding that Commerce improperly had failed to do so in the original proceeding.[5]

In light of the Court's remand order, on May 3, 2018, Commerce released the *Draft Remand Determination,*[6] finding that Hyundai's March 15, 2018 response remedied the major deficiencies in its previous further manufacturing responses with respect to SSBs. Specifically, we found that Hyundai sufficiently explained the inconsistencies and previously unexplained changes that plagued the data it submitted with respect to its SSB sales during the investigation. Based on the analysis of Hyundai's response to the remand questionnaire and verification, Commerce made adjustments to Hyundai's reported further-manufacturing expenses for SSBs in order to recalculate Hyundai's dumping margin to include its sales of SSBs.[7] Both the petitioners[8] and Hyundai[9] filed comments on the *Draft Remand Determination* on May 11, 2018. On May 11, 2018, Commerce filed the *Final Remand Determination* with the CIT.[10]

On June 22, 2018, the CIT sustained the Department's *Final Remand Determination.*[11] Thus, the CIT sustained our changes made to our margin analysis and margin calculations for Hyundai's sales of SSBs, resulting in an overall dumping margin of 7.89 percent *ad valorem* for Hyundai. Commerce has also revised the ''all others'' rate to 8.32 percent *ad valorem.*

Timken Notice

In its decision in *Timken,*[12] as clarified by *Diamond Sawblades,*[13] the Court of Appeals for the Federal Circuit held that, pursuant to section 516A(e) of the Tariff Act of 1930, as amended (the Act), the Department must publish a notice of a court decision that is not ''in harmony'' with a Department determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's June 22, 2018, final judgment sustaining the *Final Remand Determination* constitutes a final decision of the Court that is not in harmony with Commerce's *Final Determination.* This notice is published in fulfillment of the *Timken* publication requirements.

Amended Final Determination

Because there is now a final court decision, we are amending the *Final Determination* with respect to the dumping margin calculated for Hyundai. Based on the *Final Remand Determination,* as affirmed by the CIT, the revised dumping margin for Hyundai is 7.89 percent *ad valorem.* We have also re-calculated the ''all-others rate'' to 8.32 percent.

Cash Deposit Requirements

Commerce will issue revised cash deposit instructions to CBP, adjusting the cash deposit rate for Hyundai to 7.88 percent and the ''all-others'' cash deposit rate to 8.31 percent, effective July 2, 2018.[14]

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(e)(1), 751(a)(1), and 777(i)(1) of the Act.

Dated: July 23, 2018.

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. 2018–16898 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Certain Corrosion-Resistant Steel Products from the Republic of Korea: Final Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances,* 81 FR 35303 (June 2, 2016) (*Final Determination)* and accompanying Issues and Decision Memorandum (IDM).

[2] *Id.*

[3] *Id.*

[4] *See Hyundai Steel Company* v. *United States,* Court No. 16–00161, Slip Op. 18–2 (*Hyundai* v. *U.S.*).

[5] *Id.*

[6] *See* ''Draft Results of Redetermination Pursuant to Remand: Antidumping Duty (AD) Investigation on Certain-Corrosion-Resistant Steel Products (CORE) from the Republic of Korea,'' (*Draft Remand Determination)* dated May 3, 2018.

[7] *Id.*

[8] *See* United States Steel Corporation's Comments, ''Certain Corrosion-Resistant Steel Products from the Republic of Korea: Comments on the Draft Remand Redetermination,'' dated May 8, 2018.

[9] *See* Hyundai Steel Company's Comments, ''Certain Corrosion-Resistant Steel Products from the Republic of Korea: Comments on Draft Remand Redetermination,'' dated May 7, 2018.

[10] *See* Final Remand Redetermination Pursuant to *Hyundai Steel Company,* v. *United States,* Court. No. 16–00161, Slip Op. 18–2 (Court of International Trade January 10, 2018), dated May 11, 2018 (Final Remand Redetermination).

[11] *See Hyundai Steel Company* v. *United States,* CIT Slip Op. 18–2, Ct. No. 16–00161 (June 22, 2018).

[12] *See Timken Co.* v. *United States,* 893 F.2d 337, 341 (Fed. Cir. 1990) (*Timken*).

[13] *See Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

[14] *See Final Remand Determination* at FN 74: ''We intend to instruct U.S. Customs and Border Protection to require a cash deposit less the amount of the countervailing duty determined to constitute any export subsidies (.0.01 percent). Therefore, Hyundai's cash deposit rate will be 7.88 percent and the all-others cash deposit rate will be 8.31.''

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–073]

Common Alloy Aluminum Sheet From the People's Republic of China: Amended Preliminary Affirmative Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is amending the preliminary determination of the less-than-fair-value (LTFV) investigation of common alloy aluminum sheet (aluminum sheet) from the People's Republic of China (China) to correct a significant ministerial error.

DATES: Applicable August 8, 2018.

FOR FURTHER INFORMATION CONTACT: Deborah Scott or Scott Hoefke, 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) 482–2657 or (202) 482–4947, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 22, 2018, Commerce published in the **Federal Register** the *Preliminary Determination,*[1] and completed the disclosure of all calculation materials to interested parties. On June 26, 2018, Henan Mingtai Al Industrial Co., Ltd. and Zhengzhou Mingtai Industry Co., Ltd. (collectively, Mingtai), timely filed a ministerial error allegation regarding the *Preliminary Determination*.[2] Commerce did not receive ministerial error allegations or comments from any other interested party.

Period of Investigation

The period of investigation is April 1, 2017 through September 30, 2017.

Scope of the Investigation

The product covered by this investigation is aluminum sheet from China. For a complete description of the scope of this investigation, *see* the Appendix to this notice.

Analysis of Significant Ministerial Error Allegation

Commerce will analyze any comments received and, if appropriate, correct any significant ministerial error by amending the preliminary determination according to 19 CFR 351.224(e). A ministerial error is defined in 19 CFR 351.224(f) as ''an error in addition, subtraction, or other arithmetic function, clerical error resulting from inaccurate copying, duplication, or the like, and any other similar type of unintentional error which the Secretary considers ministerial.'' [3] A significant ministerial error is defined as a ministerial error, the correction of which, singly or in combination with other errors, would result in: (1) A change of at least five absolute percentage points in, but not less than 25 percent of, the antidumping duty rate calculated in the original preliminary determination; or (2) a difference between an antidumping duty rate of zero or *de minimis* and an antidumping duty rate of greater than *de minimis* or vice versa.[4]

Amended Preliminary Determination

Pursuant to 19 CFR 351.224(e) and (g)(1), Commerce is amending the *Preliminary Determination* to reflect the correction of one ministerial error made in the calculation of the estimated weighted-average dumping margin for Mingtai.[5] This error is a significant ministerial error within the meaning of 19 CFR 351.224(g) because Mingtai's margin decreases from 167.16 percent to 91.47 percent as a result of correcting this ministerial error, exceeding the specified threshold, *i.e.,* a change of at least five absolute percentage points in, but not less than 25 percent of, the antidumping duty rate calculated in the original preliminary determination.[6]

Mingtai is the only mandatory respondent for which Commerce calculated a weighted-average dumping margin in the *Preliminary Determination.* For this reason, we assigned Mingtai's calculated rate to the non-examined respondents that preliminarily received a separate rate.[7] Accordingly, as part of this amended preliminary determination, Commerce will amend the estimated weighted-average dumping margin to 91.47 percent for each non-examined respondent that preliminarily received a separate rate.

In the *Preliminary Determination,* we found that Nanjie Resources Co., Limited, Yong Jie New Material Co., Ltd., and Zhejiang Yongjie Aluminum Co., Ltd. (collectively, the Yongjie Companies), Zhejiang GKO Aluminium Stock Co., Ltd. (GKO Aluminium), and the China-wide entity failed to cooperate by not acting to the best of their ability to comply with requests for information and, thus, found that an adverse inference was warranted in selecting from the facts otherwise available.[8] In an investigation, Commerce's practice with respect to the assignment of a rate based on adverse facts available is to select the higher of: (1) The highest dumping margin alleged in the petition or (2) the highest calculated dumping margin of any respondent in the investigation.[9] In the *Preliminary Determination,* because the highest margin in the initiation of this investigation (*i.e.,* 59.72 percent) was less than the 167.16 percent margin calculated for Mingtai, we assigned the 167.16 percent rate to the Yongjie Companies, GKO Aluminium, and the China-wide entity as adverse facts available.[10] For this amended preliminary determination, we examined whether the highest margin in the initiation of the investigation (*i.e.,* 59.72 percent) was less than or equal to the highest calculated margin, and determined that the highest calculated margin of 91.47 percent was the higher of the two. Because this rate is a calculated rate based on a mandatory respondent's data in this segment of the proceeding, it does not constitute secondary information and, therefore, it does not need to be corroborated. Therefore, for this amended preliminary determination, as facts available based on an adverse inference, we have assigned to the Yongjie Companies,

[1] *See Antidumping Duty Investigation of Common Alloy Aluminum Sheet from the People's Republic of China: Affirmative Preliminary Determination of Sales at Less-Than-Fair Value, Preliminary Affirmative Determination of Critical Circumstances, and Postponement of Final Determination,* 83 FR 29088 (June 22, 2018) (*Preliminary Determination*).

[2] *See* Letter from Mingtai, ''Common Alloy Aluminum Sheet from the People's Republic of China—Ministerial Error Allegation,'' dated June 26, 2018.

[3] *See also* section 735(e) of the Tariff Act of 1930, as amended (the Act).

[4] *See* 19 CFR 351.224(g).

[5] *See* Memorandum, ''Less-Than-Fair-Value Investigation of Common Alloy Aluminum Sheet from the People's Republic of China: Allegation of Ministerial Error in the Preliminary Determination,'' dated concurrently with this notice (Ministerial Error Memorandum).

[6] *See* Memorandum, ''Analysis for the Amended Preliminary Determination of the Less-Than-Fair-Value Investigation of Common Alloy Aluminum Sheet from the People's Republic of China for Henan Mingtai Al Industrial Co., Ltd. and Zhengzhou Mingtai Industry Co., Ltd.,'' dated concurrently with this notice.

[7] *See Preliminary Determination,* 83 FR at 29090.

[8] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Antidumping Duty Investigation of Common Alloy Aluminum Sheet from the People's Republic of China,'' dated June 15, 2018 (Preliminary Decision Memorandum), at 20–26.

[9] *See, e.g., Certain Uncoated Paper from Indonesia: Final Determination of Sales at Less Than Fair Value,* 81 FR 3101 (January 20, 2016).

[10] *See* Preliminary Decision Memorandum, at 26.

GKO Aluminium, and the China-wide entity a dumping margin of 91.47 percent, which is the highest calculated rate in this proceeding.

Amended Cash Deposits and Suspension of Liquidation

The collection of cash deposits and suspension of liquidation will be revised according to the rates calculated in this amended preliminary determination. Because these amended rates result in reduced cash deposits, the amended rate for Mingtai will be effective retroactively to June 22, 2018, the date of publication of the *Preliminary Determination.* As Commerce preliminarily found that critical circumstances exist for imports of subject merchandise from the non-examined respondents that preliminarily received a separate rate, the Yongjie Companies, GKO Aluminium, and the China-wide entity,[11] the amended rates for these entities will be effective retroactively to March 24, 2018, *i.e.,* 90 days before the publication of the *Preliminary Determination.* Parties will be notified of this determination, in accordance with section 733(d) and (f) of the Act.

Amended Preliminary Determination

Commerce preliminarily determines that the following estimated weighted-average antidumping duty margins exist:

Exporter	Producer	Weighted-average margin (percent)	Cash deposit adjusted for subsidy offset (percent)
Henan Mingtai Al Industrial Co., Ltd./Zhengzhou Mingtai Industry Co., Ltd.[12].	Henan Mingtai Al Industrial Co., Ltd./Zhengzhou Mingtai Industry Co., Ltd.	91.47	91.47
Alcha International Holdings Limited	Jiangsu Alcha Aluminium Co., Ltd	91.47	91.47
Alumax Composite Material (Jiangyin) Co., Ltd	Chalco Ruimin Co., Ltd	91.47	91.47
Granges Aluminum (Shanghai) Co., Ltd	Granges Aluminum (Shanghai) Co., Ltd	91.47	91.47
Henan Founder Beyond Industry Co., Ltd	Henan Xintai Aluminum Industry Co., Ltd	91.47	91.47
Huafon Nikkei Aluminium Corporation	Huafon Nikkei Aluminium Corporation	91.47	91.47
Jiangsu Lidao New Material Co., Ltd	Henan Jinyang Luyue Co., Ltd	91.47	91.47
Jiangsu Lidao New Material Co., Ltd	Jiangsu Zhong He Aluminum Co., Ltd	91.47	91.47
Jiangyin Litai Ornamental Materials Co., Ltd	Jiangyin Litai Ornamental Materials Co., Ltd	91.47	91.47
Jiangyin New Alumax Composite Material Co. Ltd	Chalco Ruimin Co., Ltd	91.47	91.47
Shandong Fuhai Industrial Co., Ltd	Shandong Fuhai Industrial Co., Ltd	91.47	91.47
Tianjin Zhongwang Aluminium Co., Ltd	Tianjin Zhongwang Aluminium Co., Ltd	91.47	91.47
Xiamen Xiashun Aluminum Foil Co., Ltd	Xiamen Xiashun Aluminum Foil Co., Ltd	91.47	91.47
Yantai Jintai International Trade Co., Ltd	Shandong Nanshan Aluminium Co., Ltd	91.47	91.47
Yinbang Clad Material Co., Ltd	Yinbang Clad Material Co., Ltd	91.47	91.47
Zhengzhou Silverstone Limited	Henan Zhongyuan Aluminum Co., Ltd	91.47	91.47
Zhengzhou Silverstone Limited	Luoyang Xinlong Aluminum Co., Ltd	91.47	91.47
Zhengzhou Silverstone Limited	Shanghai Dongshuo Metal Trade Co., Ltd	91.47	91.47
Zhengzhou Silverstone Limited	Zhengzhou Mingtai Industry Co., Ltd	91.47	91.47
China-Wide Entity		91.47	91.47

Disclosure

We intend to disclose the calculations performed to parties in this proceeding within five days after public announcement of the amended preliminary determination, in accordance with 19 CFR 351.224.

International Trade Commission Notification

In accordance with section 733(f) of the Act, we will notify the International Trade Commission of our amended preliminary determination.

This amended preliminary determination is issued and published pursuant to sections 733(f) and 777(i) of the Act and 19 CFR 351.224(e).

Dated: July 31, 2018.

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

Scope of the Investigation

The merchandise covered by this investigation is aluminum common alloy sheet (common alloy sheet), which is a flat-rolled aluminum product having a thickness of 6.3 mm or less, but greater than 0.2 mm, in coils or cut-to-length, regardless of width. Common alloy sheet within the scope of this investigation includes both not clad aluminum sheet, as well as multi-alloy, clad aluminum sheet. With respect to not clad aluminum sheet, common alloy sheet is manufactured from a 1XXX-, 3XXX-, or 5XXX-series alloy as designated by the Aluminum Association. With respect to multi-alloy, clad aluminum sheet, common alloy sheet is produced from a 3XXX-series core, to which cladding layers are applied to either one or both sides of the core.

Common alloy sheet may be made to ASTM specification B209–14, but can also be made to other specifications. Regardless of specification, however, all common alloy sheet meeting the scope description is included in the scope. Subject merchandise includes common alloy sheet that has been further processed in a third country, including but not limited to annealing, tempering, painting, varnishing, trimming, cutting, punching, and/or slitting, or any otherprocessing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the common alloy sheet.

Excluded from the scope of this investigation is aluminum can stock, which is suitable for use in the manufacture of aluminum beverage cans, lids of such cans, or tabs used to open such cans. Aluminum can stock is produced to gauges that range from 0.200 mm to 0.292 mm, and has anH–19, H–41, H–48, or H–391 temper. In

[11] *See Preliminary Determination,* 83 FR at 29089 and Preliminary Decision Memorandum, at 4–7.

[12] We preliminarily determined that Henan Mingtai Al Industrial Co., Ltd. and Zhengzhou Mingtai Industry Co., Ltd. are a single entity. *See* Preliminary Decision Memorandum, at 17–19; *see also* Memorandum, ''Preliminary Affiliation and Collapsing Memorandum for Henan Mingtai Al Industrial Co., Ltd. and Zhengzhou Mingtai Industry Co., Ltd.,'' dated June 15, 2018.

addition, aluminum can stock has a lubricant applied to the flat surfaces of the can stock to facilitate its movement through machines used in the manufacture of beverage cans. Aluminum can stock is properly classified under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7606.12.3045 and 7606.12.3055.

Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set for the above.

Common alloy sheet is currently classifiable under HTSUS subheadings 7606.11.3060, 7606.11.6000, 7606.12.3090, 7606.12.6000, 7606.91.3090, 7606.91.6080, 7606.92.3090, and 7606.92.6080. Further, merchandise that falls within the scope of this investigation may also be entered into the United States under HTSUS subheadings 7606.11.3030, 7606.12.3030, 7606.91.3060, 7606.91.6040, 7606.92.3060, 7606.92.6040, 7607.11.9090. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

[FR Doc. 2018–16897 Filed 8–7–18; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–075]

Certain Plastic Decorative Ribbon From the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that certain plastic decorative ribbon (plastic ribbon) from the People's Republic of China (China) is being, or is likely to be, sold in the United States at less than fair value (LTFV), for the period of investigation (POI) April 1, 2017, through September 30, 2017. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable August 8, 2018.

FOR FURTHER INFORMATION CONTACT: Nancy Decker, Lauren Caserta, or Caitlin Monks, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0196, (202) 482–4737, or (202) 482–2670, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the notice of initiation of this investigation on January 23, 2018.[1] Commerce exercised its discretion to toll deadlines affected by the closure of the Federal Government from January 20 through 22, 2018.[2] Subsequently, Commerce postponed the deadline for the preliminary determination to July 30, 2018.[3] For a complete description of the events that followed the initiation of this investigation, see the Preliminary Decision Memorandum.[4] A list of topics included in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* 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 Preliminary Decision Memorandum can be found at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is plastic ribbon from China. For a full description of the scope of this investigation, *see* the ''Scope of the Investigation'' in Appendix I.

Scope Comments

In accordance with the preamble to the Commerce's regulations,[5] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[6] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments and rebuttal responses submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, see the Preliminary Scope Decision Memorandum.[7] In response to the submitted comments, Commerce is preliminarily modifying the scope language as it appeared in the *Initiation Notice* to exclude certain shredded plastic film/strip and to clarify ''exclusion (4).'' *See* ''Scope of the Investigation'' in Appendix I, which includes the additional clarifying language.

Methodology

Commerce is conducting this investigation in accordance with section 731 of the Act. Export prices have been calculated in accordance with section 772(a) of the Act. Because China is a non-market economy within the meaning of section 771(18) of the Act, we calculated normal value (NV) in accordance with section 773(c) of the Act. In addition, Commerce has preliminarily relied upon facts available under section 776(a)(1) of the Act, including the use of an adverse inference under section 776(b) of the Act, for determining the antidumping margin for one producer and exporter combination, as well as for the China-wide entity. For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.

Combination Rates

In the *Initiation Notice,* Commerce stated that it would calculate producer/exporter combination rates for the respondents that are eligible for a separate rate in this investigation. Policy Bulletin 05.1 describes this practice.[8]

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[1] *See Certain Plastic Decorative Ribbon from the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 83 FR 3126 (January 23, 2018) (Initiation Notice).

[2] *See* Memorandum, ''Deadlines Affected by the Shutdown of the Federal Government,'' dated January 23, 2018 (Tolling Memorandum). Accordingly, all deadlines in this segment of the proceeding have been extended by 3 days.

[3] Note that the revised deadline reflects a full postponement to 190 days after the date on which this investigation was initiated, in addition to the 3-day extension due to closure of the Federal Government. *See Certain Plastic Decorative Ribbon from the People's Republic of China: Postponement of Preliminary Determination in the Less-Than-Fair-Value Investigation,* 83 FR 13256 (March 28, 2018).

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Antidumping Duty Investigation of Certain Plastic Decorative Ribbon from the People's Republic of China'' (Preliminary Decision Memorandum), dated concurrently with and hereby adopted by this notice.

[5] *See Antidumping Duties; Countervailing Duties,* 62 FR 27296, 27323 (May 19, 1997).

[6] *See Initiation Notice,* 83 FR at 3126.

[7] *See* Memorandum, ''Certain Plastic Decorative Ribbon from the People's Republic of China: Scope Comments Preliminary Decision Memorandum'' (Preliminary Scope Decision Memorandum), dated concurrently with and hereby adopted by this notice.

[8] *See* Enforcement and Compliance's Policy Bulletin No. 05.1 regarding ''Separate-Rates Practice and Application of Combination Rates in Antidumping Investigations involving Non-Market Economy Countries,'' (April 5, 2005) (Policy

Preliminary Determination

Commerce preliminarily determines that the following weighted-average dumping margins exist:

Exporter	Producer	Weighted-average dumping margin (percent)
Ningbo Junlong Craft Gift Co., Ltd	Ningbo Junlong Craft Gift Co., Ltd	45.16
Dongguan Mei Song Plastic Industry Co., Ltd	Dongguan Mei Song Plastic Industry Co., Ltd	50.93
Ricai Film Artwork Materials Co., Ltd	Dongguan Ricai Plastic Technology Co., Ltd	* 370.04
Sun Rich (Asia) Ltd	Kai Feng Decoration (Hui Zhou) Co., Ltd	48.05
Sun Rich (Asia) Ltd	Sheng Yi Decoration (Dong Guan) Co., Ltd	48.05
Joynice Gifts & Crafts Co., Ltd	Joynice Gifts & Crafts Co., Ltd	48.05
Chiapton Gifts Decorative Limited	Nan Mei (Huizhou) Ribbon Art Factory Ltd	48.05
Chiapton Gifts Decorative Limited	Shantou Longhu YingXin Art Craft Factory Co. Ltd	48.05
Colorart Plastic Ribbon Productions Limited	Colorart Industrial Limited	48.05
Zhejiang Shaoxing Royal Arts & Crafts Co., Ltd	Santa's Collection Shaoxing Co. Ltd	48.05
Zhejiang Shaoxing Royal Arts & Crafts Co., Ltd	Zheijang Shaoxing Royal Arts & Crafts Co., Ltd	48.05
Wingo Gift & Crafts (Shenzhen) Co., Ltd	Wingo Gift & Crafts (Shenzhen) Co., Ltd	48.05
Seng San Enterprises Co., Ltd	Xin Seng San Handicraft (ShenZhen) Co., Ltd	48.05
Xiangxin Decoration Factory	Xiangxin Decoration Factory	48.05
Xinghui Packaging Co., Ltd	Xinghui Packaging Co., Ltd	48.05
Shenzhen SHS Technology R&D Co., Ltd	Shenzhen SHS Technology R&D Co., Ltd	48.05
China-Wide Entity		* 370.04

* Determined on the basis of adverse facts available.

As detailed in the Preliminary Decision Memorandum, because parties to whom we issued Q&V questionnaires did not provide timely quantity and value questionnaire responses or separate rate applications,[9] the China-wide entity also includes these non-responsive companies. *See* Appendix III for a list of companies that did not respond to the quantity and value questionnaire.

Suspension of Liquidation

In accordance with section 733(d)(2) of the Act, we will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of plastic ribbon from China as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**.

Pursuant to section 733(d)(1)(B) of the Act and 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the weighted-average amount by which the NV exceeds U.S. price as follows: (1) The cash deposit rate for the exporter/producer combination listed in the table above will be the rate identified for that combination in the table; (2) for all combinations of Chinese exporters/producers of merchandise under consideration that have not received their own separate rate above, the cash-deposit rate will be the cash deposit rate established for the China-wide entity, 370.04 percent; and (3) for all non-Chinese exporters of the merchandise under consideration which have not received their own separate rate above, the cash-deposit rate will be the cash deposit rate applicable to the Chinese exporter/producer combination that supplied that non-Chinese exporter. These suspension of liquidation instructions will remain in effect until further notice.

Disclosure and Public Comment

We will disclose the calculations performed to parties to this proceeding within five days of the date of announcement of this preliminary determination in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs, rebuttal briefs, and hearing requests.[10] For a schedule of the deadlines for filing case briefs, rebuttal briefs, and hearing requests, *see* the Preliminary Decision Memorandum at Section IX.

International Trade Commission (ITC) Notification

In accordance with section 733(f) of the Act, we will notify the United States International Trade Commission (ITC) of our affirmative preliminary determination of sales at LTFV. If our final determination is affirmative, the ITC will determine before the later of 120 days after the date of this preliminary determination or 45 days after our final determination whether these imports are materially injuring, or threaten material injury to, the U.S. industry.

This determination is issued and published in accordance with sections 733(f) and 777(i)(1) of the Act and 19 CFR 351.205(c).

Dated: July 30, 2018.

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

Scope of the Investigation

The merchandise covered by this investigation is certain plastic decorative ribbon having a width (measured at the narrowest span of the ribbon) of less than or equal to four (4) inches in actual measurement, including but not limited to ribbon wound onto itself; a spool, a core or a tube (with or without flanges); attached to a card or strip; wound into a keg- or egg-shaped configuration; made into bows, bow-like items, or other shapes or configurations; and whether or not packaged or labeled for

Bulletin 05.1), available on Commerce's website at *http://enforcement.trade.gov/policy/bull05-1.pdf.*

[9] *See* Memorandum to the File, ''Antidumping Duty Investigation of Plastic Decorative Ribbon from the People's Republic of China: Respondent Selection'' (March 1, 2018).

[10] *See* 19 CFR 351.309(c)–(d), 19 CFR 351.310(c).

retail sale. The subject merchandise is typically made of substrates of polypropylene, but may be made in whole or in part of any type of plastic, including without limitation, plastic derived from petroleum products and plastic derived from cellulose products. Unless the context otherwise clearly indicates, the word ''ribbon'' used in the singular includes the plural and the plural ''ribbons'' includes the singular.

The subject merchandise includes ribbons comprised of one or more layers of substrates made, in whole or in part, of plastics adhered to each other, regardless of the method used to adhere the layers together, including without limitation, ribbons comprised of layers of substrates adhered to each other through a lamination process. Subject merchandise also includes ribbons comprised of (a) one or more layers of substrates made, in whole or in part, of plastics adhered to (b) one or more layers of substrates made, in whole or in part, of non-plastic materials, including, without limitation, substrates made, in whole or in part, of fabric.

The ribbons subject to this investigation may be of any color or combination of colors (including without limitation, ribbons that are transparent, translucent or opaque) and may or may not bear words or images, including without limitation, those of a holiday motif. The subject merchandise includes ribbons with embellishments and/or treatments, including, without limitation, ribbons that are printed, hot-stamped, coated, laminated, flocked, crimped, die-cut, embossed (or that otherwise have impressed designs, images, words or patterns), and ribbons with holographic, metallic, glitter or iridescent finishes.

Subject merchandise includes ''pull-bows'' an assemblage of ribbons connected to one another, folded flat, and equipped with a means to form such ribbons into the shape of a bow by pulling on a length of material affixed to such assemblage, and ''pre-notched'' bows, an assemblage of notched ribbon loops arranged one inside the other with the notches in alignment and affixed to each other where notched, and which the end user forms into a bow by separating and spreading the loops circularly around the notches, which form the center of the bow. Subject merchandise includes ribbons that are packaged with non-subject merchandise, including ensembles that include ribbons and other products, such as gift wrap, gift bags, gift tags and/or other gift packaging products. The ribbons are covered by the scope of this investigation; the ''other products'' (*i.e.,* the other, non-subject merchandise included in the ensemble) are not covered by the scope of this investigation.

Excluded from the scope of this investigation are the following: (1) Ribbons formed exclusively by weaving plastic threads together; (2) ribbons that have metal wire in, on, or along the entirety of each of the longitudinal edges of the ribbon; (3) ribbons with an adhesive coating covering the entire span between the longitudinal edges of the ribbon for the entire length of the ribbon; (4) ribbon formed into a bow without a tab or other means for attaching the bow to an object using adhesives, where the bow has: (a) An outer layer that is either flocked or made of fabric, and (b) a flexible metal wire at the base which permits attachment to an object by twist-tying; (5) elastic ribbons, meaning ribbons that elongate when stretched and return to their original dimension when the stretching load is removed; (6) ribbons affixed as a decorative detail to non-subject merchandise, such as a gift bag, gift box, gift tin, greeting card or plush toy, or affixed (including by tying) as a decorative detail to packaging containing non subject merchandise; (7) ribbons that are (a) affixed to non-subject merchandise as a working component of such non-subject merchandise, such as where the ribbon comprises a book marker, bag cinch, or part of an identity card holder, or (b) affixed (including by tying) to non-subject merchandise as a working component that holds or packages such non-subject merchandise or attaches packaging or labeling to such non-subject merchandise, such as a ''belly band'' around a pair of pajamas, a pair of socks or a blanket; (8) imitation raffia made of plastics having a thickness not more than one (1) mil when measured in an unfolded/untwisted state; and (9) ribbons in the form of bows having a diameter of less than seven-eighths (7/8) of an inch, or having a diameter of more than 16 inches, based on actual measurement. For purposes of this exclusion, the diameter of a bow is equal to the diameter of the smallest circular ring through which the bow will pass without compressing the bow.

The scope of the investigation is not intended to include shredded plastic film or shredded plastic strip, in each case where the shred does not exceed 5 mm in width and does not exceed 18 inches in length, imported in bags.

Further, excluded from the scope of the antidumping duty investigation are any products covered by the existing antidumping duty order on polyethylene terephthalate film, sheet, and strip (PET Film) from the People's Republic of China (China). *See Polyethylene Terephthalate Film, Sheet, and Strip from Brazil, the People's Republic of China and the United Arab Emirates: Antidumping Duty Orders and Amended Final Determination of Sales at Less Than Fair Value for the United Arab Emirates,* 73 FR 66595 (November 10, 2008).

Merchandise covered by this investigation is currently classified in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 3920.20.0015 and 3926.40.0010. Merchandise covered by this investigation also may enter under subheadings 3920.10.0000; 3920.20.0055; 3920.30.0000; 3920.43.5000; 3920.49.0000; 3920.62.0050; 3920.62.0090; 3920.69.0000; 3921.90.1100; 3921.90.1500; 3921.90.1910; 3921.90.1950; 3921.90.4010; 3921.90.4090; 3926.90.9996; 5404.90.0000; 9505.90.4000; 4601.99.9000; 4602.90.0000; 5609.00.3000; 5609.00.4000; and 6307.90.9889. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of this investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

Appendix III

Unresponsive Companies

1. Best Craftwork Products Co., Ltd.
2. Billion Trend International Ltd.
3. Dongguan Xinghui Packaging Co., Ltd.
4. Fangtai Webbing Co.
5. Foshan City Shunde District Fangtai Webbing Co., Ltd.
6. Hangzhou Jiefa Materials Co., Ltd.
7. Hangzhou Owner Party Co., Ltd.
8. Jiaxing Kaiya Textile Co., Ltd.
9. Long Fine Gift & Bags Factory
10. Nan Mei Decorative Ribbons Co., Ltd.
11. Ningbo Qianyi Color Ribbon Co., Ltd.
12. Ningbo Sellers Union Co., Ltd.
13. Qingdao Hileaders Co., Ltd.
14. Shanghai Foreign Trade Enterprises Pudong Co., Ltd.
15. Shenzhen Ao Wei Gift Co., Ltd.
16. Shenzhen Gary Gifts Packing Co., Ltd.
17. Shenzhen Guangyunda Technology Co., Ltd.
18. True Color Gift Packing Co., Ltd.
19. Wellmark Gift (Shenzhen) Co Ltd
20. Wello Gift Co., Ltd.
21. Xiamen Golden Grand Lucky Ribbon & Bow Co., Ltd.
22. Xiamen Meisida Decorations Co., Ltd.
23. Yangzhou Bestpak Gifts & Crafts Co., Ltd.
24. Yiwu Eco-Tondo Artware Co., Ltd.
25. Yongjiaxin Gifts & Crafts Factory

[FR Doc. 2018–16900 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable August 8, 2018.

FOR FURTHER INFORMATION CONTACT: Stephanie Moore, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Ave. NW, Washington, DC 20230, telephone: (202) 482–3692.

SUPPLEMENTARY INFORMATION: On April 25, 2018, the Department of Commerce (Commerce), pursuant to section 702(h) of the Trade Agreements Act of 1979 (as amended) (the Act), published the quarterly update to the annual listing of foreign government subsidies on articles of cheese subject to an in-quota rate of duty covering the period October 1, 2017, through December 31, 2017.[1] In the *Fourth Quarter 2017 Update,* we requested that any party, that has information on foreign government subsidy programs that benefit articles of cheese subject to an in-quote rate of duty, to submit such information to Commerce.[2] We received no comments, information or requests for consultation from any party.

Pursuant to section 702(h) of the Act, we hereby provide Commerce's update of subsidies on articles of cheese that were imported during the period January 1, 2018, through March 31, 2018. The appendix to this notice lists the country, the subsidy program or programs, and the gross and net amounts of each subsidy for which information is currently available.

Commerce will incorporate additional programs which are found to constitute subsidies, and additional information on the subsidy programs listed, as the information is developed. Commerce encourages any person having information on foreign government subsidy programs which benefit articles of cheese subject to an in-quota rate of duty to submit such information in writing to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, 1401 Constitution Ave. NW, Washington, DC 20230.

This determination and notice are in accordance with section 702(a) of the Act.

Dated: July 31, 2018.

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

SUBSIDY PROGRAMS ON CHEESE SUBJECT TO AN IN-QUOTA RATE OF DUTY

Country	Program(s)	Gross[3] subsidy ($/lb)	Net[4] subsidy ($/lb)
28 European Union Member States[5]	European Union Restitution Payments	$0.00	$0.00
Canada	Export Assistance on Certain Types of Cheese	0.44	0.44
Norway	Indirect (Milk) Subsidy	0.00	0.00
	Consumer Subsidy	0.00	0.00
	Total	0.00	0.00
Switzerland	Deficiency Payments	0.00	0.00

[FR Doc. 2018–16899 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Proposed Information Collection; Comment Request; NIST SURF Program Student Applicant Information

AGENCY: National Institute of Standards and Technology (NIST), 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: Written comments must be submitted on or before October 9, 2018.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 1401 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 and instructions should be directed to Dr. Brandi Toliver, NIST, 100 Bureau Drive, Stop 1090, Gaithersburg, MD 20899–1090, tel. (301) 972–2371, or *brandi.toliver@nist.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The purpose of this collection is to gather information requested on behalf of the NIST Summer Undergraduate Research Fellowship (SURF) Program for both Gaithersburg and Boulder locations. The information is submitted by the university on behalf of the student applicants. The student information is utilized by laboratory program coordinators and technical evaluators to determine student eligibility, select students to appropriate research projects which match their needs, interests, and academic preparation, and ultimately, make offers to participate in the program. The information includes: Student name, host institution, email address/contact information, permanent address, choice of SURF-specific location (Boulder and/or Gaithersburg), class standing, first-

[1] *See Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty,* 83 FR 18000 (April 25, 2018) (*Fourth Quarter 2017 Update*).

[2] *Id.*

[3] Defined in 19 U.S.C. 1677(5).

[4] Defined in 19 U.S.C. 1677(6).

[5] The 28 member states of the European Union are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

and second-choice NIST laboratories/projects they wish to apply to, previous SURF participation/mentor identification, academic major/minor, current overall GPA, need for housing and gender (for housing purposes only), special skills (laboratory, computer programming etc.) availability dates, resume, personal statement of commitment and research interests, two letters of recommendation, academic transcripts, ability to verify U.S. citizenship or permanent legal residency, acknowledgement of background check, and requirements for REAL ID Act.

II. Method of Collection

The Student Application Information form will be available on the web. The collection is currently limited to paper form and is *required* to be scanned and submitted electronically.

III. Data

OMB Control Number: 0693–0042.

Form Number(s): None.

Type of Review: Renewal submission.

Affected Public: Individuals or households.

Estimated Number of Respondents: 650.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 325.

Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

NIST invites comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (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 Lead PRA Officer, Office of the Chief Information Officer.

[FR Doc. 2018–16914 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG108

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Unexploded Ordnance Investigation Survey off the Coast of Virginia

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an Incidental Harassment Authorization (IHA) to Virginia Electric and Power Company d/b/a Dominion Energy Virginia (Dominion) for the take marine mammals, by harassment, incidental to high-resolution geophysical (HRG) surveys associated with unexploded ordnance investigation activities off the coast of Virginia in the area of the Research Lease of Submerged Lands for Renewable Energy Activities on the Outer Continental Shelf Offshore Virginia (OCS–A 0497) and coastal waters where one or more cable route corridors will be established (the Survey Area).

DATES: This Authorization is in effect for one year from the date of issuance.

FOR FURTHER INFORMATION CONTACT: Dale Youngkin, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the applications and supporting documents, as well as a list of the references cited in this document, may be obtained by visiting the internet at: *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable*. In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

The MMPA states that the term ''take'' means to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Summary of Request

On March 7, 2018, NMFS received a request from Dominion for an IHA to take marine mammals incidental to high resolution geophysical (HRG) surveys off the coast of Virginia. The purpose of these surveys are to acquire data regarding the potential presence of UXO within the proposed construction and operational footprints of the Coastal Virginia Offshore Wind (CVOW) Project Area in the Lease Area and export cable route construction corridor (Survey Area). A revised application was received on April 26, 2018. NMFS deemed that request to be adequate and complete. Dominion's request is for take of nine marine mammal species by Level B harassment. Neither Dominion nor NMFS expects injury, serious injury or mortality to result from this activity and the activity is expected to last no more than one year, therefore, an IHA is appropriate.

Description of the Proposed Activity

Overview

Dominion proposes to conduct marine site characterization surveys including HRG surveys to search for UXO in the marine environment of the approximately 2,135-acre Lease Area located offshore of Virginia (see Figure 1–1 in the IHA application). Additionally, an export cable route will be established between the Lease Area and Virginia Beach, identified as the Export Cable Route Area (see Figure 1 in the IHA application). See the IHA application for further information. The survey area consists of two 1-kilometer (km) X 1-km turbine position locations, a 2 km by 300 meter (m) Inter-array cable route connecting the two turbine position locations, and a 43-km X 300 m Export Corridor Route. For the purpose of this IHA, the survey area is designated as the Lease Area and cable route corridors. Water depths across the Lease Area are estimated to range from approximately 8 to 40 m (26 to 131 feet (ft)) while the cable route corridors will extend to shallow water areas near landfall locations. Surveys would begin no earlier than August 1, 2018 and are anticipated to last for up to three months.

The purpose of the marine site characterization surveys are to acquire data regarding the potential presence of UXO within the proposed construction and operational footprints of the CVOW Project Area (*i.e.,* export cable construction corridor, inter-array cable area, and wind turbine positions) in accordance with the Bureau of Ocean Energy Management (BOEM) guidelines for archaeology surveys as well as geophysical activities. No removal of ordnance would be conducted as a part of the activities. Underwater sound resulting from Dominion's proposed HRG surveys for UXO have the potential to result in incidental take of marine mammals in the form of harassment.

Dates and Duration

Surveys will last for approximately three months and are anticipated to commence no earlier than August 1, 2018. This schedule is based on 24-hour operations and includes potential down time due to inclement weather. Based on 24-hour operations, the estimated duration of the HRG survey activities would be approximately 60 days for the export cable route corridor and approximately 15 days each for the inter-array cable route and wind turbine positions.

Specific Geographic Region

Dominion's survey activities will occur in the approximately 2,135-acre Research Lease Area located off the coast of Virginia (see Figure 1 in the IHA application). Additionally, a cable route corridor would be surveyed between the Lease Area and the coast of Virginia. The cable route corridor to be surveyed is anticipated to be 300 m wide and 43 km long. The wind turbine positions to be surveyed are twoapproximately 1 km X 1 km square areas connected by an inter-array cable route that is 300 m wide and 2 km in length.

A detailed description of the planned survey activities, including types of survey equipment planned for use, is provided in the **Federal Register** notice for the proposed IHA (83 FR 26968; June 11, 2018). Since that time, no changes have been made to the planned activities and a detailed description is not repeated here. Please refer to that **Federal Register** notice for the description of the specific activity.

Comments and Responses

NMFS published a notice of proposed IHA in the **Federal Register** on June 11, 2018 (83 FR 26968). During the 30-day public comment period, NMFS received one comment letter, which was from the Marine Mammal Commission (Commission). No other public comments were received. NMFS has posted the comment letter received online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-other-energy-activities-renewable*. The following is a summary of the Commission comments received and NMFS's responses.

Comment 1: The Commission notes that impulsive thresholds, rather than non-impulsive thresholds, were incorrectly used to model Level A harassment zones for the ultra-short baseline positioning system (UBPS) and sub-bottom profiler (SBP) sources, which resulted in overly conservative Level A harassment zones. The Commission states that NMFS should not permit applicants to arbitrarily choose which thresholds to use, and should prohibit applicants from using impulsive thresholds for non-impulsive sources.

NMFS Response: NMFS appreciates the input from the Commission. We acknowledge the error, and have corrected it in this final notice (refer to Table 4) and IHA, and will ensure it does not happen again. Take by Level A harassment was not proposed for authorization based on the fact that it is not considered likely to occur, even based on the larger (more conservative) isopleths associated with the impulsive threshold. The use of the non-impulsive threshold does not change our findings or determinations under the MMPA.

Comment 2: The Commission recommends that NMFS revise the extent of the Level A harassment zones for the Geo-Source sparker based on both the SPL_{pk} and SEL_{cum} thresholds and for the GeoPulse SBP based on the SEL_{cum} threshold.

NMFS Response: As stated above, the thresholds have been revised and are presented in Table 4 of this notice.

Comment 3: The Commission continues to recommend that, until behavioral thresholds are updated, NMFS require applicants to use the 120-decibel (dB) re 1 micropascal (μPa), rather than 160- dB re 1μPa, behavioral harassment threshold for acoustic, non-impulsive sources (*e.g.,* sub-bottom profilers/chirps, echosounders, and other sonars including side-scan and fish-finding).

NMFS Response: As NMFS has said on numerous other responses to this recommendation, certain sub-bottom profiling systems are appropriately considered to be impulsive sources (*e.g.,* boomers, sparkers); therefore, the threshold of 160 dB re 1μPa will continue to be used for those sources. Other source types referenced by the Commission produce signals that are not necessarily strictly impulsive; however, NMFS finds that the 160-dB root mean square (rms) threshold is most appropriate for use in evaluating potential behavioral impacts to marine mammals because the temporal characteristics (*i.e.,* intermittency) of these sources are better captured by this threshold. The 120-dB threshold is associated with continuous sources and was derived based on studies examining behavioral responses to drilling and dredging. Continuous sounds are those whose sound pressure level remains above that of the ambient sound, with negligibly small fluctuations in level (NIOSH, 1998; ANSI, 2005). Examples of sounds that NMFS would categorize as continuous are those associated with drilling or vibratory pile driving activities. Intermittent sounds are defined as sounds with interrupted levels of low or no sound (NIOSH, 1998). Thus, signals produced by these source types are not continuous but rather intermittent sounds. With regard to behavioral thresholds, we consider the temporal and spectral characteristics of signals produced by these source types to more closely resemble those of an impulse sound rather than a continuous sound. The threshold of 160

dB re 1μPa is typically associated with impulsive sources, which are inherently intermittent. Therefore, the 160 dB threshold (typically associated with impulsive sources) is more appropriate than the 120 dB threshold (typically associated with continuous sources) for estimating takes by behavioral harassment incidental to use of such sources.

Comment 4: The Commission commented that harbor seals have been occurring in the Virginia area earlier in fall months. The Commission recommends that NMFS include at least five harbor seal takes and one gray seal take in the Final IHA to account for their potential occurrence in the project area.

NMFS Response: NMFS has included the takes of five harbor seals and one gray seal, as recommended by the Commission.

Comment 5: The Commission noted concerns with density information and take calculations and recommended the following: NMFS should (1) clarify why various densities were revised and ensure all are correct; (2) report densities and ensonified areas out to three significant digits to ensure takes were calculated properly; (3) include takes for Risso's dolphins based on average group size, noting that Dominion estimated 0.59 takes for this species, but did not request take while estimating ''similarly low numbers'' for pilot whales and requesting take for this species based on group size.

NMFS Response: The densities were not revised and remain the same as were included in the notice for the proposed IHA (83 FR 26968, June 11, 2018), with the exception of adding three decimal places, as requested by the Commission (refer to Table 6 of this notice). The Commission erroneously states that 0.59 takes of Risso's dolphins were calculated. As shown in the notice for the proposed IHA, only 0.08 takes of Risso's dolphins were estimated based on calculations. Calculations of pilot whales estimated 1.15 takes. As Risso's dolphin calculations are so low as to not round up to one (1) take, and the applicant did not request take due to the low likelihood of encountering this species based on take estimates and lack of sighting data, NMFS did not propose takes, and is not authorizing takes for this species. However, calculated takes for pilot whales did estimate over one (1) take. Therefore, takes have been authorized for this species and the take estimate was adjusted to account for average group size for this species.

Comment 6: The Commission recommended that NMFS refrain from authorizing Level B harassment takes of any low frequency (LF) cetacean, including humpback whales and minke whales. This recommendation is based on the fact that the sound source used to calculate the Level B harassment zone (Innomar sub-bottom profiler) operates at frequencies which are 50 kHz beyond the best hearing capabilities of these species, and the sound source with the largest Level B harassment zone within the best hearing range of LF cetaceans only has a 20 m Level B harassment isopleth.

NMFS Response: NMFS has not authorized take of any LF cetaceans, as recommended by the Commission.

Comment 7: The Commission continues to express concern that the method used to estimate the numbers of takes, which summed fractions of takes for each species across project days, does not account for and negates the intent of NMFS' 24-hour reset policy and recommended that NMFS share the rounding criteria with the Commission in an expeditious manner.

NMFS Response: NMFS recently completed internal guidance on rounding and consideration of qualitative factors in the estimation of instances of take, and provided this information to the Commission. As discussed with the Commission, we believe that the methodology used for take calculation in this IHA remains appropriate and is not at odds with the 24-hour reset policy the Commission references.

Comment 8: The Commission continues to request clarification regarding certain issues associated with NMFS' notice that one-year renewals could be issued in certain limited circumstances and expressed concern that the process would bypass the public notice and comment requirements. The Commission also suggested that NMFS should discuss the possibility of renewals through a more general route, such as a rulemaking, instead of notice in a specific authorization. The Commission further recommended that if NMFS did not pursue a more general route, that the agency provide the Commission and the public with a legal analysis supporting our conclusion that this process is consistent with the requirements of section 101(a)(5)(D) of the MMPA. The Commission also noted that NMFS had recently begun utilizing abbreviated notices, referencing relevant documents, to solicit public input and suggested that NMFS use these notices and solicit review in lieu of the currently proposed renewal process.

NMFS Response: As stated in previous responses to this comment from the Commission, the process of issuing a renewal IHA does not bypass the public notice and comment requirements of the MMPA. The notice of the proposed IHA expressly notifies the public that under certain, limited conditions an applicant could seek a renewal IHA for an additional year. The notice describes the conditions under which such a renewal request could be considered and expressly seeks public comment in the event such a renewal is sought. Additional reference to this solicitation of public comment has recently been added at the beginning of the FR notices that consider renewals, requesting input specifically on the possible renewal itself. NMFS appreciates the streamlining achieved by the use of abbreviated FR notices and intends to continue using them for proposed IHAs that include minor changes from previously issued IHAs, but which do not satisfy the renewal requirements. However, we believe our proposed method for issuing renewals meets statutory requirements and maximizes efficiency.

Importantly, such renewals would be limited to circumstances where: The activities are identical or nearly identical to those analyzed in the proposed IHA; monitoring does not indicate impacts that were not previously analyzed and authorized; and, the mitigation and monitoring requirements remain the same, all of which allow the public to comment on the appropriateness and effects of a renewal at the same time the public provides comments on the initial IHA. NMFS has, however, modified the language for future proposed IHAs to clarify that all IHAs, including renewal IHAs, are valid for no more than one year and that the agency would consider only one renewal for a project at this time. In addition, notice of issuance or denial of a renewal IHA would be published in the **Federal Register**, as they are for all IHAs. The option for issuing renewal IHAs has been in NMFS's incidental take regulations since 1996. We will provide any additional information to the Commission and consider posting a description of the renewal process on our website before any renewal is issued utilizing this process.

Description of Marine Mammals in the Area of Specified Activity

Sections 3 and 4 of Dominion's IHA application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history, of the potentially affected marine mammal species. Additional information regarding population trends and threats

may be found in NMFS's Stock Assessment Reports (SAR; *www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments*) and more general information about these species (*e.g.,* physical and behavioral descriptions) may be found on NMFS's website (*www.fisheries.noaa.gov/species-directory*).

Table 1 lists all species with expected potential for occurrence in the survey area and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. For taxonomy, we follow Committee on Taxonomy (2017). PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS's SARs). While no mortality is anticipated or authorized here, PBR is included here as gross indicators of the status of the species and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS's stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS's U.S. 2017 draft SARs (*e.g.,* Hayes *et al.,* 2018). All values presented in Table 2 are the most recent available at the time of publication and are available in the 2017 draft SARs (Hayes *et al.,* 2018).

TABLE 1—MARINE MAMMALS WITH POTENTIAL OCCURRENCE IN THE SURVEY AREA

Common name	Stock	NMFS MMPA and ESA status; strategic (Y/N) [1]	Stock abundance (CV,N_{min}) [2]	PBR [3]	Occurrence and seasonality in the NW atlantic OCS
Toothed whales (Odontoceti)					
Atlantic white-sided dolphin (*Lagenorhynchus acutus*).	W. North Atlantic	-; N	48,819 (0.61; 30,403)	304	rare.
Atlantic spotted dolphin (*Stenella frontalis*).	W. North Atlantic	-; N	44,715 (0.43; 31,610)	316	rare.
Bottlenose dolphin (*Tursiops truncatus*).	W. North Atlantic, Southern Migratory Coastal.	-; Y	3,751 (0.60; 2,353)	23	Common year round.
Clymene dolphin (*Stenella clymene*).	W. North Atlantic	-; N	Unknown (unk; unk; n/a)	Undet	rare.
Pantropical Spotted dolphin (*Stenella attenuata*).	W. North Atlantic	-; N	3,333 (0.91; 1,733)	17	rare.
Risso's dolphin (*Grampus griseus*).	W. North Atlantic	-; N	18,250 (0.46; 12,619)	126	rare.
Common dolphin (*Delphinus delphis*).	W. North Atlantic	-; N	70,184 (0.28; 55,690)	557	Common year round.
Striped dolphin (*Stenella coeruleoalba*).	W. North Atlantic	-; N	54,807 (0.3; 42,804)	428	rare.
Spinner Dolphin (*Stenella longirostris*).	W. North Atlantic	-; N	Unknown (unk; unk; n/a)	Undet	rare.
Harbor porpoise (*Phocoena phocoena*).	Gulf of Maine/Bay of Fundy	-; N	79,833 (0.32; 61,415)	706	Common year round.
Killer whale (*Orcinus orca*)	W. North Atlantic	-; N	Unknown (unk; unk; n/a)	Undet	rare.
False killer whale (*Pseudorca crassidens*).	W. North Atlantic	-; Y	442 (1.06; 212)	2.1	rare.
Long-finned pilot whale (*Globicephala melas*).	W. North Atlantic	-; Y	5,636 (0.63; 3,464)	35	rare.
Short-finned pilot whale (*Globicephala macrorhynchus*).	W. North Atlantic	-; Y	21,515 (0.37; 15,913)	159	rare.
Sperm whale (*Physeter macrocephalus*).	North Atlantic	E; Y	2,288 (0.28; 1,815)	3.6	Year round in continental shelf and slope waters, occur seasonally to forage.
Pygmy sperm whale [4] (*Kogia breviceps*).	W. North Atlantic	-; N	3,785 (0.47; 2,598)	26	rare.
Dwarf sperm whale [4] (*Kogia sima*).	W. North Atlantic	-; N	3,785 (0.47; 2,598)	26	rare.
Cuvier's beaked whale (*Ziphius cavirostris*).	W. North Atlantic	-; N	6,532 (0.32; 5,021)	50	rare.
Blainville's beaked whale [5] (*Mesoplodon densirostris*).	W. North Atlantic	-; N	7,092 (0.54; 4,632)	46	rare.
Gervais' beaked whale [5] (*Mesoplodon europaeus*).	W. North Atlantic	-; N	7,092 (0.54; 4,632)	46	rare.
True's beaked whale [5] (*Mesoplodon mirus*).	W. North Atlantic	-; N	7,092 (0.54; 4,632)	46	rare.
Sowerby's Beaked Whale [5] (*Mesoplodon bidens*).	W. North Atlantic	-; N	7,092 (0.54; 4,632)	46	rare.
Melon-headed whale (*Peponocephala electra*).	W. North Atlantic	-; N	Unknown (unk; unk; n/a)	Undet	rare.
Baleen whales (Mysticeti)					
Minke whale (*Balaenoptera acutorostrata*).	Canadian East Coast	-; N	2,591 (0.81; 1,425)	14	Year round in continental shelf and slope waters, occur seasonally to forage.

TABLE 1—MARINE MAMMALS WITH POTENTIAL OCCURRENCE IN THE SURVEY AREA—Continued

Common name	Stock	NMFS MMPA and ESA status; strategic (Y/N) [1]	Stock abundance (CV,N_{min}) [2]	PBR [3]	Occurrence and seasonality in the NW atlantic OCS
Blue whale (*Balaenoptera musculus*).	W. North Atlantic	E; Y	Unknown (unk; 440)	0.9	Year round in continental shelf and slope waters, occur seasonally to forage.
Fin whale (*Balaenoptera physalus*).	W. North Atlantic	E; Y	1,618 (0.33; 1,234)	2.5	Year round in continental shelf and slope waters, occur seasonally to forage.
Humpback whale (*Megaptera novaeangliae*).	Gulf of Maine	-; Y	335 (0.42; 239)	3.7	Common year round
North Atlantic right whale (*Eubalaena glacialis*).	W. North Atlantic	E; Y	458 (0; 455)	1.4	Year round in continental shelf and slope waters, occur seasonally to forage.
Sei whale (*Balaenoptera borealis*)	Nova Scotia	E; Y	357 (0.52; 236)	0.5	Year round in continental shelf and slope waters, occur seasonally to forage.
Earless seals (Phocidae)					
Gray seal [6] (*Halichoerus grypus*)	W. North Atlantic	-; N	27,131 (0.10; 25,908)	1,554	Unlikely.
Harbor seal (*Phoca vitulina*)	W. North Atlantic	-; N	75,834 (0.15; 66,884)	2,006	Common year round.
Hooded seal (*Cystophora cristata*).	W. North Atlantic	-; N	Unknown (unk; unk)	Undet	rare.
Harp seal (*Phoca groenlandica*)	North Atlantic	-; N	Unknown (unk; unk)	Undet	rare.

[1] *ESA status:* Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR (see footnote 3) or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

[2] CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable. For certain stocks, abundance estimates are actual counts of animals and there is no associated CV. The most recent abundance survey that is reflected in the abundance estimate is presented; there may be more recent surveys that have not yet been incorporated into the estimate. All values presented here are from the 2017 Draft Atlantic SARs.

[3] Potential biological removal, defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population size (OSP).

[4] Abundance estimate includes both dwarf and pygmy sperm whales.

[5] Abundance estimate includes all species of *Mesoplodon* in the Atlantic.

[6] Abundance estimate applies to U.S. population only, actual abundance, including those occurring in Canada, is estimated at 505,000.

All species that could potentially occur in the proposed survey areas are included in Table 1. However, the temporal and/or spatial occurrence for all but 11 of the species listed in Table 2 is such that take of these species is not expected to occur, and they are not discussed further beyond the explanation provided here. Take of these species is not anticipated either because they have very low densities in the project area, are known to occur further offshore or further north than the project area, or are considered very unlikely to occur in the project area during the proposed survey due to the species' seasonal occurrence in the area. The 11 species/stocks evaluated for incidental take in the proposed IHA included: North Atlantic right whale; humpback whale; fin whale; minke whale; Atlantic white-sided dolphin; common dolphin; bottlenose dolphin; Atlantic spotted dolphin; long-finned pilot whale; short-finned pilot whale; and harbor porpoise. However, as discussed below, takes for harbor seals and gray seals have been authorized as a result of consideration of public comment on the proposed IHA.

Five marine mammal species listed in Table 2 are listed under the ESA and are known to be present, at least seasonally, in waters of the mid-Atlantic (sperm whale, north Atlantic right whale, fin whale, blue whale, and sei whale). All of these species are highly migratory and do not spend extended periods of time in the localized survey area. The offshore waters of Virginia (including the survey area) are primarily used as a migration corridor for these species, particularly north Atlantic right whales, during seasonal movements north or south between feeding and breeding grounds (Knowlton *et al.,* 2002; Firestone *et al.,* 2008). While fin and north Atlantic right whales have the potential to occur within the survey area, sperm, blue, and sei whales are more pelagic and/or northern species and their presence within the survey area is unlikely (Waring *et al.,* 2007; 2010; 2012; 2013) and these species are therefore not considered further in this analysis. In addition, the proposed IHA (83 FR 26968, June 11, 2018) noted that, while stranding data exists for harbor and gray seals along the mid-Atlantic coast south of New Jersey, their preference for colder, northern waters during the survey period makes their presence in the survey area unlikely. Winter haulout sites for harbor seals have been identified within the Chesapeake Bay region. However, the proposed IHA noted that the seals were not expected to be present during the summer and fall months when the survey activities are planned (Waring *et al.,* 2016). In addition, the proposed IHA noted that coastal Virginia represents the southern extent of the habitat range for gray seals, with few stranding records reported and sightings only occur during winter months as far south as New Jersey (Waring *et al.,* 2016). Therefore pinniped species were not considered for take in the proposed IHA. However, after review of public comments received on the proposed IHA that stated harbor seals and gray seals have more recently been observed to be present in the area earlier than expected, NMFS has added a small number of takes for these species out of an abundance of caution.

A detailed description of the species likely to be affected by Dominion's UXO survey activities, including brief introductions to the species and relevant stocks as well as available information regarding population trends and threats, and information regarding local occurrence, were provided in the **Federal Register** notice for the proposed IHA (83 FR 26968; June 11, 2018); since that time, we are not aware of any changes in the status of these species

and stocks; therefore, detailed descriptions are not repeated here. Please refer to the **Federal Register** notice for the proposed IHA for descriptions of species. Please also refer to NMFS' website (*www.fisheries.noaa.gov/species-directory*) for generalized species accounts.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The potential effects of Dominion's UXO survey activities have the potential to result in incidental take of marine mammals by harassment in the vicinity of the survey area. The **Federal Register** notice for the proposed IHA (83 FR 26968; June 11, 2018) included a discussion of the potential effects of Dominion's UXO survey activities on marine mammals and their habitat, and that information is not repeated here; please refer to that **Federal Register** notice for that information. No instances of injury, serious injury, or mortality are expected as a result of the planned activities.

Estimated Take

This section provides an estimate of the number of incidental takes authorized through this IHA, which informed both NMFS' consideration of ''small numbers'' and the negligible impact determination.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would be by Level B harassment only, as use of the HRG equipment has the potential to result in disruption of behavioral patterns for individual marine mammals. NMFS has determined take by Level A harassment is not an expected outcome of the proposed activity as discussed in greater detail below. As described previously, no mortality or serious injury is anticipated, nor is any authorized for this activity. Below we describe how the take is estimated for this project.

Described in the most basic way, we estimate take by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) and the number of days of activities. Below, we describe these components in more detail and present the take estimate.

Acoustic Thresholds

NMFS uses acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the sound source (*e.g.,* frequency, predictability, duty cycle); the environment (*e.g.,* bathymetry); and the receiving animals (hearing, motivation, experience, demography, behavioral context); therefore can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.* 2011). NMFS uses a generalized acoustic threshold based on received level to estimate the onset of Level B (behavioral) harassment. NMFS predicts that marine mammals may be behaviorally harassed when exposed to underwater anthropogenic noise above received levels 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* seismic HRG equipment) or intermittent (*e.g.,* scientific sonar) sources. Dominion's proposed activity includes the use of impulsive sources. Therefore, the 160 dB re 1 μPa (rms) criteria is applicable for analysis of Level B harassment.

Level A harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (NMFS 2016) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). The Technical Guidance identifies the received levels, or thresholds, above which individual marine mammals are predicted to experience changes in their hearing sensitivity for all underwater anthropogenic sound sources, reflects the best available science, and better predicts the potential for auditory injury than does NMFS' historical criteria.

These thresholds were developed by compiling and synthesizing the best available science and soliciting input multiple times from both the public and peer reviewers to inform the final product, and are provided in Table 2 below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS 2016 Technical Guidance, which may be accessed at: *www.nmfs.noaa.gov/pr/acoustics/guidelines.htm.* As described above, Dominion's proposed activity includes the use of intermittent and impulsive sources. We note here that for intermittent sources such as the Geo-Source 800 sparker and the Innomar Medium 100 sub-bottom profiler, it is more appropriate to consider these sources as non-impulsive for consideration of potential for Level A harassment but due to their intermittent nature they are considered impulsive for consideration of potential for Level B harassment.

TABLE 2—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT IN MARINE MAMMALS

Hearing group	PTS onset thresholds	
	Impulsive *	Non-impulsive
Low-Frequency (LF) Cetaceans	$L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	$L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	$L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	$L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	$L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	$L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	$L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	$L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	$L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	$L_{E,OW,24h}$: 219 dB.

Note: * Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (Lpk) has a reference value of 1 μPa, and cumulative sound exposure level (LE) has a reference value of 1μPa2s. In this Table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.,* varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that feed into estimating the area ensonified above the acoustic thresholds.

The proposed survey would entail the use of HRG survey equipment. The distance to the isopleth corresponding to the threshold for Level B harassment was calculated for all HRG survey equipment with the potential to result in harassment of marine mammals (see Table 1 of the Proposed IHA (83 FR 26968; June 11, 2018)). Of the HRG survey equipment planned for use that has the potential to result in harassment of marine mammals, acoustic modeling indicated the Innomar Medium 100 sub-bottom profiler would be expected to produce sound that would propagate the furthest in water (Table 3); therefore, for the purposes of the take calculation, it was assumed this equipment would be active during the entirety of the survey. Thus the distance to the isopleth corresponding to the threshold for Level B harassment for the Innomar Medium 100 sub-bottom profiler (100 m; Table 3) was used as the basis of the Level B take calculation for all marine mammals. However, this sound source operates at frequencies that are 50 kHz beyond the best hearing capabilities of LF cetaceans, so there is no potential for behavioral harassment of these species. The sound source with the next-largest Level B harassment threshold distance was the Geo-Source 800 sparker and this distance is 20 m, which is well within the required 100-m exclusion zone for large whales. Therefore, no take for LF cetaceans have been authorized.

TABLE 3—PREDICTED RADIAL DISTANCES (m) FROM HRG SOURCES TO ISOPLETHS CORRESPONDING TO LEVEL B HARASSMENT THRESHOLD

HRG system	HRG survey equipment	Modeled distance to threshold (160 dB re 1 μPa)
Pinger/Chirper	GeoPulse sub-bottom profiler	<5 m
Sparker	Geo-Source 800 sparker	<20 m
Medium penetration sub-bottom profiler	Innomar Medium 100 sub-bottom profiler	*<100 m

*We note here that the Innomar Medium 100 sub-bottom profiler operating frequencies (85–115 kHz) are beyond the best hearing capabilities of LF cetaceans (7–35 kHz), but as this sound source provides the largest Level B isopleth, this information was used to calculate the zone of influence and estimate take for all species.

Predicted distances to Level A harassment isopleths, which vary based on marine mammal functional hearing groups (Table 4), were also calculated by Dominion. The updated acoustic thresholds for impulsive sounds (such as HRG survey equipment) contained in the Technical Guidance (NMFS, 2016) were presented as dual metric acoustic thresholds using both SEL_{cum} and peak sound pressure level (SPL) metrics for all equipment in the notice of the proposed IHA (83 FR 26968, June 11, 2018). As dual metrics, NMFS considers onset of PTS (Level A harassment) to have occurred when either one of the two metrics is exceeded (*i.e.,* metric resulting in the largest isopleth). However, the Geo-Source 800 sparker and Innomar 100 sub-bottom profiler are more appropriately considered as non-impulsive sources, which considers the SEL_{cum} metric only. This information has been corrected in Table 4 below, and NMFS notes that the correction results in smaller distances to the Level A threshold than reported in the proposed IHA notice and reinforces our determination that Level A harassment is so unlikely to occur as to be discountable. The SEL_{cum} metric considers both level and duration of exposure, as well as auditory weighting functions by marine mammal hearing group. In recognition of the fact that calculating Level A harassment ensonified areas could be more technically challenging to predict due to the duration component and the use of weighting functions in the new SEL_{cum} thresholds, NMFS developed an optional User Spreadsheet that includes tools to help predict a simple isopleth that can be used in conjunction with marine mammal density or occurrence to facilitate the estimation of take numbers. Dominion used the NMFS optional User Spreadsheet to calculate distances to Level A harassment isopleths (see Appendix A of the IHA application). Modeled distances to isopleths corresponding to Level A harassment thresholds for the proposed HRG equipment and marine mammal hearing groups are shown in Table 4.

TABLE 4—MODELED RADIAL DISTANCES (m) TO ISOPLETHS CORRESPONDING TO LEVEL A HARASSMENT THRESHOLDS

Functional hearing group (Level A harassment thresholds)	PTS onset	Lateral distance (m)
GeoPulse Sub-Bottom Profiler		
Low frequency cetaceans	199 dB SEL_{cum}	—
Mid frequency cetaceans	198 dB SEL_{cum}	—

TABLE 4—MODELED RADIAL DISTANCES (m) TO ISOPLETHS CORRESPONDING TO LEVEL A HARASSMENT THRESHOLDS—Continued

Functional hearing group (Level A harassment thresholds)	PTS onset	Lateral distance (m)
High frequency cetaceans	173 dB SEL_{cum}	<1
Phocid Pinnipeds (Underwater)	201 dB SEL_{cum}	—
Geo-Source 800 Sparker		
Low frequency cetaceans	219 dB_{peak}/183 dB SEL_{cum}	5
Mid frequency cetaceans	230 dB_{peak}/185 dB SEL_{cum}	<1
High frequency cetaceans	202 dB_{peak}/155 dB SEL_{cum}	<1; 24
Phocid Pinnipeds (Underwater)	218 dB_{peak}/185 dB SEL_{cum}	3
Innomar Medium 100 Sub-Bottom Profiler		
Low frequency cetaceans	199 dB SEL_{cum}	N/A
Mid frequency cetaceans	198 dB SEL_{cum}	—
High frequency cetaceans	173 dB SEL_{cum}	<5
Phocid Pinnipeds (Underwater)	201 dB SEL_{cum}	N/A

Note: Peak SPL is unweighted (flat weighted), whereas the cumulative SEL criterion is M-weighted for the given marine mammal hearing group.
— indicates not expected to be measureable to regulatory threshold at any appreciable distance.
N/A indicates not applicable as the HRG sound source is outside the effective marine mammal hearing range.

In this case, due to the very small estimated distances to Level A harassment thresholds for all marine mammal functional hearing groups, based on both SEL_{cum} and peak SPL (Table 4), and in consideration of the mitigation measures that must be implemented, including marine mammal exclusion zones to avoid Level A harassment (see the Mitigation section for more detail) NMFS has determined that the likelihood of Level A harassment take of marine mammals occurring as a result of the proposed survey is so low as to be discountable. Therefore, NMFS has not authorized Level A harassment take of any marine mammals in the IHA.

We note that because of some of the assumptions included in the methods used, isopleths produced may be overestimates to some degree. The acoustic sources proposed for use in Dominion's survey do not radiate sound equally in all directions but were designed instead to focus acoustic energy directly toward the sea floor. Therefore, the acoustic energy produced by these sources is not received equally in all directions around the source but is instead concentrated along some narrower plane depending on the beamwidth of the source. For example, in the case of the Innomar Medium 100 sub-bottom profiler, the beamwidth is only one degree. However, the calculated distances to isopleths do not account for this directionality of the sound source and are therefore conservative. For mobile sources, such as the proposed survey, the User Spreadsheet predicts the closest distance at which a stationary animal would not incur PTS if the sound source traveled by the animal in a straight line at a constant speed. In addition to the conservative estimation of calculated distances to isopleths associated with the Innomar Medium 100 sub-bottom profiler, calculated takes may be conservative due to the fact that this sound source operates at frequencies beyond the best hearing capabilities of LF cetaceans, but calculated takes for all species were based on the isopleths associated with this sound source. As discussed above, the Innomar Medium 100 sub-bottom profiler operates at frequencies between 85 and 115 kHz and the best hearing range of LF cetaceans is between 7 and 35 kHz. Therefore, we would not expect that take of LF cetaceans would likely occur due to the use of this equipment because it operates beyond their hearing capabilities. The proposed IHA (83 FR 26968, June 11, 2018) noted takes were estimated based on these isopleths due to the fact that the largest distances were associated with this equipment. However, after consideration of public comments, NMFS has determined not to issue take of LF cetaceans for the following reasons: (1) the Innomar Medium 100 sub-bottom profiler operates at frequencies that are 50 kHz beyond the best hearing capabilities for these species, so there would be no potential for behavioral disturbance, and (2) the sound source with the next largest Level B harassment isopleth is the Geo-Source 800 Sparker, for which the distance to the Level B harassment threshold has been calculated to be 20 m, and this is well within the required 100-m exclusion zone (EZ) for large whales.

Marine Mammal Occurrence

In this section we provide the information about the presence, density, or group dynamics of marine mammals that will inform the take calculations.

The best available scientific information was considered in conducting marine mammal exposure estimates (the basis for estimating take). For cetacean species, densities calculated by Roberts *et al.* (2016) were used. The density data presented by Roberts *et al.* (2016) incorporates aerial and shipboard line-transect survey data from NMFS and from other organizations collected over the period 1992–2014. Roberts *et al.* (2016) modeled density from 8 physiographic and 16 dynamic oceanographic and biological covariates, and controlled for the influence of sea state, group size, availability bias, and perception bias on the probability of making a sighting. In general, NMFS considers the models produced by Roberts *et al.* (2016) to be the best available source of data regarding cetacean density in the Atlantic Ocean. More information, including the model results and supplementary information for each model, is available online at: *seamap.env.duke.edu/models/Duke-EC-GOM-2015/.*

For the purposes of the take calculations, density data from Roberts *et al.* (2016) were mapped within the boundary of the survey area for each survey segment (*i.e.,* the Lease Area

survey segment and the cable route area survey segment; See Figure 1 in the IHA application) using a geographic information system. Monthly density data for all cetacean species potentially taken by the proposed survey was available via Roberts *et al.* (2016). Monthly mean density within the survey area, as provided in Roberts *et al.* (2016), were averaged by season (*i.e.,* Summer (June, July, August), and Fall (September, October, November)) to provide seasonal density estimates. The highest average seasonal density as reported by Roberts *et al.* (2016), for each species, was used based on the planned survey dates of August through October.

Take Calculation and Estimation

Here we describe how the information provided above is brought together to produce a quantitative take estimate.

In order to estimate the number of marine mammals predicted to be exposed to sound levels that would result in harassment, radial distances to predicted isopleths corresponding to harassment thresholds are calculated, as described above. Those distances are then used to calculate the area(s) around the HRG survey equipment predicted to be ensonified to sound levels that exceed harassment thresholds. The area estimated to be ensonified to relevant thresholds in a single day of the survey is then calculated, based on areas predicted to be ensonified around the HRG survey equipment and estimated trackline distance traveled per day by the survey vessel. The estimated daily vessel track line distance was determined using the estimated average speed of the vessel (4 kn) multiplied by 24 (to account for the 24 hour operational period of the survey). Using the maximum distance to the regulatory threshold criteria (Tables 4 and 5) and estimated daily track line distance of approximately 177.8 km (110.5 mi), it was estimated that an area of 35.59 km^2 (13.74 mi^2) per day would be ensonified to the largest Level B harassment threshold, and 17.78 km^2 (0.69 mi^2) per day would be ensonifed to the Level A harassment threshold (largest threshold of 155 dB SEL_{cum} for HF cetaceans was used) (Table 5).

TABLE 5—ESTIMATED TRACK LINE DISTANCE PER DAY (km) AND AREA (km^2) ESTIMATED TO BE ENSONIFIED TO LEVEL B HARASSMENT THRESHOLD PER DAY

Estimated track line distance per day (km)	Estimated area ensonified to Level A harassment threshold per day (km^2)	Estimated area ensonified to Level B harassment threshold per day (km^2)
177.8	17.78	35.59

The number of marine mammals expected to be incidentally taken per day is then calculated by estimating the number of each species predicted to occur within the daily ensonified area, using estimated marine mammal densities as described above. In this case, estimated marine mammal density values varied between the turbine positions, inter-array cable route corridor survey areas, and export cable route corridors; therefore, the estimated number of each species taken per survey day was calculated separately for the these survey areas. Estimated numbers of each species taken per day are then multiplied by the number of survey days to generate an estimate of the total number of each species expected to be taken over the duration of the survey. In this case, as the estimated number of each species taken per day varied depending on survey area (turbine positions, inter-array cable route, and export cable route corridor), the number of each species taken per day in each respective survey area was multiplied by the number of survey days anticipated in each survey area (*i.e.,* 15 survey days each in the turbine position location and inter-array cable route, and 60 survey days in the export cable route corridor portion of the survey) to get a total number of takes per species in each respective survey area.

As described above, due to the very small estimated distances to Level A harassment thresholds (based on both SEL_{cum} and peak SPL; Table 4), and in consideration of the mitigation measures that must be implemented, the likelihood of the proposed survey resulting in take in the form of Level A harassment is considered so unlikely as to be discountable. Authorized take numbers are shown in Table 6. As described above, the zone of influence (ZOI) were calculated based on the sound source with the largest isopleths to the regulatory thresholds (the Innomar Medium 100 sub-bottom profiler) without consideration of the fact that this equipment operates beyond the best hearing capability of LF cetaceans, so calculated takes of these species are likely to be overestimates due to the fact that we would not necessarily expect LF cetaceans to be harassed by sound produced by this equipment. Additionally, as shown in Table 3, the Geo-Source 800 Sparker has the next largest Level B harassment threshold distance of 20 m, which is well within the required distance of 100 m for which vessels are required to avoid large cetaceans. Therefore, take for all low frequency cetaceans have been adjusted to zero.

TABLE 6—NUMBERS OF INCIDENTAL TAKE OF MARINE MAMMALS CALCULATED AND AUTHORIZED FOR LEVEL B HARASSMENT

Species	Turbine positions		Export cable route		Inter-array cable route		Totals	
	Max. seasonal density [a] (#/100 km^2)	Calculated takes	Max. seasonal density [a] (#/100 km^2)	Calculated takes	Max. seasonal density [a] (#/100 km^2)	Calculated takes	Adjusted take	% of population
North Atlantic right whale	0.003	0.018	0.003	0.070	0.003	0.018	[b c] 0	0.000
Humpback whale	0.018	0.097	0.018	0.387	0.018	0.097	[b c] 0	0.000
Fin whale	0.107	0.570	0.107	2.279	0.107	0.570	[b c] 0	0.00
Minke whale	0.027	0.144	0.027	0.575	0.027	0.144	[b c] 0	0.39
Bottlenose dolphin—N Coastal Migratory	13.991	74.691	13.991	298.765	13.991	74.691	[c d e] 350	9.33
Bottlenose dolphin—Offshore	13.991	74.691	13.991	298.765	13.991	74.691	[c d e] 350	9.33
Atlantic spotted dolphin	0.899	4.800	1.231	26.289	0.899	4.800	[d] 300	0.67
Common dolphin	2.501	13.349	2.501	53.397	2.501	13.349	[d] 400	0.57
Atlantic white-sided dolphin	0.389	2.076	0.389	8.305	0.389	2.076	[d] 200	0.41

TABLE 6—NUMBERS OF INCIDENTAL TAKE OF MARINE MAMMALS CALCULATED AND AUTHORIZED FOR LEVEL B HARASSMENT—Continued

Species	Turbine positions		Export cable route		Inter-array cable route		Totals	
	Max. seasonal density [a] (#/100 km²)	Calculated takes	Max. seasonal density [a] (#/100 km²)	Calculated takes	Max. seasonal density [a] (#/100 km²)	Calculated takes	Adjusted take	% of population
Risso's dolphin	0.007	0.035	0.001	0019	0.007	0.035	0	0.00
Short-finned/long-finned pilot whale	0.058	0.310	0.025	0.532	0.058	0.310	[f] 15	0.27
Harbor porpoise	0.272	1.452	0.230	4.915	0.272	1.452	6	0.01
Harbor seal	0.000	0.000	0.000	0.000	0.000	0.000	5	0.007
Gray seal	0.000	0.000	0.000	0.000	0.000	0.000	1	0.000

[a] Density values from Duke University (Roberts *et al.,* 2016).
[b] Mitigation (exclusion zone) will prevent take.
[c] Take calculations based on largest Level B harassment isopleth; however, the sound source is 50 kHz beyond the best hearing sensitivity for LF cetaceans and the Level B harassment isopleth for the next largest source is 20 m, which is well within the required 100-m exclusion zone for large whales. No take has been authorized for LF cetaceans.
[d] Calculated take has been modified to account for increases in actual sighting data to date (Smultea Environmental Sciences 2016; Gardline 2016b) based on similar project activities.
[e] Take adjusted to account for possible overlap of the Western North Atlantic southern migratory coastal and offshore stocks.
[f] Take adjusted to account for potential overlap of stocks (assume 50 percent of each).

Mitigation

In order to issue an IHA under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting such activity or other means of effecting the least practicable adverse impact upon the affected species or stocks and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, we carefully consider two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned) the likelihood of effective implementation (probability implemented as planned), and;

(2) The practicability of the measures for applicant implementation, which may consider such things as relative cost and impact on operations.

Mitigation Measures

With NMFS' input during the application process, and as per the BOEM Lease, Dominion must implement the following mitigation measures during the proposed marine site characterization surveys.

Marine Mammal Exclusion and Watch Zones

Marine mammal exclusion zones (EZ) must be established around the HRG survey equipment and monitored by protected species observers (PSO) during HRG surveys as follows:

- 50 m (164.0 ft) EZ for harbor porpoises, which is the extent of the largest calculated distance to the potential for onset of PTS (Level A harassment);
- 100 m (328.1 ft) EZ for ESA-listed large whales (*i.e.,* fin whales), which is the largest calculated distance to the potential for behavioral harassment (Level B behavioral harassment), and for species for which authorization has not been granted, or for species for which authorization has been granted but the authorized number of takes have been met; and
- 500 m (1,640.4 ft) EZ for North Atlantic right whales. In addition, PSOs must visually monitor to the extent of the Level B zone (100 m (328.1 ft)) for all other marine mammal species not listed above.

Visual Monitoring

Visual monitoring of the established exclusion and monitoring zones must be performed by qualified and NMFS-approved PSOs. It must be the responsibility of the Lead PSO on duty to communicate the presence of marine mammals as well as to communicate and enforce the action(s) that are necessary to ensure mitigation and monitoring requirements are implemented as appropriate. PSOs must be equipped with binoculars and have the ability to estimate distances to marine mammals located in proximity to the vessel and/or exclusion zone using range finders. Reticulated binoculars must also be available to PSOs for use as appropriate based on conditions and visibility to support the siting and monitoring of marine species. Digital single-lens reflex camera equipment must be used to record sightings and verify species identification. During surveys conducted at night, night-vision equipment and infrared technology must be available for PSO use.

Pre-Clearance of the Exclusion Zone

For all HRG survey activities, Dominion must implement a 30-minute pre-clearance period of the relevant EZs prior to the initiation of HRG survey equipment. During this period the EZs must be monitored by PSOs, using the appropriate visual technology for a 30-minute period. HRG survey equipment must not be initiated if marine mammals are observed within or approaching the relevant EZs during this pre-clearance period. If a marine mammal were observed within or approaching the relevant EZ during the

pre-clearance period, ramp-up must not begin until the animal(s) has been observed exiting the EZ or until an additional time period has elapsed with no further sighting of the animal (15 minutes for small delphinoid cetaceans and pinnipeds and 30 minutes for all other species). This pre-clearance requirement must include small cetaceans (dolphins and harbor porpoises) that approach the vessel (*e.g.,* bow ride). PSOs must also continue to monitor the zone for 30 minutes after survey equipment is shut down or survey activity has concluded.

Ramp-Up of Survey Equipment

Where technically feasible, a ramp-up procedure must be used for HRG survey equipment capable of adjusting energy levels at the start or re-start of HRG survey activities. The ramp-up procedure must be used at the beginning of HRG survey activities in order to provide additional protection to marine mammals near the survey area by allowing them to vacate the area prior to the commencement of survey equipment use at full energy. A ramp-up must begin with the power of the smallest acoustic equipment at its lowest practical power output appropriate for the survey. When technically feasible the power must then be gradually turned up and other acoustic sources added in way such that the source level would increase gradually.

Shutdown Procedures

If a marine mammal is observed within or approaching the relevant EZ (as described above) an immediate shutdown of the survey equipment is required. Subsequent restart of the survey equipment must only occur after the animal(s) has either been observed exiting the relevant EZ or until an additional time period has elapsed with no further sighting of the animal (15 minutes for harbor porpoises and 30 minutes for all other species).

If the HRG equipment shuts down for reasons other than mitigation (*i.e.,* mechanical or electronic failure) resulting in the cessation of the survey equipment for a period greater than 20 minutes, a 30 minute pre-clearance period (as described above) must precede the restart of the HRG survey equipment. If the pause is less than less than 20 minutes, the equipment shall be restarted as soon as practicable at its full operational level only if visual surveys were continued diligently throughout the silent period and the EZs remained clear of marine mammals during that entire period. If visual surveys were not continued diligently during the pause of 20 minutes or less, a 30-minute pre-clearance period (as described above) must precede the re-start of the HRG survey equipment. Following a shutdown, HRG survey equipment shall be restarted following pre-clearance of the zones as described above.

Vessel Strike Avoidance

Dominion must ensure that vessel operators and crew maintain a vigilant watch for cetaceans and pinnipeds by slowing down or stopping the vessel to avoid striking marine mammals. Survey vessel crew members responsible for navigation duties must receive site-specific training on marine mammal sighting/reporting and vessel strike avoidance measures. Vessel strike avoidance measures must include, but are not limited to, the following, except under circumstances when complying with these requirements would put the safety of the vessel or crew at risk:

- All vessel operators and crew must maintain vigilant watch for cetaceans and pinnipeds, and slow down or stop their vessel to avoid striking these protected species;
- All vessel operators must comply with 10 kn (18.5 km/hr) or less speed restrictions in any DMA. This applies to all vessels operating at any time of year. In addition (if applicable, as surveys are not anticipated to occur during this time of year), vessels over 19.8 m (65 ft) operating from November 1 through April 30 must operate at speeds of 10 kn or less;
- All vessel operators must reduce vessel speed to 10 kn (18.5 km/hr) or less when any large whale, any mother/calf pairs, pods, or large assemblages of non-delphinoid cetaceans are observed near (within 100 m (330 ft)) an underway vessel;
- All survey vessels must maintain a separation distance of 500 m (1640 ft) or greater from any sighted North Atlantic right whale;
- If underway, vessels must steer a course away from any sighted North Atlantic right whale at 10 kn (18.5 km/hr) or less until the 500 m (1640 ft) minimum separation distance has been established. If a North Atlantic right whale is sighted in a vessel's path, or within 500 m (1640 ft)) to an underway vessel, the underway vessel must reduce speed and shift the engine to neutral. Engines must not be engaged until the North Atlantic right whale has moved outside of the vessel's path and beyond 500 m. If stationary, the vessel must not engage engines until the North Atlantic right whale has moved beyond 100 m;
- All vessels must maintain a separation distance of 100 m (330 ft) or greater from any sighted non-delphinoid cetacean. If sighted, the vessel underway must reduce speed and shift the engine to neutral, and must not engage the engines until the non-delphinoid cetacean has moved outside of the vessel's path and beyond 100 m. If a survey vessel is stationary, the vessel must not engage engines until the non-delphinoid cetacean has moved out of the vessel's path and beyond 100 m;
- All vessels must maintain a separation distance of 100 m or greater from any sighted non-delphinoid cetacean. If sighted, the vessel underway must reduce speed and shift the engine to neutral, and must not engage the engines until the non-delphinoid cetacean has moved outside of the vessel's path and beyond 100 m. If a survey vessel is stationary, the vessel must not engage the engines until the non-delphinoid cetacean has moved out of the vessel's path and beyond 100 m.
- Any vessel underway must remain parallel to a sighted delphinoid cetacean's course whenever possible, and avoid excessive speed or abrupt changes in direction. Any vessel underway must reduce vessel speed to 10 kn (18.5 km/hr) or less when pods (including mother/calf pairs) or large assemblages of delphinoid cetaceans are observed. Vessels must not adjust course and speed until the delphinoid cetaceans have moved beyond 50 m and/or the abeam of the underway vessel;
- All vessels underway must not divert or alter course in order to approach any whale, delphinoid cetacean, or pinniped. Any vessel underway must avoid excessive speed or abrupt changes in direction to avoid injury to the sighted cetacean or pinniped; and
- All vessels must maintain a separation distance of 50 m (164 ft) or greater from any sighted pinniped.

Seasonal Operating Requirements

Between watch shifts, members of the monitoring team must consult NMFS' North Atlantic right whale reporting systems for the presence of North Atlantic right whales throughout survey operations. The proposed survey activities will occur in the vicinity of the Right Whale Mid-Atlantic SMA located at the mouth of the Chesapeake Bay. The proposed survey start date in August, 2018 and would last for up to three months. Therefore, it is possible that the HRG survey activities would occur outside of the seasonal mandatory speed restriction period for this SMA (November 1 through April 30). Members of the monitoring team must monitor the NMFS North Atlantic right

whale reporting systems for the establishment of a Dynamic Management Area (DMA). If NMFS should establish a DMA in the survey area, within 24 hours of the establishment of the DMA Dominion must work with NMFS to shut down and/or alter the survey activities as needed to avoid right whales to the extent possible.

These mitigation measures are designed to avoid the already low potential for injury in addition to some Level B harassment, and to minimize the potential for vessel strikes. There are no known marine mammal feeding areas, rookeries, or mating grounds in the survey area that would otherwise potentially warrant increased mitigation measures for marine mammals or their habitat (or both). The proposed survey would occur in an area that has been identified as a biologically important area for migration for North Atlantic right whales. However, given the small spatial extent of the survey area relative to the substantially larger spatial extent of the right whale migratory area, the survey is not expected to appreciably reduce migratory habitat nor to negatively impact the migration of North Atlantic right whales, thus additional mitigation to address the proposed survey's occurrence in North Atlantic right whale migratory habitat is not warranted. Further, these mitigation measures are practicable for the applicant to implement.

Based on our evaluation of the mitigation measures, NMFS has determined that the measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth, requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.,* presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) Action or environment (*e.g.,* source characterization, propagation, ambient noise); (2) affected species (*e.g.,* life history, dive patterns); (3) co-occurrence of marine mammal species with the action; or (4) biological or behavioral context of exposure (*e.g.,* age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) Long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.,* marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Monitoring Measures

As described above, visual monitoring of the EZs and monitoring zone must be performed by qualified and NMFS-approved PSOs. Observer qualifications must include direct field experience on a marine mammal observation vessel and/or aerial surveys and completion of a PSO training program, as appropriate. An observer team comprising a minimum of four NMFS-approved PSOs operating in shifts, must be employed by Dominion during the proposed surveys. PSOs must work in shifts such that no one monitor must work more than 4 consecutive hours without a 2 hour break or longer than 12 hours during any 24-hour period. During daylight hours the PSOs must rotate in shifts of one on and three off, while during nighttime operations PSOs must work in pairs. During ramp-up procedures, two PSOs must be required. Each PSO must monitor 360 degrees of the field of vision.

Also as described above, PSOs must be equipped with binoculars and have the ability to estimate distances to marine mammals located in proximity to the vessel and/or exclusion zone using range finders. Reticulated binoculars must also be available to PSOs for use as appropriate based on conditions and visibility to support the siting and monitoring of marine species. Digital single-lens reflex camera equipment must be used to record sightings and verify species identification. During night operations, night-vision equipment, and infrared technology must be used to increase the ability to detect marine mammals. Position data must be recorded using hand-held or vessel global positioning system (GPS) units for each sighting. Observations must take place from the highest available vantage point on the survey vessel. General 360-degree scanning must occur during the monitoring periods, and target scanning by the PSO must occur when alerted of a marine mammal presence.

Data on all PSO observations must be recorded based on standard PSO collection requirements. This must include dates and locations of survey operations; time of observation, location and weather; details of the sightings (*e.g.,* species, age classification (if known), numbers, behavior); and details of any observed ''taking'' (behavioral disturbances). The data sheet must be provided to NMFS for review and approval prior to the start of survey activities. In addition, prior to initiation of survey work, all crew members must undergo environmental training, a component of which must focus on the procedures for sighting and protection of marine mammals. A briefing must also be conducted between the survey supervisors and crews, the PSOs, and Dominion. The purpose of the briefing must be to establish responsibilities of each party, define the chains of command, discuss communication procedures, provide an overview of monitoring purposes, and review operational procedures.

Reporting Measures

Dominion must provide the following reports as necessary during survey activities:

Notification of Injured or Dead Marine Mammals—In the unanticipated event that the specified HRG activities lead to an injury of a marine mammal (Level A harassment) or mortality (*e.g.,* ship-strike, gear interaction, and/or entanglement), Dominion must immediately cease the specified activities and report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources and the NMFS Greater Atlantic

Stranding Coordinator. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities must not resume until NMFS is able to review the circumstances of the event. NMFS shall work with Dominion to minimize reoccurrence of such an event in the future. Dominion must not resume activities until notified by NMFS.

In the event that Dominion discovers an injured or dead marine mammal and determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.,* in less than a moderate state of decomposition), Dominion must immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources and the NMFS Greater Atlantic Stranding Coordinator. The report must include the same information identified in the paragraph above. Activities must be able to continue while NMFS reviews the circumstances of the incident. NMFS must work with Dominion to determine if modifications in the activities are appropriate.

In the event that Dominion discovers an injured or dead marine mammal and determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Dominion must report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, and the NMFS Greater Atlantic Regional Stranding Coordinator, within 24 hours of the discovery. Dominion must provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS. Dominion may continue its operations under such a case.

Within 90 days after completion of survey activities, a final technical report must be provided to NMFS that fully documents the methods and monitoring protocols, summarizes the data recorded during monitoring, estimates the number of marine mammals estimated to have been taken during survey activities, and provides an interpretation of the results and effectiveness of all mitigation and monitoring. Any recommendations made by NMFS must be addressed in the final report prior to acceptance by NMFS.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival. A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through harassment, NMFS considers other factors, such as the likely nature of any responses (*e.g.,* intensity, duration), the context of any responses (*e.g.,* critical reproductive time or location, migration), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS's implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the environmental baseline (*e.g.,* as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, our analysis applies to all the species listed in Tables 8 and 9, given that NMFS expects the anticipated effects of the proposed survey to be similar in nature.

NMFS does not anticipate that injury, serious injury, or mortality would occur as a result of Dominion's proposed survey, even in the absence of mitigation. Thus the authorization does not authorize any serious injury or mortality. Non-auditory physical effects and vessel strike are not expected to occur.

We expect that most potential takes would be in the form of short-term Level B behavioral harassment in the form of temporary avoidance of the area or decreased foraging (if such activity were occurring), reactions that are considered to be of low severity and with no lasting biological consequences (*e.g.,* Southall *et al.,* 2007).

Potential impacts to marine mammal habitat were discussed in the notice of proposed IHA (83 FR 26968; June 11, 2018, see *Potential Effects of the Specified Activity on Marine Mammals and their Habitat*). Marine mammal habitat may be impacted by elevated sound levels, but these impacts would be temporary. In addition to being temporary and short in overall duration, the acoustic footprint of the proposed survey is small relative to the overall distribution of the animals in the area and their use of the area. Feeding behavior is not likely to be significantly impacted, as no areas of biological significance for marine mammal feeding are known to exist in the survey area. Prey species are mobile and are broadly distributed throughout the project area; therefore, marine mammals that may be temporarily displaced during survey activities are expected to be able to resume foraging once they have moved away from areas with disturbing levels of underwater noise. Because of the temporary nature of the disturbance, the availability of similar habitat and resources in the surrounding area, and the lack of important or unique marine mammal feeding habitat, the impacts to marine mammals and the food sources that they utilize are not expected to cause significant or long-term consequences for individual marine mammals or their populations. In addition, there are no rookeries or mating or calving areas known to be biologically important to marine mammals within the proposed project area.

The proposed survey area is within a biologically important migratory area for North Atlantic right whales (effective March–April and November–December) that extends from Massachusetts to Florida (LaBrecque, *et al.,* 2015). Off the coast of Virginia, this biologically important migratory area extends from the coast to the just beyond the shelf break. Due to the fact that that the proposed survey is temporary and short in overall duration, and the fact that the spatial acoustic footprint of the proposed survey is very small relative to the spatial extent of the available migratory habitat in the area, North Atlantic right whale migration is not

expected to be impacted by the proposed survey.

Mitigation measures are expected to reduce the number and/or severity of takes by (1) giving animals the opportunity to move away from the sound source before HRG survey equipment reaches full energy; (2) preventing animals from being exposed to sound levels that may otherwise result in injury. Additional vessel strike avoidance requirements will further mitigate potential impacts to marine mammals during vessel transit to and within the survey area.

NMFS concludes that exposures to marine mammal species and stocks due to Dominion's proposed survey would result in only short-term (temporary and short in duration) effects to individuals exposed. Marine mammals may temporarily avoid the immediate area, but are not expected to permanently abandon the area. Major shifts in habitat use, distribution, or foraging success are not expected. NMFS does not anticipate the authorized take estimates to impact annual rates of recruitment or survival.

In summary and as described above, the following factors primarily support our determination that the impacts resulting from this activity are not expected to adversely affect the species or stock through effects on annual rates of recruitment or survival:

- No mortality or serious injury is anticipated or authorized;
- No injury is anticipated or authorized;
- The anticipated impacts of the proposed activity on marine mammals would be limited to temporary behavioral changes due to avoidance of the area around the survey vessel;
- Alternate areas of similar habitat value for marine mammals to temporarily vacate the survey area during the proposed survey and avoid exposure to sounds from the activity are available;
- The proposed project area does not contain areas of significance for feeding, mating or calving;
- Effects on species that serve as prey species for marine mammals from the proposed survey are expected to be minimal;
- Mitigation measures, including visual and acoustic monitoring and shutdowns, are expected to minimize potential impacts to marine mammals.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted above, only small numbers of incidental take may be authorized under Section 101(a)(5)(D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

The numbers of marine mammals that we authorized to be taken would be considered small relative to the relevant stocks or populations for all species and stocks (less than 10 percent of bottlenose dolphin stocks, and less than 1 percent of each of the other species and stocks). See Tables 6 and 7. Based on the analysis contained herein of the proposed activity (including the mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS finds that small numbers of marine mammals will be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an incidental harassment authorization) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (incidental harassment authorizations with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of the IHA qualifies to be categorically excluded from further NEPA review. We have reviewed all comments submitted in response to the proposed IHA notice prior to concluding our NEPA process and making this final decision on the IHA request.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat.

The NMFS Office of Protected Resources is proposing mitigation to avoid the incidental take of the species of marine mammals which are likely to be present and are listed under the ESA: The North Atlantic right and fin whales. Therefore, consultation under section 7 of the ESA is not required.

Authorization

NMFS has issued an IHA to Dominion for conducting UXO surveys offshore Virginia for a period of one year, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: July 31, 2018.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2018–16885 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Northeast Multispecies Amendment 16

AGENCY: National Oceanic and Atmospheric Administration (NOAA), 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: Written comments must be submitted on or before October 9, 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 and instructions should be directed to Liz Sullivan, (978) 282–8493 or *Liz.Sullivan@noaa.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for an extension of a current information collection. Under the Magnuson-Stevens Fishery Conservation and Management Act (MSA), the Secretary of Commerce has the responsibility for the conservation and management of marine fishery resources. We, National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service (NMFS), and the Regional Fishery Management Councils are delegated the majority of this responsibility. The New England Fishery Management Council (Council) develops management plans for fishery resources in New England.

In 2010, we implemented a new suite of regulations for the Northeast (NE) multispecies fishery through Amendment 16 to the NE Multispecies Fishery Management Plan (FMP). This action updated status determination criteria for all regulated NE multispecies or ocean pout stocks; adopted rebuilding programs for NE multispecies (groundfish) stocks newly classified as being overfished and subject to overfishing; revised management measures, including significant revisions to the sector management measures (established under Amendment 13) necessary to end overfishing, rebuild overfished regulated NE multispecies and ocean pout stocks, and mitigate the adverse economic impacts of increased effort controls. It also implemented new requirements under Amendment 16 for establishing acceptable biological catch (ABC), annual catch limits (ACLs), and accountability measures (AMs) for each stock managed under the FMP, pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

Sectors are a management tool in the NE groundfish fishery. A sector consists of three or more limited access NE multispecies vessel permits, with distinct ownership, who voluntarily enter into a contract to manage their fishing operations and to share liability. A sector is granted an annual allocation of most stocks of fish managed by the NE Multispecies FMP. In return for increased operational flexibility, such as exemptions from certain effort controls and the ability to pool and trade quota, sectors have additional reporting and monitoring requirements. The sector reporting and monitoring requirements, as established by Amendment 16 and revised by subsequent framework adjustments to the NE Multispecies FMP, are contained within this information collection.

II. Method of Collection

Respondents must submit either paper forms via postal service, or electronic forms submitted via the internet or a vessels' vessel monitoring system (VMS).

III. Data

OMB Control Number: 0648–0605.

Form Number: None.

Type of Review: Regular submission (revision and extension of a current information collection).

Affected Public: Business or for-profit organizations.

Estimated Number of Respondents: 1,334.

Estimated Time per Response: Sector operations plan and membership list updates, 176 hr/response; Monitoring service provider initial application, 10 hr/response; Monitoring service provider response to application disapproval, 10 hr/response; Data entry for sector discard monitoring system, 3 min/response; Sector weekly catch report, 4 hr/response; Sector annual report, 12 hr/response; Notification of expulsion from a sector, 30 min/response; Request to transfer Annual Catch Entitlement (ACE), 5 min/response; Request to lease day-at-sea (DAS), 5 min/response; request to downgrade, 5 min/response; VMS certification form, 10 min/response; VMS confirmation call, 5 min/response; VMS area and DAS declaration, 5 min/response; VMS trip-level catch report; VMS daily catch reports when fishing in multiple broad stock areas, 15 min/response; Daily VMS catch reports when fishing in the U.S./Canada Management Area and CA II SAPs, 15 min/response; Daily VMS catch reports when fishing in the CA I Hook Gear Haddock SAP, 15 min/response; Daily VMS catch reports when fishing in the Regular B DAS Program, 15 min/response; Pre-trip hail report, 2 min/response; Trip-end hail report, 15 min/response; Forward trip start/end hails to NMFS, 2 min/response; ASM Pre-Trip Notification, 2 min/response; Vessel notification of selection for at-sea monitoring coverage, 5 min/response; at-sea monitor deployment report, 10 min/response; at-sea monitoring service provider catch report to NMFS upon request, 5 min/response; at-sea monitor report of harassment and other issues, 30 min/response; at-sea monitoring service provider contract upon request, 30 min/response; at-sea monitoring service provider information materials upon request, 30 min/response; OLE debriefing of at-sea monitors, 2 hr/response; ASM Database and Data Entry Requirements, 3 min/response; Observer program pre-trip notification, 2 min/response; DAS Transfer Program, 5min/response; Expedited Submission of Proposed SAPs, 20 hr/response; NAFO Reporting Requirements, 10 min/response.

Estimated Total Annual Burden Hours: 39,351.

Estimated Total Annual Cost to Public: $ 4,466,172 in recordkeeping/reporting costs.

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.

Dated: August 3, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–16955 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; International Fisheries Trade To Include Shrimp and Abalone

AGENCY: National Oceanic and Atmospheric Administration (NOAA), 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: Written comments must be submitted on or before October 9, 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 and instructions should be directed to: Celeste Leroux at (301) 427–8372 or *Celeste.Leroux@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The Seafood Traceability Program (*see* 50 CFR 300.320–300.325) is the first phase of a risk-based traceability program, which establishes permit, reporting and recordkeeping requirements needed to prevent illegally harvested and misrepresented seafood from entering into U.S. Commerce. In the development of the Seafood Traceability Program rule, 13 ''priority'' species were identified as being most at risk for Illegal, Unreported, and Unregulated (IUU) fishing and misrepresentation, and are the only species currently subject to this program. For two of those species (abalone and shrimp), NMFS stayed program requirements indefinitely (50 CFR 300.324(a)(3)). *See* 81 FR 88975 (December 9, 2016). A final rule was published on April 24, 2018 (83 FR 17762) which lifted the stay and established a compliance date of December 31, 2018 for shrimp and abalone.

NMFS had stayed requirements for abalone and shrimp because gaps existed in the collection of traceability information for domestic aquaculture-raised shrimp and abalone, which is currently largely regulated at the state level. During development of the Seafood Traceability Program, NMFS explored the possibility of working with its state partners to establish reporting and recordkeeping requirements for aquaculture traceability information that could be shared with NMFS. However, this did not prove to be a viable approach. *See* 81 FR at 88977–78. In the Seafood Import Monitoring Program final rule, NMFS explained that ''[A]t such time that the domestic reporting and recordkeeping gaps have been closed, NMFS will then publish an action in the **Federal Register** to lift the stay of the effective date for § 300.324(a)(3) of the rule pertaining to shrimp and abalone. Adequate advance notice to the trade community would be provided'' to ensure all affected parties have sufficient time to come into compliance.

On March 23, 2018, the Consolidated Appropriations Act of 2018 (Pub. L. 115–141) was signed by the President and became law. Section 539 of Division B of the Act directed the Secretary of Commerce to, within 30 days, ''lift the stay on the effective date of the final rule for the Seafood Traceability Program published by the Secretary on December 9, 2016, (81 FR 88975 *et seq.*) for the species described in § 300.324(a)(3) of title 50, Code of Federal Regulations: Provided that the compliance date for the species described in § 300.324(a)(3) of title 50, Code of Federal Regulations, shall occur not later than December 31, 2018.'' A final rule was issued to implement the Act (83 FR 17762, April 24, 2018) and provides that shrimp and abalone will be subject to the requirements of the Seafood Traceability Program under 50 CFR 300.324(a)(3), with a compliance date December 31, 2018.

The Program consists of two components: (1) Reporting of harvest events at the time of entry; and (2) permitting and recordkeeping requirements with respect to both harvest events and chain of custody information. *See* 50 CFR 300.324 and *id.* §§ 300.320–300.323 and 300.325. Application of the program's reporting and recordkeeping requirements to shrimp and abalone will enable audits of imports to be conducted to determine the origin of the products and confirm that they were lawfully acquired.

The final rule to lift the stay on shrimp and abalone contains a collection-of-information requirement subject to review and approval by OMB under the Paperwork Reduction Act (PRA).

OMB had previously approved the information collection requirements for the Seafood Traceability Program under Control Number 0648–0739, but the burden estimates did not include the requirements for shrimp and abalone given the stay. The requirements for permitting, reporting and recordkeeping for imports of shrimp and abalone will be submitted to OMB for approval.

II. Method of Collection

As of the December 31, 2018 compliance date established by the final rule to lift the stay, importers of shrimp and abalone species will be required to obtain an International Fisheries Trade Permit as specified at 50 CFR 300.322, submit harvest and landing information on those products into the U.S. Customs and Border Protection International Trade Data System (ITDS) through the Automated Commercial Environment (ACE) portal prior to entry into U.S. Commerce, and maintain supply chain records from the point of harvest to the point of entry into U.S Commerce for a period of two years after entry.

III. Data

OMB Control Number: 0648–xxxx.

Form Number(s): None.

Type of Review: Regular submission (request for a new information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 2,000.

Estimated Time per Response: International Fisheries Trade Permit, 5 minutes; data entry, 1 hour.

Estimated Total Annual Burden Hours: 215,167.

Estimated Total Annual Cost to Public: $805,000 in recordkeeping/reporting costs.

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.

Dated: August 3, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–16987 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XG348

Nominations for Advisory Committee and Species Working Group Technical Advisor Appointments to the U.S. Section to the International Commission for the Conservation of Atlantic Tunas

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

ACTION: Notice of request for nominations.

SUMMARY: NMFS is soliciting nominations to the Advisory Committee to the U.S. Section to the International Commission for the Conservation of Atlantic Tunas (ICCAT) as established by the Atlantic Tunas Convention Act (ATCA). NMFS is also soliciting nominations for Technical Advisors to the Advisory Committee's species working groups.

DATES: Nominations must be received by October 1, 2018.

ADDRESSES: Nominations, including a letter of interest and a resume or curriculum vitae, should be sent via email to Terra Lederhouse at *terra.lederhouse@noaa.gov* with a copy to Grace Ferrara at *grace.ferrara@noaa.gov*. Include in the subject line whether the nomination is for the Advisory Committee or for a Technical Advisor to a species working group.

FOR FURTHER INFORMATION CONTACT: Grace Ferrara, Office of International Affairs and Seafood Inspection; telephone: (301) 427–8371; email: *grace.ferrara@noaa.gov*.

SUPPLEMENTARY INFORMATION:

The Convention and the Commission

ICCAT was established to provide an effective program of international cooperation in research and conservation in recognition of the unique problems related to the highly migratory nature of tunas and tuna-like species. The International Convention for the Conservation of Atlantic Tunas (Convention) entered into force in 1969 after receiving the required number of ratifications. The Commission holds its Annual Meeting, usually in November of each year, and convenes meetings of working groups and other ICCAT bodies between annual meetings as needed. Under Section 971a of ATCA (16 U.S.C. 971 *et seq.*), the United States is represented on the Commission by not more than three U.S. Commissioners. Additional information is available at *www.iccat.int*.

Advisory Committee and Species Working Groups to the U.S. Section to the ICCAT

Section 971b of ATCA (16 U.S.C. 971 *et seq.*) requires that an advisory committee be established that shall be comprised of: (1) Not less than 5 nor more than 20 individuals appointed by the U.S. Commissioners to ICCAT who shall select such individuals from the various groups concerned with the fisheries covered by the ICCAT Convention; and (2) the chairs (or their designees) of the New England, Mid-Atlantic, South Atlantic, Caribbean, and Gulf of Mexico Fishery Management Councils. Each member of the Advisory Committee appointed under paragraph (1) shall serve for a term of 2 years and be eligible for reappointment. The Committee meets at least twice a year when members receive information and provide advice on ICCAT-related matters. All members of the Advisory Committee are appointed in their individual professional capacity and undergo a background screening. Any individual appointed to the Committee who is unable to attend all or part of an Advisory Committee meeting may not appoint another person to attend such meetings as his or her proxy. Members of the Advisory Committee shall receive no compensation for their services. The Secretary of Commerce and the Secretary of State may pay the necessary travel expenses of members of the Advisory Committee. The terms of all currently appointed Advisory Committee members expire on December 31, 2018. NMFS is soliciting nominees to serve as members of the Advisory Committee for a term of 2 years that will expire December 31, 2020.

Section 971b–1 of ATCA specifies that the U.S. Commissioners may establish species working groups for the purpose of providing advice and recommendations to the U.S. Commissioners and to the Advisory Committee on matters relating to the conservation and management of any highly migratory species covered by the ICCAT Convention. Any species working group shall consist of no more than seven members of the Advisory Committee and no more than four Technical Advisors, as considered necessary by the Commissioners. Currently, there are four species working groups advising the Committee and the U.S. Commissioners: A Bluefin Tuna Working Group, a Swordfish/Sharks Working Group, a Billfish Working Group, and a Bigeye, Albacore, Yellowfin, and Skipjack (BAYS) Tunas Working Group. Technical Advisors to the species working groups serve at the pleasure of the Commissioners; therefore, the Commissioners can choose to alter these appointments at any time. As with Committee Members, Technical Advisors may not be represented by a proxy during meetings of the Advisory Committee.

Procedure for Submitting Nominations

Nominations to the Advisory Committee or to a species working group should include a letter of interest and a resume or curriculum vitae. Self-nominations are acceptable. Letters of recommendation are useful but not required. When making a nomination, please specify which appointment (Advisory Committee member or Technical Advisor to a species working group) is being sought. Nominees may also indicate which of the species working groups is preferred, although placement on the requested group is not guaranteed.

Dated: August 3, 2018.

John Henderschedt,

Director, Office of International Affairs and Seafood Inspection, National Marine Fisheries Service.

[FR Doc. 2018–16956 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Report of Whaling Operations.

OMB Control Number: 0648–0311.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 66.

Average Hours per Response: 30 minutes for reports on whales struck or on recovery of dead whales, including providing the information to the relevant Native American whaling organization; 5 minutes for the relevant Native American whaling organization to type in each report; and 5 hours for the relevant Native American whaling organization to consolidate and submit reports.

Burden Hours: 50.

Needs and Uses: This request is for extension of a current information collection.

Native Americans may conduct certain aboriginal subsistence whaling under the Whaling Convention Act in accordance with the provisions of the International Whaling Commission (IWC). In order to respond to obligations under the International Convention for the Regulation of Whaling, the IWC, and the Whaling Convention Act, whaling captains participating in these operations must submit certain information to the relevant Native American whaling organization about strikes on and catch of whales. Anyone retrieving a dead whale is also required to report. Captains must place a distinctive permanent identification mark on any harpoon, lance, or explosive dart used, and must also provide information on the mark and self-identification information. The relevant Native American whaling organization receives the reports, compiles them, and submits the information to NOAA.

The information is used to monitor the hunt and to ensure that quotas are not exceeded. The information is also provided to the IWC, which uses it to monitor compliance with its requirements.

Affected Public: Individuals or households; state, local, or tribal governments.

Frequency: On occasion, monthly and annually.

Respondent's Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: August 3, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–16933 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: List of Gear by Fisheries and Fishery Management Council.

OMB Control Number: 0648–0346.

Form Number(s): None.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 6.

Average Hours per Response: 90 minutes.

Burden Hours: 15 hours.

Needs and Uses: This request is for an extension of a currently approved information collection.

Under the provisions of the Magnuson-Stevens Fishery and Conservation and Management Act (Magnuson-Stevens Act) [16 U.S.C. 1801 *et seq.*], as amended by the Sustainable Fisheries Act [Pub. L. 104–297], the Secretary of Commerce (Secretary) is required to publish a list of all fisheries under authority of each Regional Fishery Management Council (Council) and all such fishing gear used in such fisheries (see section 305(a) of the Magnuson-Stevens Act). The list has been published and appears in 50 CFR part 600.725(v). Any person wishing to use gear not on the list, or engage in a fishery not on the list, must provide the appropriate Council or the Secretary, in the case of Atlantic highly migratory species, with 90 days of advance notice. If the Secretary takes no action to prohibit such a fishery or use of such a gear, the person may proceed.

Affected Public: Business or other for-profit organizations.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: August 3, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–16932 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Seafood Inspection and Certification Requirements.

OMB Control Number: 0648–0266.

Form Number(s): 89–800, 89–814, 89–819.

Type of Request: Regular (extension of a currently approved information collection).

Number of Respondents: 350.

Average Hours per Response: Contract Request, 15 minutes; label approval, 15 minutes; Inspection Request, 30 minutes.

Burden Hours: 19,728.

Needs and Uses: This request is for extension of a currently approved information collection.

The National Marine Fisheries Service (NMFS) operates a voluntary fee-for-service seafood inspection program (Program) under the authorities of the Agricultural Marketing Act of 1946, as amended, the Fish and Wildlife Act of 1956, and the Reorganization Plan No. 4 of 1970. The regulations for the Program are contained in 50 CFR part 260. The program offers inspection grading and certification services, including the use of official quality grade marks which indicate that specific products have been Federally inspected. Those wishing to participate in the program must request the services and submit specific compliance information. In July 1992, NMFS announced new inspection services, which were fully based on guidelines recommended by

the National Academy of Sciences, known as Hazard Analysis Critical Control Point (HACCP). The information collection requirements fall under § 260.15 of the regulations. These guidelines required that a facility's quality control system have a written plan of the operation, identification of control points with acceptance criteria and a corrective action plan, as well as identified personnel responsible for oversight of the system.

Affected Public: Business or other for-profit organizations; not-for-profit institutions; state, local or tribal government.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or maintain benefits.

This information collection request may be viewed at *reginfo.gov.* Follow the instructions to view Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: August 3, 2018.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2018–16934 Filed 8–7–18; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0049)

Military Aviation and Installation Assurance Siting Clearinghouse; Notice and Request for Public Comment on Boardman, Oregon, and NAS Patuxent River, Maryland, Geographic Areas of Concern

AGENCY: Under Secretary of Defense for Acquisition and Sustainment, Department of Defense.

ACTION: Notice and request for public comment on the Boardman, Oregon, and NAS Patuxent River, Maryland, Geographic Areas of Concern.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that the Boardman, Oregon, and Naval Air Station (NAS) Patuxent River, Maryland, Geographic Areas of Concern (GAOC) maps are now available for review and to request public comment on the proposed maps. The maps are intended to support outreach efforts by DoD to the energy industry.

DATES: The public comment period will end on September 7, 2018.

ADDRESSES: You may submit comments, identified by DOD–2018–OS–0049, to the following:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Chief Management Officer, Directorate for Oversight and Compliance, Regulatory and Advisory Committee Division, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

FOR FURTHER INFORMATION CONTACT: Steven J. Sample, Deputy Director of the Military Aviation and Installation Assurance Siting Clearinghouse, at 703–571–0076 during normal business hours Monday through Friday, from 9:00 a.m. to 5:00 p.m. (EDT) or by email: *steven.j.sample4.civ@mail.mil.*

SUPPLEMENTARY INFORMATION: Section 183a(d)(2)(B) of title 10, United States Code, provides that, solely for purposes of informing preliminary reviews under section 183a(c)(1) and early outreach efforts under section 183a(c)(5), DoD shall identify distinct geographic areas selected as proposed locations for projects filed, or for projects that are reasonably expected to be filed in the near future, with the Secretary of Transportation pursuant to section 44178 of title 49, United States Code, where the Secretary of Defense can demonstrate such projects could have an adverse impact on military operations and readiness, including military training routes, and categorize the risk of adverse impact in such areas. Section 183a defines adverse impact on military operations and readiness as any impact upon military operations and readiness, including flight operations, research, development, testing, and evaluation and training, that is demonstrable and likely to impair or degrade the ability of the armed forces to perform their warfighting missions. The identification of a GAOC does not equate to a determination that a project in the GAOC would result in an unacceptable risk to the national security of the United States. It only means that such a project would have an adverse impact and requires further review by the Military Aviation and Installation Assurance Siting Clearinghouse.

The Boardman GAOC is identified due to possible effects upon two main DoD military missions. The Naval Weapons Systems Training Facility at Boardman and its associated airspace are the U.S. Navy's primary resource for all airborne electronic attack aircraft air combat maneuver training. This training includes low level aircraft operations. Tall structures, such as wind turbines and electrical transmission lines, constructed under Restricted Airspace (R–5701) and Military Training Routes will prevent the U.S. Navy from fulfilling the training mission. Secondly, the Fossil common air route surveillance radar (CARSR) (a long range radar) in Fossil, Oregon, is a vital resource for the North American Aerospace Defense Command (NORAD). NORAD defends Canada and the United States against air threats, and an accurate ''air picture'' is essential for NORAD to accomplish its air defense mission. Rotating wind turbine blades can appear as unwanted false targets (clutter) and desensitize the radar, resulting in degraded target acquisition and tracking. Much of the information and data used to establish the GAOC for the Fossil CARSR is not available for public review due to security concerns.

The NAS Patuxent River GAOC is identified due to possible effects upon two DoD military missions. The missions that could be degraded or impaired due to wind turbines are the Advanced Dynamic Aircraft Measurement System (ADAMS) and the Digital Airport Surveillance Radar (DASR), both located at NAS Patuxent River. ADAMS is a national test asset and the Department of Navy's only open-air dynamic radar cross section (RCS) measurement facility supporting all military services as well as other government agencies. ADAMS is used to make precise ground-to-air radar signature measurements during aircraft maneuvers. The DASR is used to facilitate critical safety of flight control instructions for all DoD and civilian aircraft that operate within the confines of the NAS Patuxent River Air Traffic Control (ATC) Area of Responsibility (AoR). ATC services require the ability to use radar to positively identify targets that enter, work within, and depart the AoR to prevent mid-air collision and loss of life. The DASR is also utilized by ATC to monitor air traffic that might attempt to illegally enter the Washington, DC Flight Restricted Zone, thereby posing a significant threat to the national security. Rotating wind turbine blades can appear as unwanted false targets (clutter) and desensitize the radar, resulting in degraded target acquisition and tracking for both the ADAMS and DASR at NAS Patuxent River.

Comments received by the end of the comment period will be considered when making the final findings on the designation of these proposed GAOCs. Any comment, if applying to only one

GAOC, should identify that GAOC as the subject.

Maps identifying the Boardman and NAS Patuxent River GAOCs can be viewed in the docket listed above on *Regulations.gov*.

Dated: August 2, 2018.

Shelly E. Finke,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–16886 Filed 8–7–18; 8:45 am]

BILLING CODE 5001–06–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: RP18–1005–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Neg Rate Agmt and Cap Rel Agmt w/Neg Rate Provisions (So 49811, Emera 49884) to be effective 8/1/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5010.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1006–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Petrohawk 41455 releases eff 8–1–2018) to be effective 8/1/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5012.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1007–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Remove Expired Agmts from Tariff Effective 8/1/2018 to be effective 8/1/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5013.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1008–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmts (Atlanta Gas 8438 to various shippers eff 8–1–2018) to be effective 8/1/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5014.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1009–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Housekeeping Filing eff 8–31–2018 to be effective 8/31/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5015.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1010–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Modification to Negotiated Rate Provision to be effective 8/31/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5016.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1011–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: Coastal Bend Pooling Service Clarification to be effective 8/31/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5017.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1012–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (Newfield 18 to Spire 2020) to be effective 8/1/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5019.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1013–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: § 4(d) Rate Filing: Revise Certain Pro Forma Agreements to be effective 8/31/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5024.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1014–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: § 4(d) Rate Filing: Housekeeping Filing eff 8–31–2018 to be effective 8/31/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5028.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1015–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: § 4(d) Rate Filing: Modification to Negotiated Rate Provision to be effective 8/31/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5032.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1016–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Separate Fuel Negotiated Rate Agreement to be effective 8/31/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5035.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1017–000.
Applicants: Southern Star Central Gas Pipeline, Inc.
Description: § 4(d) Rate Filing: Vol 2—Neg. and Non-Conforming Agreement—Scout Energy Group III to be effective 8/1/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5067.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1019–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Cherokee AGL—Replacement Shippers—Aug 2018 to be effective 8/1/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5076.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1020–000.
Applicants: Wyoming Interstate Company, L.L.C.
Description: § 4(d) Rate Filing: FL&U Update Quarterly to be effective 9/1/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5078.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1021–000.
Applicants: Algonquin Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates ConEd releases eff 8–1–2018 to be effective 8/1/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5079.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1022–000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20180731 Negotiated Rate to be effective 8/1/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5094.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1023–000.
Applicants: El Paso Natural Gas Company, L.L.C.
Description: § 4(d) Rate Filing: Negotiated Agreement Update (APS August 2018) to be effective 8/1/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5103.
Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1024–000.
Applicants: Transcontinental Gas Pipe Line Company, LLC.
Description: § 4(d) Rate Filing: Negotiated Rates—Woodbridge/CPV—REV to be effective 8/1/2018.
Filed Date: 7/31/18.
Accession Number: 20180731–5104.

Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1025–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Negotiated Rate—Plymouth Rock eff 8–1–2018 to be effective 8/1/2018.

Filed Date: 7/31/18.

Accession Number: 20180731–5109.

Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1026–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Non-Conforming—Leidy Southeast_PSNC Superseding to be effective 7/27/2018.

Filed Date: 7/31/18.

Accession Number: 20180731–5166.

Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1027–000.

Applicants: Rockies Express Pipeline LLC.

Description: § 4(d) Rate Filing: Neg Rate 2018–7–31 10 Neg Rates E2W to be effective 8/1/2018.

Filed Date: 7/31/18.

Accession Number: 20180731–5186.

Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1028–000.

Applicants: MarkWest Pioneer, L.L.C.

Description: § 4(d) Rate Filing: Nonconforming Negotiated Rate Service Agreements to be effective 8/1/2018.

Filed Date: 7/31/18.

Accession Number: 20180731–5189.

Comments Due: 5 p.m. ET 8/13/18.

Docket Numbers: RP18–1029–000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Non-Conforming Agreement Amendment (SWG 2018) to be effective 8/1/2018.

Filed Date: 7/31/18.

Accession Number: 20180731–5190.

Comments Due: 5 p.m. ET 8/13/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern Time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 1, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–16909 Filed 8–7–18; 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: EC18–130–000.

Applicants: Wheelabrator Technologies Inc., Wheelabrator Baltimore, L.P., Wheelabrator Bridgeport, L.P., Wheelabrator Falls Inc., Wheelabrator Frackville Energy Company Inc., Wheelabrator Millbury Inc., Wheelabrator North Andover Inc., Wheelabrator Portsmouth Inc., Wheelabrator Ridge Energy Inc., Wheelabrator Saugus Inc., Wheelabrator Shasta Energy Company Inc., Wheelabrator South Broward Inc., Wheelabrator Westchester, L.P.

Description: Application for Authorization Under Section 203 of the Federal Power Act of Wheelabrator Technologies Inc.

Filed Date: 8/2/18.

Accession Number: 20180802–5076.

Comments Due: 5 p.m. ET 8/23/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER18–1222–003.

Applicants: PSEG Energy Resources & Trade LLC.

Description: Compliance filing: Informational Filing KEC Effective Date to be effective 7/4/2018.

Filed Date: 8/2/18.

Accession Number: 20180802–5018.

Comments Due: 5 p.m. ET 8/23/18.

Docket Numbers: ER18–1724–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Report Filing: 2018–08–02_SA 3116 ATC–WPL PCA Refund Report_Hawk to be effective N/A.

Filed Date: 8/2/18.

Accession Number: 20180802–5096.

Comments Due: 5 p.m. ET 8/23/18.

Docket Numbers: ER18–1725–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Report Filing: 2018–08–02_SA 3117 ATC–WPL PCA Refund Report_Schofield to be effective N/A.

Filed Date: 8/2/18.

Accession Number: 20180802–5097.

Comments Due: 5 p.m. ET 8/23/18.

Docket Numbers: ER18–1777–002.

Applicants: Meadowlark Wind I LLC.

Description: Tariff Amendment: Second Amendment to Filing to be effective 8/12/2018.

Filed Date: 8/2/18.

Accession Number: 20180802–5093.

Comments Due: 5 p.m. ET 8/23/18.

Docket Numbers: ER18–1824–000.

Applicants: Southwestern Electric Power Company.

Description: Report Filing: Revised and Restated Prescott PSA to be effective N/A.

Filed Date: 7/23/18.

Accession Number: 20180723–5152.

Comments Due: 5 p.m. ET 8/10/18.

Docket Numbers: ER18–2131–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Cancellation: Notice of Cancellation of WMPA, SA No. 4942 to be effective 7/13/2018.

Filed Date: 8/1/18.

Accession Number: 20180801–5153.

Comments Due: 5 p.m. ET 8/22/18.

Docket Numbers: ER18–2132–000

Applicants: PacifiCorp

Description: Tariff Cancellation: Termination of Idaho Power Construct Agmt ? Goshen-Jefferson to be effective 10/18/2018.

Filed Date: 8/2/18

Accession Number: 20180802–5024.

Comments Due: 5 p.m. ET 8/23/18.

Docket Numbers: ER18–2133–000.

Applicants: Wisconsin Electric Power Company.

Description: § 205(d) Rate Filing: Revised Balancing Area Operations Coordination Agreement to be effective 10/2/2018.

Filed Date: 8/2/18.

Accession Number: 20180802–5034.

Comments Due: 5 p.m. ET 8/23/18.

Docket Numbers: ER18–2134–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to two ISAs, Service Agreement Nos. 3461 and 3467, NQ80 and NQ79 to be effective 11/28/2012.

Filed Date: 8/2/18.

Accession Number: 20180802–5037.

Comments Due: 5 p.m. ET 8/23/18.

Docket Numbers: ER18–2135–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Revisions to Extend Tariff Administration between SPP and SPA through 12/31/2018 to be effective 8/1/2018.

Filed Date: 8/2/18.

Accession Number: 20180802–5049.

Comments Due: 5 p.m. ET 8/23/18.

Docket Numbers: ER18–2136–000.

Applicants: Spruance Genco, LLC.
Description: § 205(d) Rate Filing: Revisions to Market-Based Rate Tariff to be effective 10/2/2018.
Filed Date: 8/2/18.
Accession Number: 20180802–5056.
Comments Due: 5 p.m. ET 8/23/18.
Docket Numbers: ER18–2137–000.
Applicants: Big Sky North, LLC.
Description: Baseline eTariff Filing: Master Interconnection Services Agreement to be effective 8/16/2018.
Filed Date: 8/2/18.
Accession Number: 20180802–5072.
Comments Due: 5 p.m. ET 8/23/18.
Docket Numbers: ER18–2138–000.
Applicants: Arizona Public Service Company.
Description: § 205(d) Rate Filing: Service Agreement No. 209—Amendment No. 3 to be effective 7/3/2018.
Filed Date: 8/2/18.
Accession Number: 20180802–5079.
Comments Due: 5 p.m. ET 8/23/18.
Docket Numbers: ER18–2139–000.
Applicants: Central Hudson Gas & Electric Corporation.
Description: § 205(d) Rate Filing: Revision to FERC Rate Schedule 206 to be effective 7/1/2018.
Filed Date: 8/2/18.
Accession Number: 20180802–5086.
Comments Due: 5 p.m. ET 8/23/18.
Docket Numbers: ER18–2140–000.
Applicants: Persimmon Creek Wind Farm 1, LLC.
Description: Baseline eTariff Filing: Application for Market-Based Rate Authority to be effective 8/3/2018.
Filed Date: 8/2/18.
Accession Number: 20180802–5092.
Comments Due: 5 p.m. ET 8/23/18.
Docket Numbers: ER18–2141–000.
Applicants: Antelope Expansion 2, LLC.
Description: Baseline eTariff Filing: Master Interconnection Services Agreement to be effective 8/16/2018.
Filed Date: 8/2/18.
Accession Number: 20180802–5098.
Comments Due: 5 p.m. ET 8/23/18.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH18–11–000.
Applicants: Canada Pension Plan Investment Board.
Description: FERC 65B Notice of Material Change in Facts and FERC 65 Revised Notification of Holding Company Status of Canada Pension Plan Investment Board.
Filed Date: 8/1/18.
Accession Number: 20180801–5192.
Comments Due: 5 p.m. ET 8/22/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern Time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 2, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–16908 Filed 8–7–18; 8:45 am]

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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: RP18–1030–000.
Applicants: Equitrans, L.P.
Description: § 4(d) Rate Filing: Negotiated Capacity Release Agreements—8/1/2018 to be effective 8/1/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5031.
Comments Due: 5 p.m. ET 8/13/18.
Docket Numbers: RP18–1031–000.
Applicants: WBI Energy Transmission, Inc.
Description: § 4(d) Rate Filing: 2018 Negotiated Rate Non-Conforming SA's FT–1463 and FT–1464 to be effective 9/1/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5037.
Comments Due: 5 p.m. ET 8/13/18.
Docket Numbers: RP18–1032–000.
Applicants: Portland Natural Gas Transmission System.
Description: § 4(d) Rate Filing: Implementation of Navigates to be effective 9/1/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5051.
Comments Due: 5 p.m. ET 8/13/18.
Docket Numbers: RP18–1033–000.
Applicants: Gulf Crossing Pipeline Company LLC.
Description: § 4(d) Rate Filing: Cap Rel Neg Rate Agmt (XTO 1846 to Southwest Energy 2022) to be effective 8/1/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5053.
Comments Due: 5 p.m. ET 8/13/18.
Docket Numbers: RP18–1034–000.
Applicants: Texas Gas Transmission, LLC.
Description: § 4(d) Rate Filing: Remove Expired Agreements eff 8/1/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5054.
Comments Due: 5 p.m. ET 8/13/18.
Docket Numbers: RP18–1035–000.
Applicants: Northern Natural Gas Company.
Description: § 4(d) Rate Filing: 20180801 Non Conforming to be effective 9/1/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5106.
Comments Due: 5 p.m. ET 8/13/18.
Docket Numbers: RP18–1036–000.
Applicants: Gulf South Pipeline Company, LP.
Description: § 4(d) Rate Filing: NC Neg Rate Agmt Filing (Interim St Charles Exp Proj Entergy LA 48765) to be effective 9/1/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5122.
Comments Due: 5 p.m. ET 8/13/18.
Docket Numbers: RP18–1037–000.
Applicants: NEXUS Gas Transmission, LLC.
Description: Compliance filing NEXUS Baseline Tariff re Docket No. CP16–22 to be effective 9/30/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5124.
Comments Due: 5 p.m. ET 8/13/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 2, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–16910 Filed 8–7–18; 8:45 am]

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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL18–189–000]

Independent Power Producers of New York, Inc. v. New York Independent System Operator, Inc.; Notice of Complaint

Take notice that on July 31, 2018, 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, Independent Power Producers of New York, Inc. (Complainant) filed a formal complaint against New York Independent System Operator, Inc. (Respondent) alleging that the Respondent is improperly applying its Market Administration and Control Area Services Tariff by allowing resources in the PJM Interconnection, L.L.C. market to deliver installed capacity (ICAP) to New York across merchant transmission facilities that are not qualified to deliver ICAP to New York, all as more fully explained in the complaint.

The Complainant certifies that copies of the complaint were served on the contacts for the Respondent 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 website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 20, 2018.

Dated: August 1, 2018.

Kimberly D. Bose,

Secretary.

[FR Doc. 2018–16887 Filed 8–7–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG18–117–000.

Applicants: Persimmon Creek Wind Farm 1, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Persimmon Creek Wind Farm 1, LLC.

Filed Date: 8/1/18.

Accession Number: 20180801–5036.

Comments Due: 5 p.m. ET 8/22/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–3169–014.

Applicants: Michigan Power Limited Partnership.

Description: Notice of Non-Material Change in Status of Michigan Power Limited Partnership.

Filed Date: 8/1/18.

Accession Number: 20180801–5074.

Comments Due: 5 p.m. ET 8/22/18.

Docket Numbers: ER17–2059–001.

Applicants: Puget Sound Energy, Inc.

Description: Notice of Non-Material Change in Status of Puget Sound Energy, Inc.

Filed Date: 7/31/18.

Accession Number: 20180731–5231.

Comments Due: 5 p.m. ET 8/21/18.

Docket Numbers: ER18–614–004.

Applicants: Monongahela Power Company, PJM Interconnection, L.L.C.

Description: Compliance filing: PJM TOs submit compliance filing re: Commission's 7/2/2018 order in ER18–614 to be effective 12/31/9998.

Filed Date: 8/1/18.

Accession Number: 20180801–5110.

Comments Due: 5 p.m. ET 8/22/18.

Docket Numbers: ER18–1174–000.

Applicants: Imperial Valley Solar 2, LLC.

Description: Report Filing: Supplement to 2 to be effective N/A.

Filed Date: 7/27/18.

Accession Number: 20180727–5200.

Comments Due: 5 p.m. ET 8/17/18.

Docket Numbers: ER18–2071–001.

Applicants: Niagara Mohawk Power Corporation, New York Independent System Operator, Inc.

Description: Tariff Amendment: Amendment filing: cancellation notice SA 1755 Niagara Mohawk & Village of Ilion to be effective 9/26/2018.

Filed Date: 8/1/18.

Accession Number: 20180801–5081.

Comments Due: 5 p.m. ET 8/22/18.

Docket Numbers: ER18–2115–000.

Applicants: Wisconsin Public Service Corporation.

Description: § 205(d) Rate Filing: Reactive Power Rate Filing of Wisconsin Public Service Corporation to be effective 10/1/2018.

Filed Date: 7/31/18.

Accession Number: 20180731–5184.

Comments Due: 5 p.m. ET 8/21/18.

Docket Numbers: ER18–2116–000.

Applicants: New England Power Pool Participants Committee.

Description: § 205(d) Rate Filing: August 2018 Membership Filing to be effective 7/1/2018.

Filed Date: 7/31/18.

Accession Number: 20180731–5191.

Comments Due: 5 p.m. ET 8/21/18.

Docket Numbers: ER18–2117–000.

Applicants: Pacific Gas and Electric Company.

Description: § 205(d) Rate Filing: Q2 2018 Quarterly Filing of City and County of San Francisco's WDT SA (SA 275) to be effective 6/30/2018.

Filed Date: 7/31/18.

Accession Number: 20180731–5198.

Comments Due: 5 p.m. ET 8/21/18.

Docket Numbers: ER18–2118–000.

Applicants: Armadillo Flats Wind Project, LLC.

Description: Baseline eTariff Filing: Armadillo Flats Wind Project, LLC Application for Market-Based Rates to be effective 10/1/2018.

Filed Date: 7/31/18.

Accession Number: 20180731–5205.

Comments Due: 5 p.m. ET 8/21/18.

Docket Numbers: ER18–2119–000.

Applicants: Pioneer Transmission LLC, Midcontinent Independent System Operator, Inc.

Description: Regulatory Asset Request of Pioneer Transmission LLC and Midcontinent Independent System Operator, Inc.
Filed Date: 7/31/18.
Accession Number: 20180731–5206.
Comments Due: 5 p.m. ET 8/21/18.
Docket Numbers: ER18–2120–000.
Applicants: Jersey Central Power & Light Company, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Jersey Central Power & Light Company submits IA SA No. 5030 to be effective 9/30/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5032.
Comments Due: 5 p.m. ET 8/22/18.
Docket Numbers: ER18–2121–000.
Applicants: Jersey Central Power & Light Company, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: JCP&L submits one ECSA, Service Agreement No. 5118 to be effective 9/30/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5052.
Comments Due: 5 p.m. ET 8/22/18.
Docket Numbers: ER18–2122–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2018–08–01 Order 745 Effective Date True-up Filing to be effective 10/11/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5055.
Comments Due: 5 p.m. ET 8/22/18.
Docket Numbers: ER18–2123–000.
Applicants: Emera Maine.
Description: Initial rate filing: ReEnergy Ashland LLC TSA to be effective 10/1/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5071.
Comments Due: 5 p.m. ET 8/22/18.
Docket Numbers: ER18–2124–000.
Applicants: Emera Maine.
Description: Initial rate filing: ReEnergy Fort Fairfield LLC TSA to be effective 10/1/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5072.
Comments Due: 5 p.m. ET 8/22/18.
Docket Numbers: ER18–2125–000.
Applicants: ISO New England Inc., New England Power Pool Participants Committee.
Description: § 205(d) Rate Filing: ISO–NE and NEPOOL; FCM Cost Allocation Improvements to be effective 10/1/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5080.
Comments Due: 5 p.m. ET 8/22/18.
Docket Numbers: ER18–2126–000.
Applicants: Duke Energy Florida, LLC.
Description: § 205(d) Rate Filing: DEF-Shady Hills Power Corp LGIA (SA–235/Q181) to be effective 8/2/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5094.
Comments Due: 5 p.m. ET 8/22/18.
Docket Numbers: ER18–2127–000.
Applicants: Alabama Power Company.
Description: Tariff Cancellation: Terrell County Solar LGIA Termination Filing to be effective 7/12/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5098.
Comments Due: 5 p.m. ET 8/22/18.
Docket Numbers: ER18–2128–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 3458 WAPA, Great River Energy & MISO Interconnection Agr to be effective 4/27/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5100.
Comments Due: 5 p.m. ET 8/22/18.
Docket Numbers: ER18–2129–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2018–08–01_SA 3133 WAPA–GRE Interconnection Agreement to be effective 4/27/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5109.
Comments Due: 5 p.m. ET 8/22/18.
Docket Numbers: ER18–2130–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: Navajo Tribal Utility Authority—NITSA to be effective 8/1/2018.
Filed Date: 8/1/18.
Accession Number: 20180801–5125.
Comments Due: 5 p.m. ET 8/22/18.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES18–48–000.
Applicants: Wolverine Power Supply Cooperative, Inc.
Description: Application for Authorization under Section 204 of the Federal Power Act for Assumption of Liabilities and the Issuance Securities of Wolverine Power Supply Cooperative, Inc.
Filed Date: 7/31/18.
Accession Number: 20180731–5212.
Comments Due: 5 p.m. ET 8/21/18.
Docket Numbers: ES18–49–000; ES18–50–000; ES18–51–000; ES18–52–000; ES18–53–000.
Applicants: Entergy Arkansas, LLC, Entergy Louisiana, LLC, Entergy Mississippi, LLC, Entergy Texas, Inc., System Energy Resources, Inc.
Description: Joint Application for Authorization under Section 204 of the Federal Power Act of Entergy Arkansas, LLC, et al.
Filed Date: 7/31/18.
Accession Number: 20180731–5213.
Comments Due: 5 p.m. ET 8/21/18.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf*. For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 1, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–16911 Filed 8–7–18; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0750; FRL–9981–20]

Registration Review Proposed Interim Decisions for Several Pesticides; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's proposed interim registration review decisions and opens a 60-day public comment period on the proposed interim decisions for the chemicals listed in the Table in Unit IV of this Notice.

DATES: Comments must be received on or before October 9, 2018.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number for the specific pesticide of interest provided in the Table in Unit IV, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT:

For pesticide specific information, contact: The Chemical Review Manager for the pesticide of interest identified in the Table in Unit IV.

For general information on the registration review program, contact: Dana Friedman, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (703) 347–8827; email address: *friedman.dana@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager for the pesticide of interest identified in the Table in Unit IV.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html*.

II. Background

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed proposed interim decisions for all pesticides listed in the Table in Unit IV. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

III. Authority

EPA is conducting its registration review of the chemicals listed in the Table in Unit IV pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

IV. What action is the Agency taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's proposed interim registration review decisions for the pesticides shown in the following table, and opens a 60-day public comment period on the proposed interim decisions.

TABLE—REGISTRATION REVIEW PROPOSED INTERIM DECISIONS BEING ISSUED

Registration review case name and number	Docket ID No.	Chemical review manager and contact information
Ammonia & Ammonium Sulfate, Case Numbers 7440 & 5073.	EPA–HQ–OPP–2012–0684	Stephen Savage, *savage.stephen@epa.gov*, (703) 347–0345.
Bacillus popilliae, Case 4102	EPA–HQ–OPP–2016–0043	Daniel Schoeff, *schoeff.daniel@epa.gov*, (703) 347–0143.
Benfluralin, Case 2030	EPA–HQ–OPP–2011–0931	Michelle Nolan, *nolan.michelle@epa.gov*, (703) 347–0258.
Chlorpropham, Case 0271	EPA–HQ–OPP–2010–0923	Marianne Mannix, *mannix.marianne@epa.gov*, (703) 347–0275.
Citronellol (3, 7-Dimethyl-6-Octen-1-ol), Case 6086	EPA–HQ–OPP–2017–0250	Maggie Rudick, *rudick.maggie@epa.gov*, (703) 347–0257.
Clomazone, Case 7203	EPA–HQ–OPP–2006–0113	Nicole Zinn, *zinn.nicole@epa.gov*, (703) 308–7076.
Cytokinins, Case 4107	EPA–HQ–OPP–2012–0671	Daniel Schoeff, *schoeff.daniel@epa.gov*, (703) 347–0143.
Dichlobenil, Case 0236	EPA–HQ–OPP–2012–0395	Linsey Walsh, *walsh.linsey@epa.gov*, (703) 347–8030.
Diflufenzopyr & Diflufenzopyr-Sodium, Case 7246	EPA–HQ–OPP–2011–0911	Bilin Basu, *basu.bilin@epa.gov*, (703) 347–0455.
Emamectin Benzoate, Case 7607	EPA–HQ–OPP–2011–0483	Susan Bartow, *bartow.susan@epa.gov*, (703) 603–0065.
Fluopicolide, Case 7055	EPA–HQ–OPP–2013–0037	Khue Nguyen, *nguyen.khue@epa.gov*, (703) 347–0248.
Fluridone, Case 7200	EPA–HQ–OPP–2009–0160	Leigh Rimmer, *rimmer.leigh@epa.gov*, (703) 347–0553.
German cockroach pheromone, Case 6023	EPA–HQ–OPP–2017–0261	Daniel Schoeff, *schoeff.daniel@epa.gov*, (703) 347–0143.

TABLE—REGISTRATION REVIEW PROPOSED INTERIM DECISIONS BEING ISSUED—Continued

Registration review case name and number	Docket ID No.	Chemical review manager and contact information
Gibberellins, Case 4110	EPA–HQ–OPP–2012–0939	Cody Kendrick, *kendrick.cody@epa.gov*, (703) 347–0468.
Indole-3-Butyric Acid, Case 2330	EPA–HQ–OPP–2010–0608	Seiichi Murasaki, *murasaki.seiichi@epa.gov*, (703) 347–0163.
Indoxacarb, Case 7613	EPA–HQ–OPP–2013–0367	Moana Appleyard, *appleyard.moana@epa.gov*, (703) 308–8175.
Methyl Eugenol, Case 6203	EPA–HQ–OPP–2016–0173	Chris Pfeifer, *pfeifer.chris@epa.gov*, (703) 308–0031.
Methyl Isopropenyl, Case 6090	EPA–HQ–OPP–2017–0253	Alexandra Boukedes, *boukedes.alexandra@epa.gov*, (703) 347–0305.
Naphthenate salts, Case 3099	EPA–HQ–OPP–2010–0455	Rachel Ricciardi, *ricciardi.rachel@epa.gov*, (703) 347–0465.
Nuranone, Case 4113	EPA–HQ–OPP–2012–0126	Seiichi Murasaki, *murasaki.seiichi@epa.gov*, (703) 347–0163.
Oxamyl, Case 0253	EPA–HQ–OPP–2010–0028	Bilin Basu, *basu.bilin@epa.gov*, (703) 347–0455.
Prometryn, Case 0467	EPA–HQ–OPP–2013–0032	Christina Scheltema, *scheltema.christina@epa.gov*, (703) 308–2201.
Pyriproxyfen, Case 7424	EPA–HQ–OPP–2011–0677	Khue Nguyen, *nguyen.khue@epa.gov*, (703) 347–0248.
Quillaja extract (Quillaja Saponins), Case 6512	EPA–HQ–OPP–2017–0230	Maggie Rudick, *rudick.maggie@epa.gov*, (703) 347–0257.
Quinoa Saponins (Extract of *Chenopodium Quinoa* Saponins), Case 6200.	EPA–HQ–OPP–2017–0274	Daniel Schoeff, *schoeff.daniel@epa.gov*, (703) 347–0143.
Rhamnolipid biosurfactant, Case 6085	EPA–HQ–OPP–2017–0275	Cody Kendrick, *kendrick.cody@epa.gov*, (703) 347–0468.
Salicylic Acid and Methyl Salicylate, Case 4080	EPA–HQ–OPP–2017–0328	Maggie Rudick, *rudick.maggie@epa.gov*, (703) 347–0257.
Trifloxystrobin, Case 7028	EPA–HQ–OPP–2013–0074	Moana Appleyard, *appleyard.moana@epa.gov*, (703) 308–8175.
(Z)-9-tricosene (Muscalure), Case 4112	EPA–HQ–OPP–2010–0925	Alexandra Boukedes, *boukedes.alexandra@epa.gov*, (703) 347–0305.

The registration review docket for a pesticide includes earlier documents related to the registration review case. For example, the review opened with a Preliminary Work Plan, for public comment. A Final Work Plan was placed in the docket following public comment on the Preliminary Work Plan.

The documents in the dockets describe EPA's rationales for conducting additional risk assessments for the registration review of the pesticides included in the table in Unit IV, as well as the Agency's subsequent risk findings and consideration of possible risk mitigation measures. These proposed interim registration review decisions are supported by the rationales included in those documents. Following public comment, the Agency will issue interim or final registration review decisions for the pesticides listed in the table in Unit IV.

The registration review final rule at 40 CFR 155.58(a) provides for a minimum 60-day public comment period on all proposed interim registration review decisions. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the proposed interim decision. All comments should be submitted using the methods in **ADDRESSES**, and must be received by EPA on or before the closing date. These comments will become part of the docket for the pesticides included in the Table in Unit IV. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

The Agency will carefully consider all comments received by the closing date and may provide a ''Response to Comments Memorandum'' in the docket. The interim registration review decision will explain the effect that any comments had on the interim decision and provide the Agency's response to significant comments.

Background on the registration review program is provided at: *http://www.epa.gov/pesticide-reevaluation.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: July 16, 2018.

Yu-Ting Guilaran,

Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2018–16988 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2018–0517; FRL–9980–76]

FIFRA Scientific Advisory Panel; Notice of Public Meeting and Request for Nomination of Ad Hoc Expert Members

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: There will be a 4-day, in-person meeting of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel (FIFRA SAP) to consider and review the Evaluation of a Proposed Approach to Refine the Inhalation Risk Assessment for Point of Contact Toxicity: A Case Study Using a New Approach Methodology (NAM). Preceding the in-person meeting, there will be a half-day virtual preparatory meeting, conducted via webinar using Adobe Connect, to consider and review the clarity and scope of the meeting's draft charge questions. In addition, EPA is requesting nominations of prospective candidates for service as ad hoc members of FIFRA SAP for this meeting. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates

for this meeting by following the instructions provided in this document.

DATES:

Meeting: The 4-day, in-person meeting will be held December 4 to December 7, 2018, from approximately 9 a.m. to 5 p.m.

Nominations: Nominations of candidates to serve as ad hoc members of the FIFRA SAP for this review should be provided on or before September 7, 2018.

Special accommodations: Requests for special accommodations should be submitted on or before November 16, 2018, to allow EPA time to process your request.

Comments: Written comments should be submitted on or before October 19, 2018, and EPA encourages individuals and groups that wish to make oral comments to submit the request to make oral comments by November 9, 2018.

ADDRESSES:

Meeting: The in-person meeting will be held at the Environmental Protection Agency, Conference Center, Lobby Level, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA 22202. The virtual meeting will be webcast. Please refer to the following website for information on how to access the webcast: *http://www.epa.gov/sap.*

Nominations: Submit nominations of candidates to serve as ad hoc members of the FIFRA SAP Meeting to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

Special accommodations: For information on access or services for individuals with disabilities, and to request accommodation for a disability, please contact the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**.

Comments. Submit requests to present oral comments to the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

Submit your written comments, identified by docket identification (ID) number EPA–HQ–OPP–2018–0517, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.* For additional instructions related to this meeting, see Unit I.C. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Dr. Marquea D. King, DFO, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: 202–564–3626; email address: *king.marquea@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general. This action may be of interest to persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) and FIFRA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI information to EPA through regulations.gov or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting your comments.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *http://www.epa.gov/dockets/comments.html.*

C. How may I participate in both meetings?

You may participate in both meetings by following the instructions in this unit. To ensure proper receipt of comments, nominations or other requests by EPA, it is imperative that you identify docket ID number EPA–HQ–OPP–2018–0517 in the subject line on the first page of your request.

1. *Written comments.* Written comments for both the in-person and virtual meetings should be submitted, using the instructions in **ADDRESSES** and Unit I.B., on or before October 19, 2018, to provide FIFRA SAP the time necessary to consider and review the written comments. FIFRA SAP may not be able to fully consider written comments submitted after October 19, 2018.

2. *Oral comments.* To be included on the meeting agenda, the Agency encourages each individual or group wishing to make brief oral comments to FIFRA SAP during the in-person or virtual meetings to submit their request to the DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before November 9, 2018. To the extent that time permits, the Chair of the FIFRA SAP may permit the presentation of oral comments at the meeting by interested persons who have not previously requested time. Oral comments during the virtual meeting are limited to approximately 5 minutes due to the time constraints of this webcast. Oral comments during the 4-day, in-person meeting are limited to approximately 5 minutes unless arrangements have been made prior to November 9, 2018. The request should identify the name of the individual making the presentation, the organization (if any) the individual will represent, and any requirements for audiovisual equipment. In addition, each speaker should bring 15 copies of his or her oral remarks and presentation slides (if required) for distribution to the FIFRA SAP at the meeting by the DFO.

3. *Seating at the meeting.* Seating at the in-person meeting will be open and on a first-come basis.

4. *Request for nominations to serve as ad hoc expert members of FIFRA SAP for this meeting.* As part of a broader process for developing a pool of candidates for each meeting, FIFRA SAP staff routinely solicits the stakeholder community for nominations of prospective candidates for service as ad hoc members of FIFRA SAP. Any interested person or organization may nominate qualified individuals to be considered as prospective candidates for a specific meeting. Individuals nominated for this meeting should have expertise in one or more of the following areas: (i) Development and implementation of new approach methodologies (NAMs); (ii) inhalation alternative testing; (iii) inhalation toxicology; (iv) inhalation exposure assessment; (v) inhalation/computational fluid dynamic (CFD) modeling; and (vi) risk assessment. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to provide expert comments on the scientific issues for this meeting. Nominees should be identified by name, occupation, position, address, email address, and telephone number. Nominations should be provided to the

DFO listed under **FOR FURTHER INFORMATION CONTACT** on or before September 7, 2018. The Agency will consider all nominations of prospective candidates for this meeting that are received on or before that date. However, final selection of ad hoc members for this meeting is a discretionary function of the Agency.

The selection of scientists to serve on FIFRA SAP is based on the function of the Panel and the expertise needed to address the Agency's charge to the Panel. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a Federal department or agency or their employment by a Federal department or agency, except EPA. Other factors considered during the selection process include availability of the potential Panel member to fully participate in the Panel's review, absence of any conflicts of interest or appearance of loss of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of loss of impartiality, lack of independence, and bias may result in disqualification, the absence of such concerns does not assure that a candidate will be selected to serve on FIFRA SAP. Numerous qualified candidates are identified for each Panel; therefore, selection decisions involve carefully weighing a number of factors, including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives on the Panel. In order to have the collective breadth of experience needed to address the Agency's peer review charge for this meeting, the Agency anticipates selecting approximately 13 ad hoc scientists.

FIFRA SAP members are subject to the provisions of 5 CFR part 2634—Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture, as supplemented by EPA in 5 CFR part 6401. In anticipation of this requirement, prospective candidates for service on FIFRA SAP will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks, and bonds, and where applicable, sources of research support. EPA will evaluate the candidate's financial disclosure form to assess whether there are financial conflicts of interest, appearance of a loss of impartiality, or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on FIFRA SAP. Those who are selected from the pool of prospective candidates will be asked to attend the public meetings and to participate in the discussion of key issues and assumptions at these meetings. In addition, they will be asked to review and to help finalize the meeting minutes and final report. The list of FIFRA SAP members participating at this meeting will be posted on the FIFRA SAP website at *http://www.epa.gov/scipoly/sap* or may be obtained from the OPP Docket at *http://www.regulations.gov.*

II. Background

A. Purpose of FIFRA SAP

The FIFRA SAP serves as one of the primary scientific peer review mechanisms of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) and is structured to provide independent scientific advice, information and recommendations to the EPA Administrator on pesticides and pesticide-related issues as to the impact of regulatory actions on human health and the environment. FIFRA SAP is a Federal advisory committee established in 1975 under FIFRA that operates in accordance with requirements of the Federal Advisory Committee Act (5 U.S.C. Appendix). The FIFRA SAP is composed of a permanent panel consisting of seven members who are appointed by the EPA Administrator from nominees provided by the National Institutes of Health (NIH) and the National Science Foundation (NSF). FIFRA established a Science Review Board (SRB) consisting of at least 60 scientists who are available to FIFRA SAP on an ad hoc basis to assist in reviews conducted by FIFRA SAP. As a scientific peer review mechanism, FIFRA SAP provides comments, evaluations, and recommendations to improve the effectiveness and quality of analyses made by Agency scientists. Members of FIFRA SAP are scientists who have sufficient professional qualifications, including training and experience, to provide expert advice and recommendation to the Agency.

B. Public Meeting

EPA conducts human health risk assessments to evaluate the potential health effects of pesticides and toxic chemicals in residential and occupational settings based on the use pattern or conditions of use. For evaluating effects via the inhalation route, registrants and manufacturers conduct subchronic inhalation toxicity studies according to test guideline requirements (OPPTS 870.3465, 40 CFR part 798, OECD TG 412 and 413). In these studies, several groups of experimental animals are exposed daily for a defined period to graduated concentrations of test substance as a gas or aerosol/particulate. These studies are used to determine a no observed adverse effect concentration (NOAEC) for effects following repeated inhalation exposure that may be used for human health risk assessment.

The anatomy and physiology of human and animal respiratory tracts differ in several ways that can impact changes in airflow and deposition of inhaled substances and, therefore, influence the animal to human dose response extrapolation. Furthermore, traditional *in vivo* toxicity tests used to extrapolate from test species to humans are expensive, time-consuming, and can cause stress to laboratory animals. As a result, efforts to develop alternative methods and strategies for evaluating toxic effects from inhaled chemicals using *in vitro* test systems with human tissues combined with human dosimetry modeling provide inherent advantages over using *in vivo* animal studies. These alternatives are also consistent with the National Research Council's (NRC) long-range vision to advance toxicity testing in the 21st century, as well as the strategic roadmap released by Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) to accomplish NRC's vision in the United States.

New approach methodologies (NAMs) has been adopted as a broadly descriptive reference to any non-animal technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment. An example of a NAM for refining inhalation risk assessment has been submitted to the Agency for the pesticide chlorothalonil. Chlorothalonil is a contact irritant that has been found to be toxic via the inhalation route. Due to the irritant nature of chlorothalonil and animal welfare concerns, the registrant (Syngenta Crop Protection) indicated that a 90-day inhalation toxicity study was not feasible to fulfill the regulatory requirement of a subchronic inhalation study. Subsequently, Syngenta proposed an alternative approach using an in vitro assay (MucilAir™ using human nasal tissue) to characterize the hazard of chlorothalonil and derive a point of departure (POD) for use in human health risk assessment. In order to calculate human equivalent concentrations for the purposes of human health risk assessment, an in

vitro POD has been proposed in conjunction with surface concentrations of deposited chlorothalonil particles from a computational fluid dynamic (CFD) model for the upper airway of a human. As a proof of concept, Syngenta also used the calculated human equivalent concentrations for pesticide operators/applicators to provide potential risk estimates supported by this proposed approach.

The Agency is soliciting advice from the FIFRA Scientific Advisory Panel (SAP) on the derivation of the POD from the in vitro assay and the integration of the in vitro POD for calculation of human equivalent concentrations for the inhalation risk assessment. Chlorothalonil will be presented as a case study to solicit advice on the proposed overall approach expected to be applied to other pesticides or industrial chemicals in the future.

The 4-day, in-person FIFRA SAP meeting may also be webcast. You may refer to the FIFRA SAP website at *http://www.epa.gov/sap* for information on how to access the webcast. Please note that the webcast for the in-person meeting is a supplementary public process provided only for convenience. If difficulties arise resulting in webcasting outages, the in-person meeting will continue as planned.

C. Virtual Preparatory Meeting

Preceding the in-person meeting, there will be a half-day virtual preparatory meeting, conducted via webinar using Adobe Connect, to consider and review the clarity and scope of the meeting's draft charge questions. The virtual preparatory meeting will be webcast only, and registration is required to attend this virtual meeting. The date and registration instructions will be announced in a future **Federal Register** Notice and on the FIFRA SAP website (*http://www.epa.gov/sap)* by mid-September.

D. FIFRA SAP Documents and Meeting Minutes

EPA's background paper, charge/questions to FIFRA SAP, and related supporting materials will be available by early September 2018. In addition, a list of candidates under consideration as prospective ad hoc panelists for this meeting will be available for a 15-day public comment period by early to mid-September 2018. You may obtain electronic copies of most meeting documents, including FIFRA SAP composition (*i.e.,* members and ad hoc members for this meeting) and the meeting agenda, at *http://www.regulations.gov* and the FIFRA SAP website at *http://www.epa.gov/scipoly/sap.*

FIFRA SAP will prepare the meeting minutes and final report approximately 90 calendar days after the in-person meeting. The meeting minutes and final report will be posted on the FIFRA SAP website: *https://www.epa.gov/sap* and may be accessed in the docket at *https://www.regulations.gov.*

Authority: 7 U.S.C. 136 *et. seq.;* 21 U.S.C. 301 *et seq.*

Dated: July 12, 2018.

Stanley Barone, Jr.,

Acting Director, Office of Science Coordination and Policy.

[FR Doc. 2018–16990 Filed 8–7–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Information Collection Approved by the Office of the Management and Budget (OMB)

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The Federal Communications Commission has received Office of Management and Budget (OMB) approval for a revised information collection pursuant to the Paperwork Reduction Act (PRA) of 1995. An agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number, and no person is required to respond to a collection of information unless it displays a currently valid OMB control number. Comments concerning the accuracy of the burden estimates and any suggestions for reducing the burden should be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section below.

FOR FURTHER INFORMATION CONTACT: Nicole Ongele, Office of the Managing Director, at (202) 418–2991, or via email: *Nicole.Ongele@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0986.

OMB Approval Date: July 2, 2018.

OMB Expiration Date: July 31, 2021.

Title: High-Cost Universal Service Support.

Form Numbers: FCC Form 481 and FCC Form 525.

Respondents: Business or other for-profit, not-for-profit institutions and state, local or tribal government.

Number of Respondents and Responses: 1,877 respondents; 14,335 responses.

Estimated Time per Response: 0.5–15 hours.

Frequency of Response: On occasion, quarterly and annual reporting requirements, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151–154, 155, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, 405, 410, and 1302.

Total Annual Burden: 63,486 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: The Commission notes that USAC must preserve the confidentiality of all data obtained from respondents; must not use the data except for purposes of administering the universal service programs; and must not disclose data in company-specific form unless directed to do so by the Commission. Privately-held rate-of-return carriers may file the financial information they disclose in FCC Form 481 pursuant to a protective order.

Needs and Uses: The Commission received OMB approval for this revised information collection. On July 7, 2017, the Commission released *Connect America Fund; ETC Annual Reports and Certifications,* WC Docket Nos. 10–90 and 14–58, Order, FCC 17–87 (*ETC Reporting Streamlining Order*), which streamlined the annual reporting requirements for eligible telecommunications carriers (ETCs) that receive high-cost universal service support by eliminating several rules that are either duplicative of other reporting requirements or are simply no longer necessary. In doing this, the Commission reduced ETCs' regulatory burdens while strengthening the tools for program oversight in furtherance of our goal of protecting the high cost universal support program against waste, fraud, and abuse. Specifically, the Commission eliminated its annual high-cost reporting rules regarding network outage information, unfulfilled service requests, the number of complaints received by an ETC per 1,000 subscribers for both voice and broadband services, pricing for voice and broadband services, service quality certification, and duplicate filing of the FCC Form 481 without compromising its ability to monitor whether ETCs are using high-cost universal service support for its intended purpose, adopted in the *ETC Reporting Streamlining Order.*

This revised information collection addresses the removal of those duplicative or otherwise unnecessary

reporting requirements and the reorganization of remaining requirements, which were not substantively changed.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2018–16895 Filed 8–7–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary by email at *Secretary@fmc.gov,* or by mail, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. A copy of the agreement is available through the Commission's website (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 201264.

Agreement Name: Maersk/MSC Turkey Space Charter Agreement.

Parties: Maersk Line A/S and Mediterranean Shipping Company S.A.

Filing Party: Wayne Rohde, Cozen O'Connor.

Synopsis: The Agreement authorizes Maersk to charter space to MSC in the trade from Turkey to the U.S. East Coast.

Proposed Effective Date: 9/10/2018.

Location: https://www2.fmc.gov/FMC.Agreements.Web/Public/AgreementHistory/15239.

Dated: August 3, 2018.

Rachel Dickon,

Secretary.

[FR Doc. 2018–16981 Filed 8–7–18; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, with revision, the Financial Statements of U.S. Nonbank Subsidiaries of U.S. Holding Companies, and the Abbreviated Financial Statements of U.S. Nonbank Subsidiaries of U.S. Holding Companies (FR Y–11 and FR Y–11S; OMB No. 7100–0244); the Financial Statements of Foreign Subsidiaries of U.S. Banking Organizations and the Abbreviated Financial Statements of Foreign Subsidiaries of U.S. Banking Organizations (FR 2314 and FR 2314S; OMB No. 7100–0073); and the Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations, Abbreviated Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations, and the Capital and Asset Report of Foreign Banking Organizations (FR Y–7N, FR Y–7NS, and FR Y–Q; OMB No. 7100–0125).

DATES: The revisions became effective for reports reflecting the June 30, 2018, report date.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC, 20551 (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Board may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, With, of the Following Reports:

1. Report title: Financial Statements of U.S. Nonbank Subsidiaries of U.S. Holding Companies and the Abbreviated Financial Statements of U.S. Nonbank Subsidiaries of U.S. Holding Companies.

Agency form number: FR Y–11 and FR Y–11S.

OMB control number: 7100–0244.

Frequency: Quarterly and annually.

Reporters: Domestic bank holding companies (BHCs), savings and loan holding companies (SLHCs), securities holding companies, and intermediate holding companies (IHCs) (collectively, ''holding companies'').

Estimated annual reporting hours: FR Y–11 (quarterly): 12,539; FR Y–11 (annual): 1,299; FR Y–11S: 287.

Estimated average hours per response: FR Y–11 (quarterly): 6.8; FR Y–11 (annual): 6.8; FR Y–11S: 1.

Number of respondents: FR Y–11 (quarterly): 461; FR Y–11 (annual): 191; FR Y–11S: 287.

General Description of Report: The FR Y–11 family of reports collects financial information for individual U.S. nonbank subsidiaries of domestic holding companies, which is essential for monitoring the subsidiaries' potential impact on the condition of the holding company or its subsidiary banks. Holding companies file the FR Y–11 on a quarterly or annual basis or the FR Y–11S on an annual basis, predominantly based on whether the organization meets certain asset size thresholds.

Legal authorization and confidentiality: The Board has the authority to require BHCs and any subsidiary thereof, SLHCs and any subsidiary thereof, and securities holding companies and any affiliate thereof to file the FR Y–11 pursuant to, respectively, section 5(c) of the Bank Holding Company Act (BHC Act) (12 U.S.C. 1844(c)), section 10(b) of the Homeowners' Loan Act (12 U.S.C. 1467a(b)), and section 618 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) (12 U.S.C. 1850a). With respect to foreign banking organizations (FBOs) and their subsidiary IHCs, section 5(c) of the BHC Act, in conjunction with section 8 of the International Banking Act (12 U.S.C. 3106), authorizes the board to require FBOs and any subsidiary thereof to file the FR Y–11 reports. These reports are mandatory.

Information collected in these reports generally is not considered confidential. However, because the information is collected as part of the Board's

supervisory process, certain information may be afforded confidential treatment pursuant to exemption 8 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(8)). Individual respondents may request that certain data be afforded confidential treatment pursuant to exemption 4 of the FOIA if the data has not previously been publically disclosed and the release of the data would likely cause substantial harm to the competitive position of the respondent (5 U.S.C. 552(b)(4)). Additionally, individual respondents may request that personally identifiable information be afforded confidential treatment pursuant to exemption 6 of the FOIA if the release of the information would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552(b)(6)). The applicability of FOIA exemptions 4 and 6 would be determined on a case-by-case basis.

2. Report title: Financial Statements of Foreign Subsidiaries of U.S. Banking Organizations and the Abbreviated Financial Statements of Foreign Subsidiaries of U.S. Banking Organizations.

Agency form number: FR 2314 and FR 2314S.

OMB control number: 7100–0073.

Frequency: Quarterly and annually.

Reporters: U.S. state member banks (SMBs), BHCs, SLHCs, IHCs, and Edge or agreement corporations.

Estimated annual reporting hours: FR 2314 (quarterly): 12,514; FR 2314 (annual): 1,485; FR 2314S: 297.

Estimated average hours per response: FR 2314 (quarterly): 6.8; FR 2314 (annual): 6.8; FR 2314S: 1.

Number of respondents: FR 2314 (quarterly): 474; FR 2314 (annual): 225; FR 2314S: 297.

General Description of Report: The FR 2314 family of reports is the only source of comprehensive and systematic data on the assets, liabilities, and earnings of the foreign nonbank subsidiaries of U.S. banking organizations, and the data are used to monitor the growth, profitability, and activities of these foreign companies. The data help the Federal Reserve identify present and potential problems of these companies, monitor their activities in specific countries, and develop a better understanding of activities within the industry and within specific institutions. Parent organizations (SMBs, Edge and agreement corporations, or holding companies) file the FR 2314 on a quarterly or annual basis, or the FR 2314S on an annual basis, predominantly based on whether the organization meets certain asset size thresholds.

Legal authorization and confidentiality: The Board has the authority to require BHCs and any subsidiary thereof, SLHCs and any subsidiary thereof, and securities holding companies and any affiliate thereof to file the FR 2314 pursuant to, respectively, section 5(c) of the BHC Act (12 U.S.C. 1844(c)), section 10(b) of the Homeowners' Loan Act (12 U.S.C. 1467a(b)), and section 618 of the Dodd-Frank Act (12 U.S.C. 1850a). The Board has the authority to require SMBs, agreement corporations, and Edge corporations to file the FR 2314 pursuant to, respectively, sections 9(6), 25(7), and 25A(17) of the Federal Reserve Act (12 U.S.C. 324, 602, and 625). With respect to FBOs and their subsidiary IHCs, section 5(c) of the BHC Act, in conjunction with section 8 of the International Banking Act (12 U.S.C. 3106), authorizes the board to require FBOs and any subsidiary thereof to file the FR 2314 reports. These reports are mandatory. Information collected in these reports generally is not considered confidential. However, because the information is collected as part of the Board's supervisory process, certain information may be afforded confidential treatment pursuant to exemption 8 of the FOIA (5 U.S.C. 552(b)(8)). Individual respondents may request that certain data be afforded confidential treatment pursuant to exemption 4 of the FOIA if the data has not previously been publically disclosed and the release of the data would likely cause substantial harm to the competitive position of the respondent (5 U.S.C. 552(b)(4)). Additionally, individual respondents may request that personally identifiable information be afforded confidential treatment pursuant to exemption 6 of the FOIA if the release of the information would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552(b)(6)). The applicability of FOIA exemptions 4 and 6 would be determined on a case-by-case basis.

3. Report title: The Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations, Abbreviated Financial Statements of U.S. Nonbank Subsidiaries Held by Foreign Banking Organizations, and the Capital and Asset Report of Foreign Banking Organizations.

Agency form number: FR Y–7N, FR Y–7NS, and FR Y–7Q.

OMB control number: 7100–0125.

Frequency: Quarterly and annually.

Reporters: FBOs.

Estimated annual reporting hours: FR Y–7N (quarterly): 1,224; FR Y–7N (annual): 156; FR Y–7NS: 31; FR Y–7Q (quarterly): 1,632; FR Y–7Q (annual): 48.

Estimated average hours per response: FR Y–7N (quarterly): 6.8; FR Y–7N (annual): 6.8; FR Y–7NS: 1; FR Y–7Q (quarterly): 3; FR Y–7Q (annual): 1.5.

Number of respondents: FR Y–7N (quarterly): 45; FR Y–7N (annual): 23 FR Y–7NS: 31; FR Y–7Q (quarterly): 136; FR Y–7Q (annual): 32.

General Description of Report: The FR Y–7N and the FR Y–7NS are used to assess an FBO's ability to be a continuing source of strength to its U.S. operations and to determine compliance with U.S. laws and regulations. FBOs file the FR Y–7N quarterly or annually or the FR Y–7NS annually predominantly based on asset size thresholds. The FR Y–7Q is used to assess consolidated regulatory capital and asset information from all FBOs. The FR Y–7Q is filed quarterly by FBOs that have effectively elected to become or be treated as a U.S. financial holding company (FHC) and by FBOs that have total consolidated assets of $50 billion or more, regardless of FHC status. All other FBOs file the FR Y–7Q annually.

Legal authorization and confidentiality: With respect to FBOs and their subsidiary IHCs, section 5(c) of the BHC Act, in conjunction with section 8 of the International Banking Act (12 U.S.C. 3106), authorizes the board to require FBOs and any subsidiary thereof to file the FR Y–7N reports, and the FR Y–7Q.

Information collected in these reports generally is not considered confidential. However, because the information is collected as part of the Board's supervisory process, certain information may be afforded confidential treatment pursuant to exemption 8 of FOIA (5 U.S.C. 552(b)(8)). Individual respondents may request that certain data be afforded confidential treatment pursuant to exemption 4 of the FOIA if the data has not previously been publically disclosed and the release of the data would likely cause substantial harm to the competitive position of the respondent (5 U.S.C. 552(b)(4)). Additionally, individual respondents may request that personally identifiable information be afforded confidential treatment pursuant to exemption 6 of the FOIA if the release of the information would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552(b)(6)). The applicability of FOIA exemptions 4 and 6 would be determined on a case-by-case basis.

Current actions: On May 1, 2018, the Board published an initial notice in the **Federal Register** (83 FR 19062) requesting public comment for 60 days

on the extension, with revision, of these reports. The Board is adopting revisions to the FR Y–11, FR 2314, and FR Y–7N report forms and instructions that are consistent with certain recent changes to the FR Y–9 family of reports (OMB No. 7100–0128)[1] and the Federal Financial Institutions Examination Council (FFIEC) Consolidated Reports of Condition and Income (Call Reports) (FFIEC 031, 041, and 051; OMB No. 7100–0036).[2] Specifically, the changes (1) add a new data item to the balance sheet to separate and reclassify equity securities with readily determinable fair values not held for trading from the ''available for sale'' category in accordance with Financial Accounting Standards Board's (FASB) Accounting Standards Update (ASU) No. 2016–01, ''Recognition and Measurement of Financial Assets and Financial Liabilities;'' and (2) add new data items to the income statement to reflect the proper reporting of income associated with these securities. These revisions are effective for reports reflecting the June 30, 2018, report date. The comment period for this notice expired on July 2, 2018, and the Board did not receive any comments.

Board of Governors of the Federal Reserve System, August 2, 2018.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2018–16916 Filed 8–7–18; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision, the Senior Financial Officer Survey (FR 2023; OMB No. 7100–0223).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Board may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Report

Report title: Senior Financial Officer Survey.

Agency form number: FR 2023.

OMB control number: 7100–0223.

Frequency: Up to four times a year.

Respondents: Domestically chartered large commercial banks.

Estimated number of respondents: 80.

Estimated average hours per response: 3 hours.

Estimated annual burden hours: 960 hours.

General description of report: The Board uses the surveys in this collection to gather qualitative and limited quantitative information about liability management, the provision of financial services, and the functioning of key financial markets. Responses are obtained from a senior officer at each participating institution usually through an electronic submission. Although a survey may not be collected in a given year, the Board may conduct up to four surveys per year when informational needs arise and cannot be met from existing data sources. The survey does not have a fixed set of questions; each survey consists of a limited number of questions directed at topics of timely interest.

Legal authorization and confidentiality: The FR 2023 is a voluntary survey. Section 2A of the Federal Reserve Act (FRA) requires that the Board and the Federal Open Market Committee (FOMC) maintain long-run growth of the monetary and credit aggregates commensurate with the economy's long run potential to increase production, so as to promote effectively the goals of maximum employment, stable prices, and moderate long-term interest rates (12 U.S.C. 225a). In addition, under section 12A of the FRA, the FOMC is required to implement regulations relating to the open market operations conducted by Federal Reserve Banks. Those transactions must be governed with a view to accommodating commerce and business and with regard to their bearing upon the general credit situation of the country (12 U.S.C. 263). The Board and the FOMC use the information obtained from the FR 2023 to help fulfill these obligations.

The questions asked on each survey will vary, so the ability of the Board to maintain the confidentiality of information collected must be determined on a case by case basis. It is likely that much of the information collected would constitute confidential financial information obtained from a person and would thus be protected from disclosure under exemption 4 to the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4)). Exemption 8 of the FOIA, which protects information related to examination, operating, or condition reports prepared for the use of an agency supervising financial institutions, may also occasionally apply (5 U.S.C. 552(b)(8)).

Current actions: On May 15, 2018, the Board published a notice in the **Federal Register** (83 FR 22488) requesting public comment for 60 days on the extension, without revision, of the Board's clearance for the Senior Financial Officer Survey. The comment period for this notice expired on July 16, 2018. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, August, 2, 2018.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2018–16918 Filed 8–7–18; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

[1] See 83 FR 12395 (March 21, 2018).

[2] See 83 FR 939 (January 08, 2018).

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to revise, without extension, Capital Assessments and Stress Testing (FR Y–14A/Q/M; OMB No. 7100–0341).

DATES: Comments must be submitted on or before October 9, 2018.

ADDRESSES: You may submit comments, identified by FR Y–14A, FR Y–14Q, or FR Y–14M, by any of the following methods:

- *Agency website: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx.*
- *Email: regs.comments@federalreserve.gov.* Include OMB number in the subject line of the message.
- *FAX:* (202) 452–3819 or (202) 452–3102.
- *Mail:* Ann E. Misback, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

All public comments are available from the Board's website at *http://www.federalreserve.gov/apps/foia/proposedregs.aspx* as submitted, unless modified for technical reasons. Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room 3515, 1801 K Street NW (between 18th and 19th Streets NW), Washington, DC 20006 between 9:00 a.m. and 5:00 p.m. on weekdays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452–3684. Upon arrival, visitors will be required to present valid government-issued photo identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files, if approved. These documents will also be made available on the Federal Reserve Board's public website at: *http://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears below.

Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION: On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;

b. The accuracy of the Federal Reserve's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

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

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

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Federal Reserve should modify the proposal.

Proposal To Approve Under OMB Delegated Authority the Revision, Without Extension, of the Following Report

Report title: Capital Assessments and Stress Testing.

Agency form number: FR Y–14A/Q/M.

OMB control number: 7100–0341.

Frequency: Annually, semi-annually, quarterly, and monthly.

Respondents: The respondent panel consists of any top-tier bank holding company (BHC) that has $100 billion or more in total consolidated assets, as determined based on: (i) The average of the firm's total consolidated assets in the four most recent quarters as reported quarterly on the firm's FR Y–9C; or (ii) the average of the firm's total consolidated assets in the most recent consecutive quarters as reported quarterly on the firm's FR Y–9Cs, if the firm has not filed an FR Y–9C for each of the most recent four quarters. The respondent panel also consists of any U.S. intermediate holding company (IHC). Reporting is required as of the first day of the quarter immediately following the quarter in which the respondent meets this asset threshold, unless otherwise directed by the Board.

Number of respondents: 36.

Estimated annual reporting hours: FR Y–14A: Summary, 63,864 hours; Macro Scenario, 2,232 hours; Operational Risk, 648 hours; Regulatory Capital Instruments, 756 hours; Business Plan Changes, 576 hours; and Adjusted Capital Plan Submission, 500 hours. FR Y–14Q: Retail, 2,160 hours; Securities, 1,872 hours; Pre-Provision Net Revenue (PPNR), 102,385 hours; Wholesale, 21,744 hours; Trading, 92,448 hours; Regulatory Capital Transitions, 3,312 hours; Regulatory Capital Instruments, 7,776 hours; Operational risk, 7,200 hours; Mortgage Servicing Rights (MSR) Valuation, 1,380 hours; Supplemental, 576 hours; Retail Fair Value Option/Held for Sale (Retail FVO/HFS), 1,500 hours; Counterparty, 24,672 hours; and Balances, 2,304 hours. FR Y–14M: 1st Lien Mortgage, 210,528 hours; Home Equity, 173,376 hours; and Credit Card, 86,016 hours. FR Y–14 On-going Automation Revisions, 17,280 hours. FR Y–14 Attestation On-going Audit and Review, 33,280 hours.

Estimated average hours per response: FR Y–14A: Summary, 887 hours; Macro Scenario, 31 hours; Operational Risk, 18 hours; Regulatory Capital Instruments, 21 hours; Business Plan Changes, 16 hours; and Adjusted Capital Plan Submission, 100 hours. FR Y–14Q: Retail, 15 hours; Securities, 13 hours; PPNR, 711 hours; Wholesale, 151 hours; Trading, 1,926 hours; Regulatory Capital

Transitions, 23 hours; Regulatory Capital Instruments, 54 hours; Operational Risk, 50 hours; MSR Valuation, 23 hours; Supplemental, 4 hours; Retail FVO/HFS, 15 hours; Counterparty, 514 hours; and Balances, 16 hours. FR Y–14M: 1st Lien Mortgage, 516 hours; Home Equity, 516 hours; and Credit Card, 512 hours. FR Y–14 On-going Automation Revisions, 480 hours. FR Y–14 Attestation On-going Audit and Review, 2,560 hours.

General description of report: These collections of information are applicable to top-tier BHCs with total consolidated assets of $100 billion or more and U.S. IHCs. This family of information collections is composed of the following three reports:

- The FR Y–14A collects quantitative projections of balance sheet, income, losses, and capital across a range of macroeconomic scenarios and qualitative information on methodologies used to develop internal projections of capital across scenarios either annually or semi-annually.
- The quarterly FR Y–14Q collects granular data on various asset classes, including loans, securities, and trading assets, and PPNR for the reporting period.
- The monthly FR Y–14M is comprised of three retail portfolio- and loan-level schedules, and one detailed address-matching schedule to supplement two of the portfolio and loan-level schedules.

The data collected through the FR Y–14A/Q/M reports provide the Board with the information and perspective needed to help ensure that large firms have strong, firm-wide risk measurement and management processes supporting their internal assessments of capital adequacy and that their capital resources are sufficient given their business focus, activities, and resulting risk exposures. The annual Comprehensive Capital Analysis and Review (CCAR) exercise complements other Board supervisory efforts aimed at enhancing the continued viability of large firms, including continuous monitoring of firms' planning and management of liquidity and funding resources, as well as regular assessments of credit, market and operational risks, and associated risk management practices. Information gathered in this data collection is also used in the supervision and regulation of these financial institutions. To fully evaluate the data submissions, the Board may conduct follow-up discussions with, or request responses to follow up questions from, respondents. Respondent firms are currently required to complete and submit up to 18 filings each year: two semi-annual FR Y–14A filings, four quarterly FR Y–14Q filings, and 12 monthly FR Y–14M filings. Compliance with the information collection is mandatory.

Proposed revisions: In December 2017, the Board approved modifications to the FR Y–14 series of reports and a notice was published in the **Federal Register** (December 15, 2017; 82 FR 59608). The proposal modified the FR Y–14Q, Schedule L (Counterparty) effective as of the March 31, 2018, report date. These changes included simplifying the ranking methodology required for reporting positions and combining the previously separate collections of counterparties as ranked by derivatives and securities financing transactions (SFTs), respectively. Following the finalization and adoption of these proposed changes, the Board became aware of unintended omissions from the report forms and instructions for the FR Y–14Q. The omitted items required respondents to report their total stressed net current exposure under the two supervisory stressed scenarios.

To rectify the unintended changes, the Board is proposing to revise sub-schedule L.5 (Derivatives and SFT Profile) on the FR Y–14Q by adding the mistakenly omitted items. This modification would allow continued operationalization of supervisory modeling, and would provide for total stressed net current exposure reporting under the two supervisory stressed scenarios.

With the addition of the total stressed net current exposure item, the instructions would be changed to modify the associated ranking methodologies for the yearly stressed/CCAR submission in sub-schedule L.5 to require the top 25 counterparties to be reported as ranked by the total stressed net current exposure. This modification would ensure that top counterparties are properly rank-ordered by the total stressed net current exposure to be added on sub-schedule L.5 in a manner that captures both derivative and securities financing transaction exposures.

The proposed revisions do not result in a change to the estimated burden for this series of reports, as the burden from the proposed revisions is already captured in the burden estimates associated with the FR Y–14Q report.

Board of Governors of the Federal Reserve System, August 2, 2018.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2018–16917 Filed 8–7–18; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

Privacy Act of 1974; System of Records

AGENCY: Federal Trade Commission (FTC).

ACTION: Notice of modified systems of records.

SUMMARY: The FTC is publishing in final form a modification to all FTC Privacy Act system of records notices (SORNs) by amending and bifurcating an existing global routine use relating to assistance in data breach responses, to conform with Office of Management and Budget (OMB) guidance to federal agencies, OMB Memorandum 17–12.

DATES: August 8, 2018, except that the new routine use shall be effective September 7, 2018.

FOR FURTHER INFORMATION CONTACT: G. Richard Gold and Alex Tang, Attorneys, Office of the General Counsel, FTC, 600 Pennsylvania Avenue NW, Washington, DC 20580, (202) 326–2424.

SUPPLEMENTARY INFORMATION: In a document previously published in the **Federal Register**, 83 FR 19560 (May 3, 2018), the Federal Trade Commission, as required by the Privacy Act, sought comments on a proposal to modify and bifurcate an existing routine use relating to assistance in data breach responses, which is applicable to all Federal Trade Commission SORNs, to conform with OMB Memorandum M–17–12, Preparing for and Responding to a Breach of Personally Identifiable Information (January 3, 2017). *See* 5 U.S.C. 552a(e)(4) and (11).

The comment period closed on June 4, 2018, and the FTC received three comments to the proposal to modify and bifurcate an existing routine use relating to assistance in data breach responses. The commenters were Xyampza Kerz, Thomas Dickinson, and Dave Root. Xyampza Kerz's comment expressed concerns about the privacy of homeowner's personal information posted on the Web when they buy a home and about internet searches that allow a searcher to find out your age and possibly lead to discrimination. M/M. Kerz also complains about the practices of an online entity and asks that the entity be shut down. These are important privacy issues but are not

germane to the current public notice and comment process. We have referred M/M. Kerz's comment to the FTC's Consumer Response Center for entry into the Consumer Sentinel Network of complaints and related inquiries.

The second commenter, Thomas Dickinson, also filed a comment that is non-germane to the current public notice and comment process. Mr. Dickinson asks the FTC to apply a ''monitor'' to individuals' home phones that identifies violations of the Do-Not-Call Rule and allows the FTC to take appropriate punitive actions. We have also referred Mr. Dickinson's complaint to the FTC's Consumer Response Center for entry into the Consumer Sentinel Network.

The third commenter, Dave Root, commented that ''due process and . . . [his] . . . privacy . . . [would] . . . be harmed by open access to sharing . . . [his] . . . personal info between all government agencies as outlined in this notice.'' Mr. Root asked if there are ''any safeguards against 'political weaponization' without any accountability, by any federal, state or local governmental agency having access to this information.'' Mr. Root asked for '''teeth' in the rule for anyone . . . that purposefully uses this information incorrectly . . . [meaning] . . . seriously enforced jail time for anyone who fails to act in the investigation and prosecution process.''

The revised routine use would not provide ''open access'' to ''all government agencies'' but would require that the FTC receive a request from another Federal agency or Federal entity that provides enough supporting information such that the FTC can determine that information from an FTC Privacy Act system or systems is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

The Privacy Act specifically provides civil remedies, 5 U.S.C. 552a(g), including damages, and criminal penalties, 5 U.S.C. 552a(i), for violations of the Act. In addition, an individual may be fined up to $5,000 for knowingly and willfully requesting or gaining access to a record about an individual under false pretenses. 5 U.S.C. 552a(i)(3).

As stated in the **Federal Register** Notice dated May 3, 2018, the FTC believes that the modified and bifurcated routine use on data breaches is compatible with the collection of information pertaining to individuals affected by a breach, and that the disclosure of such records will help prevent, minimize or remedy a data breach or compromise that may affect such individuals. By contrast, the FTC believes that failure to take reasonable steps to help prevent, minimize or remedy the harm that may result from such a breach or compromise would jeopardize, rather than promote, the privacy of such individuals.

The FTC provided a public comment period and notice to OMB and Congress as required by the Privacy Act and implementing OMB guidelines.[1]

Accordingly, the FTC hereby amends Appendix I of its Privacy Act system notices, as published at 73 FR 33591, by revising item number (22), adding new item number (23), and re-designating the former item number (23) as (24) (without any other change) at the end of the existing routine uses set forth in that Appendix:

* * * * *

(22) To appropriate agencies, entities, and persons when (a) the FTC suspects or has confirmed that there has been a breach of the system of records; (b) the FTC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the FTC (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the FTC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

(23) To another Federal agency or Federal entity, when the FTC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

(24) May be disclosed to FTC contractors, volunteers, interns or other authorized individuals who have a need for the record in order to perform their officially assigned or designated duties for or on behalf of the FTC.

[1] See U.S.C. 552a(e)(11) and 552a(r); OMB Circular A–108 (2016).

HISTORY

73 FR 33591–33634 (June 12, 2008).

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2018–16935 Filed 8–7–18; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Trade Commission (''FTC'' or ''Commission'').

ACTION: Notice.

SUMMARY: The FTC intends to ask the Office of Management and Budget (''OMB'') to extend for an additional three years the current Paperwork Reduction Act (''PRA'') clearance for the information collection requirements in the FTC Red Flags, Card Issuers, and Address Discrepancies Rules [1] (''Rules''). That clearance expires on November 30, 2018.

DATES: Comments must be submitted by October 9, 2018.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Red Flags Rule, PRA Comment, Project No. P095406'' on your comment. File your comment online at *https://ftcpublic.commentworks.com/ftc/RedFlagsPRA* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to Mark Eichorn, Assistant Director, Division of Privacy and Identity Protection, Bureau of Consumer Protection, (202) 326–3053, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

[1] 16 CFR 681.1 (Duties regarding the detection, prevention, and mitigation of identity theft); 16 CFR 681.2 (Duties of card issuers regarding changes of address); 16 CFR 641.1 (Duties of users of consumer reports regarding address discrepancies).

SUPPLEMENTARY INFORMATION:

I. Overview of the Rules

The Red Flags Rule requires financial institutions and certain creditors to develop and implement written Identity Theft Prevention Programs (''Program''). The Card Issuers Rule requires credit and debit card issuers (''card issuers'') to assess the validity of notifications of address changes under certain circumstances. The Address Discrepancy Rule provides guidance on what users of consumer reports must do when they receive a notice of address discrepancy from a nationwide consumer reporting agency (''CRA''). Collectively, these three anti-identity theft provisions are intended to prevent impostors from misusing another person's personal information for a fraudulent purpose.

The Rules implement sections 114 and 315 of the FACT Act, Public Law 108–159, which amended the Fair Credit Reporting Act (''FCRA''), 15 U.S.C. 1681 *et seq.,* to require businesses to undertake measures to prevent identity theft and increase the accuracy of consumer reports.

Since promulgation of the original Rule, President Obama signed the Red Flag Program Clarification Act of 2010 (''Clarification Act''), which narrowed the definition of ''creditor'' for purposes of the Red Flags Rule. Specifically, the Clarification Act limits application of the Red Flags Rule to creditors that regularly and in the ordinary course of business: (1) Obtain or use consumer reports, directly or indirectly, in connection with a credit transaction; (2) furnish information to consumer reporting agencies in connection with a credit transaction; or (3) advance funds to or on behalf of a person, based on an obligation of the person to repay the funds or to make repayment from specific property pledged by or on behalf of the person. This third prong does not include a creditor that advances funds on behalf of a person for expenses incidental to a service provided by the creditor to that person.

II. Description of Collection of Information

A. FACT Act Section 114

The FTC Red Flags and Card Issuers Rules implement requirements under Section 114 of the FACT Act. The Red Flags Rule requires financial institutions and covered creditors to develop and implement a written Program to detect, prevent, and mitigate identity theft in connection with existing accounts or the opening of new accounts. Under the Rule, financial institutions and certain creditors must conduct a periodic risk assessment to determine if they maintain ''covered accounts.'' The Rule defines the term ''covered account'' as either: (1) A consumer account that is designed to permit multiple payments or transactions, or (2) any other account for which there is a reasonably foreseeable risk of identity theft. Each financial institution and covered creditor that has covered accounts must create a written Program that contains reasonable policies and procedures to identify relevant indicators of the possible existence of identity theft (''red flags''); detect red flags that have been incorporated into the Program; respond appropriately to any red flags that are detected to prevent and mitigate identity theft; and update the Program periodically to ensure it reflects change in risks to customers.

The Red Flags Rule also requires financial institutions and covered creditors to: (1) Obtain approval of the initial written Program by the board of directors; a committee thereof; or, if there is no board, an appropriate senior employee; (2) ensure oversight of the development, implementation, and administration of the Program; and (3) exercise appropriate and effective oversight of service provider arrangements.

In addition, the Card Issuers Rule requires that card issuers generally must assess the validity of change of address notifications. Specifically, if the card issuer receives a notice of change of address for an existing account and, within a short period of time (during at least the first 30 days), receives a request for an additional or replacement card for the same account, the issuer must follow reasonable policies and procedures to assess the validity of the change of address.

B. FACT Act Section 315

In implementing section 315 of the FACT Act, the Address Discrepancies Rule requires each user of consumer reports to have reasonable policies and procedures in place to employ when the user receives a notice of address discrepancy from a CRA. Specifically, each user must develop reasonable policies and procedures to: (1) Enable the user to form a reasonable belief that a consumer report relates to the consumer about whom it has requested the report; and (2) in certain circumstances, provide to the CRA from which it received the notice an address for the consumer that the user has reasonably confirmed is accurate.

II. Burden Estimates

Under the PRA, 44 U.S.C. 3501–3521, Federal agencies must get OMB approval for each collection of information they conduct or sponsor. ''Collection of information'' includes agency requests or requirements to submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). The figures below reflect FTC staff's estimates of the hours burden and labor costs to complete the tasks described above that fall within reporting, disclosure, or recordkeeping requirements. FTC staff believes that the Rules impose negligible capital or other non-labor costs, as the affected entities are likely to have the necessary supplies and/or equipment already (*e.g.* offices and computers) for the information collection described herein.

Overall estimated burden hours regarding sections 114 and 315, combined, total 2,296,863 hours and the associated estimated labor costs are $92,465,982.

A. FACT Act Section 114

1. Estimated Hours Burden—Red Flags Rule

As noted above, the Rule requires financial institutions and certain creditors with covered accounts to develop and implement a written Program. Under the FCRA, financial institutions over which the FTC has jurisdiction include state chartered credit unions and certain insurance companies, among other entities.

Although narrowed by the Clarification Act, the definition of ''creditor'' still covers a broad array of entities, and application of the Rule depends upon an entity's course of conduct, not its status as a particular type of business. For these reasons, it is difficult to determine precisely the number of creditors subject to the FTC's jurisdiction. There are numerous small businesses under the FTC's jurisdiction that may qualify as ''creditors,'' and there is no formal way to track them. Nonetheless, FTC staff estimates that the Rule's requirement to have a written Program affects 6,278 financial institutions [2] and 157,585 creditors.[3]

[2] The total number of financial institutions is derived from an analysis of state credit unions and insurers within the FTC's jurisdiction using 2015 Census data (''County Business Patterns,'' U.S.) and other online industry data.

[3] The total number of creditors (157,585) is derived mostly from an analysis of 2015 Census data and industry data for businesses or organizations that market goods and services to consumers or other businesses or organizations subject to the FTC's jurisdiction, reduced by (1)

Continued

To estimate burden hours for the Red Flags Rule under section 114, FTC staff divided affected entities into two categories, based on the nature of their business: (1) Entities that are subject to high risk of identity theft, and (2) entities that are subject to a low risk of identity theft, but have covered accounts that will require them to have a written Program.

a. High-Risk Entities

FTC staff estimates that high-risk entities [4] will each require 25 hours to create and implement a written Program, with an annual recurring burden of one hour. FTC staff anticipates that these entities will incorporate into their Program policies and procedures that they likely already have in place. Further, FTC staff estimates that preparation for an annual report will require each high-risk entity four hours initially, with an annual recurring burden of one hour. Finally, FTC staff believes that many of the high-risk entities, as part of their usual and customary business practice, already take steps to minimize losses due to fraud, including conducting employee training. Accordingly, only relevant staff need be trained to implement the Program: for example, staff already trained as part of a covered entity's anti-fraud prevention efforts do not need to be re-trained. FTC staff estimates that training connected with the implementation of a Program of a high-risk entity will require four hours, and annual training thereafter will require one hour.

Thus, estimated hours for high-risk entities are as follows:

- 94,052 high-risk entities subject to the FTC's jurisdiction at an average annual burden of 13 hours per entity [average annual burden over 3-year clearance period for creation and implementation of a Program ((25 + 1 + 1) hours/3), plus average annual burden over 3-year clearance period for staff training ((4 + 1 + 1) hours/3), plus average annual burden over 3-year clearance period for preparing an annual report ((4 + 1 + 1) hours/3)], for a total of 1,222,676 hours.

b. Low-Risk Entities

Entities that have a minimal risk of identity theft,[5] but that have covered accounts, must develop a Program; however, they likely will only need a streamlined Program. FTC staff estimates that such entities will require one hour to create such a Program, with an annual recurring burden of five minutes. Training staff of low-risk entities to be attentive to future risks of identity theft should require no more than 10 minutes in an initial year, with an annual recurring burden of five minutes. FTC staff further estimates that these entities will require, initially, 10 minutes to prepare an annual report, with an annual recurring burden of five minutes.

Thus, the estimated hours burden for low-risk entities is as follows:

- 63,533 low risk entities that have covered account subject to the FTC's jurisdiction at an average annual burden of approximately 37 minutes per entity [average annual burden over 3-year clearance period for creation and implementation of streamlined Program ((60 + 5 + 5) minutes/3), plus average annual burden over 3-year clearance period for staff training ((10 + 5 + 5) minutes/3), plus average annual burden over 3-year clearance period for preparing annual report ((10 + 5 + 5) minutes/3], for a total of 39,179 hours.

2. Estimated Hours Burden—Card Issuers Rule

As noted above, section 114 also requires financial institutions and covered creditors that issue credit or debit cards to establish policies and procedures to assess the validity of a change of address request, including notifying the cardholder or using another means of assessing the validity of the change of address.

- FTC staff estimates that the Rule affects as many as 16,742 [6] card issuers within the FTC's jurisdiction. FTC staff believes that most of these card issuers already have automated the process of notifying the cardholder or are using another means to assess the validity of the change of address, such that implementation will pose no further burden. Nevertheless, taking a conservative approach, FTC staff estimates that it will take each card issuer 4 hours to develop and implement policy and procedures to assess the validity of a change of address request for a total burden of 66,968 hours.

Thus, the total average annual estimated burden for Section 114 is 1,328,823 hours.

3. Estimated Cost Burden—Red Flags and Card Issuers Rules

The FTC staff estimates labor costs by applying appropriate estimated hourly cost figures to the burden hours described above. It is difficult to calculate with precision the labor costs associated with compliance with the Rule, as they entail varying compensation levels of management (*e.g.,* administrative services, computer and information systems, training and development) and/or technical staff (*e.g.,* computer support specialists, systems analysts, network and computer systems administrators) among companies of different sizes. FTC staff assumes that for all entities, professional technical personnel and/or management personnel will create and implement the Program, prepare the annual report, and train employees, at an hourly rate of $49.[7]

Based on the above estimates and assumptions, the total annual labor costs for all categories of covered entities under the Red Flags and Card Issuers Rules for Section 114 is $65,112,327 (1,328,823 hours × $49).

B. FACT Act Section 315—The Address Discrepancy Rule

As discussed above, the Rule's implementation of Section 315 provides guidance on reasonable policies and procedures that a user of consumer reports must employ when a user receives a notice of address discrepancy from a CRA. Given the broad scope of users of consumer reports, it is difficult to determine with precision the number of users of consumer reports that are subject to the FTC's jurisdiction. As noted above, there are numerous small businesses under the FTC's jurisdiction, and there is no formal way to track them; moreover, as a whole, the entities under the FTC's jurisdiction are so

entities not likely to obtain credit reports, report credit transactions, or advance loans; and (2) entities not likely to have covered accounts under the Rule.

[4] High-risk entities include, for example, financial institutions within the FTC's jurisdiction and utilities, motor vehicle dealerships, telecommunications firms, colleges and universities, and hospitals.

[5] Low-risk entities include, for example, public warehouse and storage firms, nursing and residential care facilities, automotive equipment rental and leasing firms, office supplies and stationery stores, fuel dealers, and financial transaction processing firms.

[6] Card issuers within the FTC's jurisdiction include, for example, state credit unions, general retail merchandise stores, colleges and universities, and telecoms.

[7] This estimate is based on mean hourly wages found at *http://www.bls.gov/news.release/ocwage.t01.htm,* ''Occupational Employment and Wages Summary—May 2017,'' U.S. Department of Labor, Table 1, released March 30, 2018 (''National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2017'') for the various managerial and technical staff support exemplified above (administrative service managers, computer & information systems managers, training & development managers, computer systems analysts, network & computer systems administrators, and computer support specialists).

varied that there are no general sources that provide a record of their existence. Nonetheless, FTC staff estimates that the Rule's implementation of section 315 affects approximately 1,967,161 users of consumer reports subject to the FTC's jurisdiction.[8] Commission staff estimates that approximately 10,000 of these users will receive notice of a discrepancy, in the course of their usual and customary business practices, and thereby have to furnish to CRAs an address confirmation.[9]

For section 315, as detailed below, FTC staff estimates that the average annual burden during the three-year period for which OMB clearance is sought will be 919,678 hours with an associated labor cost of $17,473,882.

1. Estimated Hours Burden

Prior to enactment of the Address Discrepancy Rule, users of consumer reports could compare the address on a consumer report to the address provided by the consumer and discern for themselves any discrepancy. As a result, FTC staff believes that many users of consumer reports have developed methods of reconciling address discrepancies, and the following estimates represent the incremental amount of time users of consumer reports may require to develop and comply with the policies and procedures for when they receive a notice of address discrepancy.

a. Customer Verification

Given the varied nature of the entities under the FTC's jurisdiction, it is difficult to determine precisely the appropriate burden estimates. Nonetheless, FTC staff estimates that it would require an infrequent user of consumer reports no more than 16 minutes to develop and comply with the policies and procedures that it will employ when it receives a notice of address discrepancy, while a frequent user might require one hour. Similarly, FTC staff estimates that, during the remaining two years of clearance, it may take an infrequent user no more than one minute to comply with the policies and procedures it will employ when it receives a notice of address discrepancy, while a frequent user might require 45 minutes. Taking into account these extremes, FTC staff estimates that, during the first year, it will take users of consumer reports under the FTC's jurisdiction an average of 38 minutes [the midrange between 16 minutes and 60 minutes] to develop and comply with the policies and procedures that they will employ when they receive a notice of address discrepancy. FTC staff also estimates that the average recurring burden for users of consumer reports to comply with the Rule will be 23 minutes [the midrange between one minute and 45 minutes].

Thus, for these 1,967,167 entities, the average annual burden for each of them to perform these collective tasks will be 28 minutes [(38 + 23 +23) ÷ 3]; cumulatively, 918,011 hours.

b. Address Verification

For the estimated 10,000 users of consumer reports that will additionally have to furnish to CRAs an address confirmation upon notice of a discrepancy, staff estimates that these entities will require, initially, 30 minutes to develop related policies and procedures. But, these 10,000 affected entities likely will have automated the process of furnishing the correct address in the first year of a three-year PRA clearance cycle. Thus, allowing for 30 minutes in the first year, with no annual recurring burden in the second and third years of clearance, yields an average annual burden of 10 minutes per entity to furnish a correct address to a CRA, for a total of 1,667 hours.

2. Estimated Cost Burden

FTC staff assumes that the policies and procedures for compliance with the address discrepancy part of the Rule will be set up by administrative support personnel at an hourly rate of $19.[10] Based on the above estimates and assumptions, the total annual labor cost for the two categories of burden under section 315 is $17,473,882.

C. Burden Totals for FACT Act Sections 114 and 315

Cumulatively, then, estimated burden is 2,246,834 hours (1,328,823 hours for section 114 and 918,011 hours for section 315) and $82,586,209 ($65,112,327 and $17,473,882) in associated labor costs.

IV. Request for Comment

Pursuant to Section 3506(c)(2)(A) of the PRA, the FTC invites comments on: (1) Whether the disclosure requirements are necessary, including whether the information will be practically useful; (2) the accuracy of our burden estimates, including whether the methodology and assumptions used are useful; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of providing the required information to consumers.

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before October 9, 2018. Write: ''Red Flags Rule, PRA Comment, Project No. P095406'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission website, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission website.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online, or to send them to the Commission by courier or overnight service. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/RedFlagsPRA* by following the instructions on the web-based form. When this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that website.

If you file your comment on paper, write ''Red Flags Rule PRA, Project No. P095406'' on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible FTC website at *https://www.ftc.gov/,* you are solely responsible for making sure that your

[8] This estimate is derived from an analysis of Census databases of U.S. businesses based on NAICS codes for businesses in industries that typically use consumer reports from CRAs described in the Rule, which total 1,967,161 users of consumer reports subject to the FTC's jurisdiction.

[9] Report to Congress Under Sections 318 and 319 of the Fair and Accurate Credit Transactions of 2003, Federal Trade Commission, 80 (Dec. 2004) available at *http://www.ftc.gov/reports/facta/041209factarpt.pdf.*

[10] This estimate—rounded to the nearest dollar—is based on mean hourly wages for all management occupations found within the ''Bureau of Labor Statistics, Economic News Release,'' March 30, 2018, Table 1, ''National employment and wage data from the Occupational Employment Statistics survey by occupation, May 2017.'' *http://www.bls.gov/news.release/ocwage.t01.htm.*

comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the public FTC website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from the FTC website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 9, 2018. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Heather Hippsley,

Acting Principal Deputy General Counsel.

[FR Doc. 2018–16936 Filed 8–7–18; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–18–1072]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Enhanced STD surveillance Network (SSuN) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on March, 15, 2018 to obtain comments from the public and affected agencies. CDC received 37 comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

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

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Enhanced STD surveillance Network (SSuN)—Reinstatement with Change—Division of STD Prevention (DSTDP), National Center for HIV/AIDS, Viral Hepatitis, STD, and TB prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Enhanced STD surveillance network project was created to provide enhanced behavioral, demographic, and clinical information on gonorrhea cases reported to state and local health departments, to provide information on patients presenting for care in STD clinical settings, and to provide an infrastructure for identifying emerging sequelae of STDs.

Enhanced SSuN continues to be a collaboration between different branches of the CDC Division of STD Prevention and selected state/local public health departments and their associated STD specialty care clinics in the US. Data from enhanced SSuN data is used to (1) provide a dataset of supplemental information on gonorrhea case reports; (2) provide geographic information on case reports of STDs of interest for investigating social determinants of STDs, (3) monitor STD screening, incidence, prevalence, epidemiologic and health care access trends in populations of interest, (4) monitor STD treatment and prevention service practices, and (5) monitor selected adverse health outcomes of STDs, including neuro/ocular syphilis,

This project will continue to utilize two distinct surveillance strategies to collect information. The first strategy employs facility-based sentinel surveillance, which will abstract routine standardized data from existing electronic medical records for all patient visits to participating STD clinics during the project period. For the facility-based component of enhanced SSuN, participating sites have developed common protocols stipulating data elements to be collected, including patient demographics, clinical, risk and sexual behaviors. The specified data elements are abstracted by clinic staff from

existing electronic medical records for all patient visits to participating STD clinics. Some of the participating facilities are satellite clinics of large network providers where clinical data systems are centralized. Hence, there are 10 unique clinic data managers that will be abstracting the facility data. Each of the clinic data managers will spend three hours to extract and transmit data to local/state health departments. Individual patient records are de-identified (all patient-specific identifiers are removed) by clinic staff before being transmitted to health departments, who recode the data into standardized formats before being transmitted to CDC through secure file transport mechanisms. Each enhanced SSuN site will spend 16 hours to recode and transmit the data to CDC every other month. At CDC, data will be aggregated across all participating sites in a common data structure and formatted for analysis.

Under this revision, the second strategy, population-based STD surveillance is being expanded to include not only a random sample of reported gonorrhea cases but also include patients diagnosed with early syphilis that report neurologic/ocular manifestations. For the gonorrhea population component, a probability sample of gonorrhea cases (up to 10% of total gonorrhea morbidity for participating jurisdictions) will be contacted by health department staff for a standardized interview either by phone or in-person. Enhanced gonorrhea investigations will also include verification of treatment and an internal health department record review (performed on either all cases or on the sampled cases). The focus of the new population activity focuses on obtaining additional clinical information on early syphilis cases who report neurologic/ocular symptoms. The subset of patients reporting these symptoms are asked to participate in an interview to obtain additional clinical information for a more complete assessment of neurologic/ocular involvement as well as obtain additional clinical information from the diagnosing or reporting provider. Lastly, early syphilis cases reporting neurologic and/or ocular symptoms are recontacted at approximately three months following prescribed treatment to ascertain whether initial symptoms have resolved.

The population data will be directly entered into existing STD surveillance information systems at each health department. Data will be locally extracted, de-identified and recoded into standardized formats prior to being transmitted to CDC through secure file transport mechanisms on bimonthly basis. Patient participation in the interview is voluntary and refusal to participate has no impact on other STD services the health department provides to persons diagnosed with gonorrhea.

This project will not collect name, social security number, or date of birth. A Patient ID, a unique patient identifier assigned by the clinic or health department depending on the component, is requested and will be provided to CDC for purposes of enhanced surveillance. Patient IDs are not linkable across enhanced SSuN components. Sensitive information such as sex of sex partners, HIV status, sex work exposure, and injection drug use are collected. All personally identifiable information (PII) is retained by the STD clinics and/or health departments and is not recorded with data sent to CDC. The electronic enhanced SSuN database is stored on the CDC mainframe computer and only approved Division of STD Prevention (DSTDP) staff have access rights to the data. As part of the revision, we will continue to systematically identify the risks and potential effects of collecting, maintaining, and disseminating PII and to examine and evaluate alternative processes for handling that information to mitigate potential privacy risks and risks to confidentiality.

Both components of enhanced SSuN are designed to (1) Integrate traditional surveillance methods with innovative data management technologies to produce high-quality, timely surveillance and epidemiologic data, (2) provide valuable information to direct public health STD prevention and control efforts, (3) enhance understanding of the community burden of disease, (4) identify syndemic patterns and population at greatest risk, and, (5) monitor long-term health consequences of STDs. The enhanced SSuN surveillance platform allows CDC to establish and maintain common standards for data collection, transmission, and analysis, and to build and maintain STD surveillance expertise in 10 state/local health departments. Such common systems, established mechanisms of communication, and in-place expertise are all critical components for timely, flexible, and high quality surveillance. The total estimated annual burden is 3,479 hours. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Data manager at Sentinel STD clinics	Record Abstraction	10	6	3
General Public—Adults (persons diagnosed and reported with gonorrhea or early syphilis.	Interview	5492	1	10/60
Diagnosing Provider	Data for early syphilis cases	406	1	10/60
General Public—Adults (persons with early syphilis who were reported with neurologic/ocular manifestations.	3 month follow-up telephone Interview	203	1	5/60
Data Managers: 10 local/state health department.	Data cleaning/validation/reformatting	10	12	19

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2018–16947 Filed 8–7–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2485]

Fougera Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 27 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 27 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of September 7, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 061467	Pyocidin-Otic (hydrocortisone and polymyxin B sulfate) Otic Solution, 5 milligrams (mg)/10,000 units per milliliter (mL).	Fougera Pharmaceuticals, Inc., 60 Baylis Rd., P.O. Box 2006, Melville, NY 11747.
ANDA 061653	Tetrex (tetracycline phosphate complex) Capsules, Equivalent to (EQ) 100 mg Hydrochloride (HCl), EQ 250 mg HCl and EQ 500 mg HCl.	Bristol-Myers Squibb Co., P.O. Box 4000, Princeton, NJ 08543.
ANDA 061658	Bristacycline (tetracycline HCl) Capsules, 250 mg and 500 mg	Do.
ANDA 061711	Penicillin V Potassium Tablets	Do.
ANDA 061721	Ampicillin Capsules, 250 mg and 500 mg	Do.
ANDA 061726	Azotrex (phenazopyridine HCl, sulfamethizole and tetracycline phosphate complex) Capsules, 50 mg/250 mg/125 mg.	Do.
ANDA 061790	Hetacillin Potassium	Do.
ANDA 061887	Bristamycin (erythromycin stearate) Tablets, EQ 250 mg base	Do.
ANDA 061888	Bristacycline (tetracycline HCl) Capsules, 250 mg and 500 mg	Do.
ANDA 061889	Tetrex (tetracycline phosphate complex) Capsules, EQ 250 mg HCl and EQ 500 mg HCl.	Do.
ANDA 061890	Azotrex (phenazopyridine HCl, sulfamethizole, and tetracycline) Capsules, 50 mg/250 mg/125 mg.	Do.
ANDA 061891	Tetrex-S (tetracycline) Syrup, 125 mg/5 mL	Do.
ANDA 061975	Cephradine Powder for Injection	Do.
ANDA 062168	Cephradine Tablets	Do.
ANDA 062259	Amphotericin B for Use in Parenteral Products	Do.
ANDA 062543	Mycolog (nystatin, neomycin sulfate, gramicidin, and triamcinolone acetonide) Ointment.	Do.
ANDA 071793	Foamcoat (aluminum hydroxide; magnesium trisilicate) Chewable Tablets, 80 mg/20 mg (OTC).	Guardian Drug Co., 2 Charles Court, Dayton, NJ 08810.
ANDA 072035	Nuprin (ibuprofen) Tablets, 200 mg	Bristol-Myers Squibb Co.
ANDA 072036	Nuprin (ibuprofen) Tablets, 200 mg	Do.
ANDA 074911	Phrenilin with Caffeine and Codeine (acetaminophen, butalbital, caffeine, and codeine phosphate) Capsules, 325 mg/50 mg/40 mg/30 mg.	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 074944	Atracurium Besylate Injection, 10 mg/mL	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 075206	Cytosar-U (cytarabine) for Injection USP, 100 mg/vial, 500 mg/vial, 1 gram (g)/vial, and 2 g/vial.	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 077337	Rosiglitazone Maleate and Metformin HCl Tablets, EQ 1 mg base/500 mg, EQ 2 mg base/500 mg, EQ 4 mg base/500 mg, EQ 2 mg base/1 g, and EQ 4 mg base/1 g.	Do.
ANDA 077930	Meloxicam Tablets, 7.5 mg and 15 mg	Impax Laboratories, Inc., 30831 Huntwood Ave., Hayward, CA 94544.
ANDA 080658	Procaine HCl Injection, 1% and 2%	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 083128	Hydrocortisone Acetate Injectable Suspension, 25 mg/mL	Do.
ANDA 090181	Ifosfamide for Injection, 1 g/20 mL and 3 g/60 mL	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of September 7, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on September 7, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16985 Filed 8–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2702]

Merck Sharp & Dohme Corporation, et al.; Withdrawal of Approval of Four New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of four new drug applications (NDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of September 7, 2018.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 005619	Aminohippurate Sodium (PAH) 20% sterile solution Injection, 2 grams in 10 milliliter (mL) vials.	Merck Sharp & Dohme Corp., Subsidiary of Merck & Company, Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889.
NDA 008506	Hydrocortone (hydrocortisone) Tablets USP, 10 milligrams (mg) and 20 mg.	Do.
NDA 011891	Durabolin (nandrolone phenpropionate) Injection, 25 mg/mL and 50 mg/mL.	Organon USA, Inc., Subsidiary of Merck & Company, Inc., 2000 Galloping Hill Rd., Kenilworth, NJ 07033.
NDA 020301	Ortho-Cept (desogestrel and ethinyl estradiol) Tablets USP, 0.15 mg/0.03 mg (21-Day and 28-Day Regimens).	Janssen Pharmaceuticals, Inc., 920 U.S. Hwy. 202, P.O. Box 300, Raritan, NJ 08869–0602.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of September 7, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on September 7, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16982 Filed 8–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1692]

Elemental Impurities in Drug Products; 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 final guidance for industry entitled ''Elemental Impurities in Drug Products.'' This guidance finalizes the draft guidance issued July 1, 2016, which provides recommendations regarding the control of elemental impurities of human drug products marketed in the United States consistent with the implementation of International Council for Harmonisation (ICH) guidance for industry entitled ''Q3D Elemental Impurities'' (ICH Q3D). This guidance will also assist manufacturers of compendial drug products in responding to the issuance of the United States Pharmacopeia (USP) requirement for the control of elemental impurities.

DATES: The announcement of the guidance is published in the **Federal Register** on August 8, 2018.

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–2016–D–1692 for ''Elemental Impurities in Drug Products.'' 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; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Danae Christodoulou, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, Rm. 2602, Silver Spring, MD 20993–0002, 301–796–1342; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Elemental Impurities in Drug Products.'' This guidance provides recommendations regarding the control of elemental impurities of human drug products marketed in the United States consistent with implementation of ICH Q3D. The guidance will also assist manufacturers of compendial drug products in responding to the issuance of the USP chapters for the control of elemental impurities.

USP introduced new limits and analytical procedures for elemental impurities in General Chapters <232> Elemental Impurities—Limits and <233> Elemental Impurities—Procedures. Their primary goals are to (1) set limits for acceptable levels of elemental impurities in finished drug products, and (2) update the methodology used to test for elemental impurities in drug products to include modern analytical procedures. ICH Q3D contains recommendations for manufacturers of human drugs and biologics on applying a risk-based approach to control elemental impurities and permitted daily exposure. USP worked closely with ICH to align its new General Chapters with ICH Q3D.

Because elemental impurities pose toxicological concerns and do not provide any therapeutic benefit to the patient, their levels in drug products should be controlled within acceptable limits. In general, FDA recommends that the manufacturer of any U.S. marketed drug product follow ICH Q3D recommendations to establish appropriate procedures for identifying and controlling elemental impurities in the drug product based on risk assessment and product-specific considerations, unless the drug product must comply with *USP-National Formulary* requirements. This guidance outlines approaches for implementation of USP <232>, <233>, and ICH Q3D in new and existing products.

This guidance finalizes the draft guidance issued July 1, 2016 (81 FR 43211). Since the draft guidance was issued, USP <232> was harmonized with ICH Q3D with respect to the all elements and their limits. Originally, prior to issuance of the draft guidance, USP <232> included a fraction (15) of elemental impurities (EIs) listed in ICH Q3D. A number of stakeholder comments to the draft guidance referred to the update and harmonization of USP <232> with ICH Q3D, which is now reflected in the final guidance. In addition, a number of stakeholder comments requested clarification regarding the applicability of the guidance to biologics license applications (BLAs). The final guidance now states that ''for control of EIs in approved or pending BLAs, see ICH Q3D.'' This differs from the draft, where it was stated that the guidance pertained to biotechnology products covered by new drug applications (NDAs).

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 ''Elemental Impurities in Drug Products.'' It does not establish any rights for any person and is not binding on FDA or the public.

You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information 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 part 314 for submitting NDAs and abbreviated new drug applications, including supplemental applications and annual reports, have been approved under OMB control number 0910–0001. The collections of information in 21 CFR parts 211 and 212 (current good manufacturing practices) have been approved under OMB control numbers 0910–0139 and 0910–0667.

III. Electronic Access

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

Dated: August 3, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16984 Filed 8–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0776]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reclassification Petitions for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 7, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0138. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reclassification Petitions for Medical Devices

OMB Control Number 0910–0138—Extension

Under sections 513(e) and (f), 514(b), 515(b), and 520(*l*) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360c(e) and (f), 360d(b), 360e(b), and 360j(*l*)) and part 860 (21 CFR part 860), subpart C, FDA has the responsibility to collect data and information contained in reclassification petitions. The reclassification provisions of the FD&C Act allow any person to petition for reclassification of a device from any of the three classes, *i.e.,* I, II, and III, to another class. The reclassification content regulation (§ 860.123) requires the submission of valid scientific evidence demonstrating that the proposed reclassification will provide a reasonable assurance of safety and effectiveness of the device type for its indications for use.

The reclassification procedure regulation requires the submission of specific data when a manufacturer is petitioning for reclassification. This includes a ''Supplemental Data Sheet,'' Form FDA 3427, and a ''General Device Classification Questionnaire,'' Form FDA 3429. Both forms contain a series of questions concerning the safety and effectiveness of the device type.

In the **Federal Register** of March 25, 2014 (79 FR 16252), FDA issued a proposed rule that would eliminate the need for Forms FDA 3427 and 3429. However, because the proposed rule has not been finalized, we continue to include the forms in the burden estimate for this information collection.

The reclassification provisions of the FD&C Act serve primarily as a vehicle for manufacturers to seek reclassification from a higher to a lower class, thereby reducing the regulatory requirements applicable to a particular device type, or to seek reclassification from a lower to a higher class, thereby increasing the regulatory requirements applicable to that device type. If approved, petitions requesting classification from class III to class II or class I provide an alternative route to market in lieu of premarket approval for class III devices. If approved, petitions requesting reclassification from class I or II, to a different class, may increase requirements.

In the **Federal Register** of March 07, 2018 (83 FR 9743), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment.

The comment supports continued use of Forms FDA 3427 and FDA 3429. Specifically, the commenter is addressing the issue of discontinuing the forms as previously referenced, wherein FDA issued a proposed rule (79 FR 16252) to eliminate the need for the forms. Because FDA is not discontinuing use of the forms at this time, and this comment relates to the proposed rule (79 FR 16252) and not to the information collection itself, we make no changes to this information collection based on the comment.

The Center for Devices and Radiological Health (CDRH) has continually maintained contact with industry. Informal communications concerning the importance and effect of reclassification are provided primarily through trade organizations, and via CDRH's website (*https://www.fda.gov/MedicalDevices/default.htm*).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Supporting data for reclassification petition—21 CFR 860.123	.....	6	1	6	497	2,982
Supplemental Data Sheet	3427	6	1	6	1.5	9
General Device Classification Questionnaire	3429	6	1	6	1.5	9
Total	.....	.....	.....	.....	.....	3,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on reclassification petitions received in the past 3 years, FDA anticipates that six petitions will be submitted each year. The time required to prepare and submit a reclassification petition, including the time needed to assemble supporting data, averages 500 hours per petition. This average is based upon estimates by FDA administrative and technical staff who: (1) Are familiar with the requirements for submission of a reclassification petition, (2) have consulted and advised manufacturers on these requirements, and (3) have reviewed the documentation submitted.

The burden estimate for this information collection has not changed since the past OMB approval.

Dated: August 2, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16983 Filed 8–7–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the President's Council on Sports, Fitness, and Nutrition; Correction

AGENCY: Office of the Assistant Secretary for Health, President's Council on Sports, Fitness, and Nutrition, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting; correction.

SUMMARY: The Department of Health and Human Services published a document in the **Federal Register** of July 27, 2018, concerning the upcoming annual meeting of the President's Council on Sports, Fitness, and Nutrition (PCSFN). The document contained an incorrect location and time.

FOR FURTHER INFORMATION CONTACT: Ms. Holli M. Richmond, Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, Tower Building, 1101 Wootton Parkway, Suite 560, Rockville, MD 20852, (240) 276–9567.

Correction

In the **Federal Register** of July 27, 2018, in FR Vol. 83 No. 145, on page 35662, in the second column, correct the **DATES** and **ADDRESSES** captions to read:

DATES: The meeting will be held on September 21, 2018, from 9:00 a.m. to 12:30 p.m.

ADDRESSES: Hubert H. Humphrey Building, 200 Independence Avenue SW, Room 800, Washington, DC 20201.

Dated: August 1, 2018.

Holli M. Richmond,

Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, U.S. Department of Health and Human Services.

[FR Doc. 2018–16970 Filed 8–7–18; 8:45 am]

BILLING CODE 4150–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the President's Council on Sports, Fitness, and Nutrition; Correction

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, President's Council on Sports, Fitness, and Nutrition.

ACTION: Notice of meeting; correction.

SUMMARY: The Department of Health and Human Services published a document in the **Federal Register** of July 27, 2018, concerning the upcoming annual meeting of the President's Council on Sports, Fitness, and Nutrition (PCSFN). The document contained an incorrect location and time.

FOR FURTHER INFORMATION CONTACT: Ms. Holli M. Richmond, Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, Tower Building, 1101 Wootton Parkway, Suite 560, Rockville, MD 20852, (240) 276–9567.

Correction

In the **Federal Register** of July 27, 2018, in FR Vol. 83 No. 145, on page 35662, in the second column, correct the **DATES** and **ADDRESSES** captions to read:

DATES: The meeting will be held on September 21, 2018, from 9:00 a.m. to 12:30 p.m.

ADDRESSES: Hubert H. Humphrey Building, 200 Independence Avenue SW, Room 800, Washington, DC 20201.

Dated: August 1, 2018.

Holli M. Richmond,

Executive Director, Office of the President's Council on Sports, Fitness, and Nutrition, U.S. Department of Health and Human Services.

[FR Doc. 2018–16969 Filed 8–7–18; 8:45 am]

BILLING CODE 4150–35–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Nursing Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose

confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Nursing Research.

Date: September 4–5, 2018.

Open: September 4, 2018, 1:00 p.m. to 5:00 p.m.

Agenda: Discussion of Program Policies and Issues.

Place: National Institutes of Health, Building 31, 6th Floor, C Wing, Room 6, 31 Center Drive, Bethesda, MD 20892.

Closed: September 5, 2018, 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 6th Floor, C Wing, Room 6, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Marguerite Littleton Kearney, Director Division of Extramural Science Programs, National Institute of Nursing Research National Institutes of Health, 6701 Democracy Boulevard, Room 708, Bethesda, MD 20892, 301–402–7932, *marguerite.kearnet@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *https://www.ninr.nih.gov/aboutninr/nacnr,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS).

Dated: August 3, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16978 Filed 8–7–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Clinical Center Research Hospital Board; Notice of Charter Renewal

In accordance with Title 41 of the U.S. Code of Federal Regulations, Section 102–3.65(a), notice is hereby given that the Charter for the NIH Clinical Center Research Hospital Board was renewed for an additional two-year period on May 29, 2018.

It is determined that the NIH Clinical Center Research Hospital Board is in the public interest in connection with the performance of duties imposed on the National Institutes of Health by law, and that these duties can best be performed through the advice and counsel of this group.

Inquiries may be directed to Claire Harris, Acting Director, Office of Federal Advisory Committee Policy, Office of the Director, National Institutes of Health, 6701 Democracy Boulevard, Suite 1000, Bethesda, Maryland 20892 (Mail Stop Code 4875), *harriscl@nih.gov* or Telephone (301) 496–2123.

Dated: August 2, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16979 Filed 8–7–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Cooperative Centers on Human Immunology.

Date: September 5–11, 2018.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Paul A. Amstad, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G41, NIAID/NIH/DHHS, 5601 Fishers Lane, Bethesda, MD 20892–7616, 240–669–5067, *pamstad@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Investigator Initiated Clinical Trial Planning and Implementation Applications.

Date: September 24, 2018.

Time: 12:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: Lynn Rust, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room 3G42A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5069, *lrust@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 3, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16974 Filed 8–7–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Minority Health and Health Disparities.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: September 6–7, 2018.

Closed: September 6, 2018, 1:30 p.m. to adjournment.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Rooms E1 and E2, Bethesda, MD 20892.

Open: September 7, 2018, 8:00 a.m. to 12:00 p.m.

Agenda: The agenda will include opening remarks, administrative matters, Director's report, NIH Health Disparities update, and other business of the Council.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Conference Rooms E1 and E2, Bethesda, MD 20892.

Contact Person: Dr. Joyce A. Hunter, Deputy Director, NIMHD, National Institutes of Health, National Institute on Minority Health and Heath Disparities, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 402–1366, *hunterj@nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus.

All visitor vehicles, including taxis, hotel, and airport shuttles, will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Dated: August 2, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16976 Filed 8–7–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

Date: September 5, 2018.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, Building 31, Rm: 6C10, 31 Center Drive, Bethesda, MD 20892.

Closed: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, Rm: 6C10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Melinda Nelson, Acting Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases, Grants Management Branch, 45 Center Drive, Room 5A49, Bethesda, MD 20892, (301) 594–3535, *mn23z@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: August 3, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16975 Filed 8–7–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Minority Health and Health Disparities; Special Emphasis Panel; Review of R01 Applications in Response to RFA–MD–18–005, ''Youth Violence Prevention Interventions''.

Date: October 19, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications (Teleconference).

Place: National Institutes of Health, Gateway Plaza, 7201 Wisconsin Ave, Bethesda, MD 20817.

Contact Person: Deborah Ismond, Ph.D., Scientific Review Officer, Division of Scientific Programs, National Institute on Minority Health and Health Disparities, National Institutes of Health, 7201 Wisconsin Ave., Suite 525, Bethesda, MD 20814, (301) 594–2704, *ismonddr@mail.nih.gov.*

Dated: August 2, 2018.

David D. Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–16977 Filed 8–7–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2016–1061]

Termination of U.S. Coast Guard Rebroadcast of HYDROLANT and HYDROPAC Information

ACTION: Notice of rebroadcast termination.

SUMMARY: The United States Coast Guard is ceasing the rebroadcast of HYDROLANT and HYDROPAC (defined below) navigational warnings over HF SITOR (defined below). There is no requirement for the Coast Guard to rebroadcast this information, although the Coast Guard has been voluntarily doing so for a number of years, and doing so is duplicative of the National Geospatial-Intelligence Agency's broadcast. The information will continue to be disseminated by the National Geospatial-Intelligence Agency.

DATES: The Coast Guard will cease rebroadcasting HYDROLANT and HYDROPAC navigational warnings on August 30th, 2018.

FOR FURTHER INFORMATION CONTACT: For information about this document, please call or email Derrick Croinex, Chief, Spectrum Management and Telecommunications Policy, U.S. Coast Guard (Commandant CG–672); telephone: 202–475–3551; email: *derrick.j.croinex@uscg.mil.*

SUPPLEMENTARY INFORMATION: On May 14, 2018, we published a notice in the **Federal Register** at 83 FR 22276 that the Coast Guard was considering no longer rebroadcasting HYDROLANT and HYDROPAC navigational warnings over HF SITOR (High Frequency Simplex Teletype Over Radio service). HYDROLANT warnings are Navigational Warnings Categorized by their Atlantic Ocean Location. HYDROPAC warnings are Navigational Warnings Categorized by their Pacific Ocean/Pacific Rim Location. Both are products of the National Geospatial-Intelligence Agency. The May notice included relevant background information on these navigational warnings and reasons for terminating rebroadcast. After a full consideration of the matter, including public comment, we have decided to stop rebroadcast. The Coast Guard will cease rebroadcasting HYDROLANT and HYDROPAC navigational warnings in 30 days.

In the notice, we requested feedback from the public on the proposed termination. The comment period closed on July 13, 2018. We received one submission in response to our inquiry. The commenter was concerned that the information contained in the Coast Guard rebroadcast would no longer be available. In response to the comment, we would like to reiterate that the HYDROLANT and HYDROPAC products will still be available via satellite from the National Geospatial-Intelligence Agency as originally intended. The Coast Guard is only terminating the rebroadcast of these products, and only these products, via HF. All other HF Broadcast content will continue to be available.

This notice is issued under authority of 14 U.S.C. 93(a)(16) and in accordance with 5 U.S.C. 552(a).

Dated: July 30, 2018.

Derrick J. Croinex,

Chief, Spectrum Management and Telecommunications Policy.

[FR Doc. 2018–16954 Filed 8–7–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–0494]

Merchant Marine Personnel Advisory Committee

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Merchant Marine Personnel Advisory Committee and its Working Groups will meet to discuss various issues related to the training and fitness of merchant marine personnel. The meetings will be open to the public.

DATES: *Meetings:* The Merchant Marine Personnel Advisory Committee and its Working Groups are scheduled to meet on Tuesday, September 11, 2018, from 8:00 a.m. until 5:30 p.m., and the full Committee is scheduled to meet on Wednesday, September 12, 2018, from 8:00 a.m. until 5:30 p.m. Please note that these meetings may adjourn early if the Committee has completed its business.

Comments and supporting documentation: To ensure your comments are received by Committee members before the meetings, submit your written comments no later than September 5, 2018.

ADDRESSES: The meetings will be held at the STAR Center, 2 West Dixie Highway, Dania Beach, FL 33004, *https://www.star-center.com/.*

Pre-registration Information: Pre-registration is not required for access. All attendees will be required to provide a driver's license or government-issued identification card in order to gain admittance to the building.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the Alternate Designated Federal Officer as soon as possible using the contact information provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Instructions: You are free to submit comments at any time, including orally at the meetings, but if you want Committee members to review your comment before the meetings, please submit your comments no later than September 5, 2018. We are particularly interested in comments on the issues in the ''Agenda'' section below. You must include ''Department of Homeland Security'' and the docket number USCG–2018–0494. Written comments may also be submitted using the Federal eRulemaking Portal at *http://www.regulations.gov.* If you encounter technical difficulties with comments submission, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section below. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided. You may review the Privacy and Security Notice for the Federal Docket Management System at *https://www.regulations.gov/privacyNotice.*

Docket Search: For access to the docket to read documents or comments related to this notice, go to *http://www.regulations.gov,* type USCG–2018–0494 in the ''Search'' box, press Enter, and then click on the item you wish to view.

FOR FURTHER INFORMATION CONTACT: Mr. Davis Breyer, Alternate Designated Federal Officer of the Merchant Marine Personnel Advisory Committee, 2703 Martin Luther King Jr. Ave SE, Stop 7509, Washington, DC 20593–7509, telephone 202–372–1445, fax 202–372–8382 or *davis.j.breyer@uscg.mil.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given pursuant to the *Federal Advisory Committee Act,* Title 5 United States Code Appendix.

The Merchant Marine Personnel Advisory Committee was established under authority of U.S. Code, title 46, section 8108. The Committee acts solely in an advisory capacity to the Secretary of the Department of Homeland Security through the Commandant of the U.S. Coast Guard on matters relating to personnel in the United States merchant marine, including training, qualifications, certification, documentation, and fitness standards and other matters as assigned by the Commandant. The Committee also reviews and comments on proposed U.S. Coast Guard regulations and policies relating to personnel in the United States merchant marine, including training, qualifications, certification, documentation, and fitness standards.

Agenda

Day 1

The agenda for the September 11, 2018, meeting is as follows:

(1) The full Committee will meet briefly to discuss the Working Groups' business/task statements, which are listed under paragraph (3) (a)–(e) below.

(2) A job task analysis briefing will be presented to the full Committee regarding the merchant mariner credentialing program's efforts to establish or validate credentialing examinations, performance assessments, and training curriculum standards within the context of current occupational practices associated with each credentiale.

(3) Working Groups will separately address the following task statements which are available for viewing at *https://homeport.uscg.mil/missions/ports-and-waterways/safety-advisory-committees/merpac;*

(a) Task Statement 87, Review of policy documents providing guidance on the implementation of the December 24, 2013, International Convention on Standards of Training, Certification and Watchkeeping for Seafarers rulemaking;

(b) Task Statement 98, To continue the progress made by the military services towards meeting the goals on the use of Military Education, Training and Assessment for STCW and National Mariner Endorsements as identified in the Howard Coble Coast Guard and Maritime Transportation Act of 2014 and subsequent legislation;

(c) Task Statement 101, Provide feedback and avenues to further enhance open communication between external stakeholders and the U.S. Coast Guard's mariner credentialing program regarding all aspects of the program;

(d) Task Statement 101a, Review of the draft medical certificate cancellation policy;

(e) Task Statement 104, National Transportation Safety Board recommendations to the U.S. Coast Guard regarding the sinking of the S.S. El Faro.

(4) Public comment period.

(5) Reports of Working Groups. At the end of the day, the Working Groups will report to the full Committee on what was accomplished in their meetings. The full Committee will not take action on these reports on this date. Any official action taken as a result of these Working Group meetings will be taken on day two of the meeting.

(6) Adjournment of meeting.

Day 2

The agenda for the September 12, 2018 full Committee meeting is as follows:

(1) Introduction.

(2) Swearing in of newly appointed Committee members.

(3) Remarks from U.S. Coast Guard Leadership.

(4) Designated Federal Officer announcements.

(5) Roll call of Committee members and determination of a quorum.

(6) Reports from the following Working Groups:

(a) Task Statement 87, Review of policy documents providing guidance on the implementation of the December 24, 2013, International Convention on Standards of Training, Certification and Watchkeeping for Seafarers rulemaking;

(b) Task Statement 89, Review and update of the International Maritime Organization's Maritime Safety Committee Circular MSC/Circ.1014 Guidelines on fatigue mitigation and management;

(c) Task Statement 90, Review of International Maritime Organization's Model Courses Being Validated by the International Maritime Organization's Subcommittee on Human Element, Training and Watchkeeping;

(d) Task Statement 94, Review the MERPAC recommendations with a view to evaluating their current relevance;

(e) Task Statement 96, Review and comment on the course and program approval requirements including 46 CFR 10.402, 10.403, 10.407 and Navigation and Vessel Inspection Circular 03–14 guidelines for approval of training courses and programs;

(f) Task Statement 98, To continue the progress made by the military services towards meeting the goals on the use of Military Education, Training and Assessment for STCW and National Mariner Endorsements as identified in the Howard Coble Coast Guard and Maritime Transportation Act of 2014 and subsequent legislation;

(g) Task Statement 99, Review and comment on the ''Guidelines for Issuing Endorsements for Tankerman PIC Restricted to Fuel Transfers on Towing Vessels'' policy letter (CG–MMC Policy Letter No. 01–17);

(h) Task Statement 101, Provide feedback and avenues to further enhance open communication between external stakeholders and the Coast Guard's mariner credentialing program regarding all aspects of the program;

(i) Task Statement 101a, Review of the draft medical certificate cancellation policy;

(j) Task Statement 102, Consider and make recommendations regarding the current requirement for a U.S. Merchant Mariner to read and write using English; and

(k) Task Statement 104, National Safety Board recommendations to the U.S. Coast Guard regarding the sinking of the S.S. El Faro.

(7) Other items for discussion:

(a) Report on the Mariner Credentialing Program;

(b) Report on National Maritime Center activities from the National Maritime Center Commanding Officer;

(c) Report on International Maritime Organization Activities affecting merchant mariner credentialing; and

(d) Briefings about other on-going U.S. Coast Guard projects related to personnel in the U.S. merchant marine.

(8) Public comment period.

(9) Discussion of Working Group recommendations. The Committee will review the information presented on each issue, deliberate on any recommendations presented by the Working Groups, approve/formulate recommendations and close any completed tasks. Official action on these recommendations may be taken on this date.

(10) Closing remarks/plans for next meeting.

(11) Adjournment of meeting.

A public comment period will be held during each Working Group and full Committee meeting concerning matters being discussed.

A copy of all meeting documentation will be available at *https://homeport.uscg.mil/missions/ports-and-waterways/safety-advisory-committees/merpac* no later than September 5, 2018. Alternatively, you may contact Mr. Davis Breyer as noted in the **FOR FURTHER INFORMATION CONTACT** section above.

Public comments will be limited to three minutes per speaker. Please note that the public comment periods will

end following the last call for comments. Please contact Mr. Davis Breyer, listed in the **FOR FURTHER INFORMATION CONTACT** section, to register as a speaker. Please note that the meeting may adjourn early if the work is completed.

Dated: July 31, 2018.

Jeffrey G. Lantz,

Director of Commercial Regulations and Standards.

[FR Doc. 2018–16948 Filed 8–7–18; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2018–0002; Internal Agency Docket No. FEMA–B–1844]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Federal Regulations. The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will be finalized on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

David I. Maurstad,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Arizona:						
Mohave	Town of Colorado City (18–09–1337X).	The Honorable Joseph Allred, Mayor, Town of Colorado City, P.O. Box 70, Colorado City, AZ 86021..	Town Hall, 25 South Central Street, Colorado City, AZ 86401..	*https://msc.fema.gov/portal/advanceSearch..*	Nov. 2, 2018 ...	040059
Mohave	Unincorporated Areas of Mohave County, (18–09–1337X).	The Honorable Gary Watson, Chairman, Board of Supervisors, Mohave County, 700 West Beale Street, Kingman, AZ 86402..	Mohave County Administration Building, 700 West Beale Street, Kingman, AZ 86402..	*https://msc.fema.gov/portal/advanceSearch..*	Nov. 2, 2018 ...	040058
California:						
Riverside	City of Riverside, (18–09–0497P).	The Honorable Rusty Bailey, Mayor, City of Riverside, 3900 Main Street, Riverside, CA 92522..	Public Works Department, 3900 Main Street, 4th Floor, Riverside, CA 92522..	*https://msc.fema.gov/portal/advanceSearch..*	Oct. 22, 2018 ..	060260
Riverside	Unincorporated Areas of Riverside County, (18–09–0497P).	The Honorable Chuck Washington, Chairman, Board of Supervisors, Riverside County, 4080 Lemon Street, 5th Floor, Riverside, CA 92501..	Riverside County Flood Control and, Water Conservation District, 1995 Market Street, Riverside, CA 92501..	*https://msc.fema.gov/portal/advanceSearch..*	Oct. 22, 2018 ..	060245
Hawaii: Honolulu	City and County of Honolulu, (18–09–1196P).	The Honorable Kirk Caldwell, Mayor, City and County of Honolulu, 530 South King Street Room 306, Honolulu, HI 96813..	Department of Planning and Permitting, 650 South King Street, Honolulu, HI 96813..	*https://msc.fema.gov/portal/advanceSearch..*	Oct. 30, 2018 ..	150001
Illinois:						
Cook	Village of Flossmoor, (18–05–2185P).	The Honorable Paul Braun, Mayor, Village of Flossmoor, 2800 Flossmoor Road, Flossmoor, IL 60422..	Public Works Service Center, 1700 Central Park Avenue, Flossmoor, IL 60422..	*https://msc.fema.gov/portal/advanceSearch..*	Oct. 26, 2018 ..	170091
Cook	Village of Homewood, (18–05–2185P).	The Honorable Richard Hofeld, Mayor, Village of Homewood, 2020 Chestnut Road, Homewood, IL 60430..	Public Works, 17755 South Ashland Avenue, Homewood, IL 60430..	*https://msc.fema.gov/portal/advanceSearch..*	Oct. 26, 2018 ..	170109
Minnesota: Olmsted ..	City of Rochester, (18–05–0869P).	The Honorable Ardell F. Brede, Mayor, City of Rochester, City Hall, 201 4th Street Southeast Room 281, Rochester, MN 55904..	City Hall, 201 4th Street Southeast, Rochester, MN 55904..	*https://msc.fema.gov/portal/advanceSearch..*	Oct. 18, 2018 ..	275246
Nevada: Clark	Unincorporated Areas of Clark County, (18–09–0773P).	The Honorable Steve Sisolak, Chairman, Board of Commissioners, Clark County, 500 South Grand Central Parkway, 6th Floor, Las Vegas, NV 89106..	Clark County, Office of the Director of Public Works, 500 South Grand Central Parkway, Las Vegas, NV 89155..	*https://msc.fema.gov/portal/advanceSearch..*	Oct. 18, 2018 ..	320003
Oregon: Multnomah ..	City of Portland, (18–10–0454P).	The Honorable Ted Wheeler, Mayor, City of Portland, 1221 Southwest 4th Avenue, Room 340, Portland, OR 97204..	Bureau of Environmental Services, 1221 Southwest 4th Avenue, Room 230, Portland, OR 97204..	*https://msc.fema.gov/portal/advanceSearch..*	Nov. 2, 2018 ...	410183
Virginia: Roanoke	City of Roanoke, (18–03–0502P).	The Honorable Sherman P. Lea, Sr., Mayor, City of Roanoke, 215 Church Avenue Southwest, Room 456, Roanoke, VA 24011..	Engineering Department Municipal Building, 215 Church Avenue, Roanoke, VA 24011..	*https://msc.fema.gov/portal/advanceSearch..*	Oct. 11, 2018 ..	510130
Wisconsin: Dane	City of Verona, (18–05–0637P).	The Honorable Luke Diaz, Mayor, City of Verona, Verona City Center, 111 Lincoln Street, Verona, WI 53593..	City Hall, 111 Lincoln Street, Verona, WI 53593..	*https://msc.fema.gov/portal/advanceSearch..*	Oct. 5, 2018	550092

[FR Doc. 2018–16902 Filed 8–7–18; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R5–ES–2018–N050; FXES11130500000–189–FF05E00000]

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Reviews of 19 Northeastern Species

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; request for information.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are initiating 5-year reviews under the Endangered Species Act, as amended (ESA), for 19 northeastern species. A 5-year review is based on the best scientific and commercial data available at the time of the review. We are requesting submission of any such information that has become available since the previous 5-year review for each species.

DATES: To ensure consideration, please submit your written information by September 7, 2018. However, we will continue to accept new information about any listed species at any time.

ADDRESSES: For instructions on how and where to submit information, see Request for Information and Table 2—Contacts under **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: For information regarding a particular species, contact the appropriate person or office listed in Table 2—Contacts in **SUPPLEMENTARY INFORMATION**. For general information, contact Mary Parkin, by U.S. mail at U.S. Fish and Wildlife Service, 300 Westgate Center Drive, Hadley, MA 01035; by telephone at 617–417–3331; or by electronic mail at *mary_parkin@fws.gov.*

SUPPLEMENTARY INFORMATION: We, the Service, are initiating 5-year reviews under the ESA (16 U.S.C. 1531 *et seq.*) for 19 northeastern species: The endangered sandplain gerardia, roseate tern (northeastern North American population), Roanoke logperch, Virginia big-eared bat, dwarf wedgemussel, northern riffleshell, clubshell, purple bean, Peter's Mountain mallow, Furbish's lousewort, and northeastern bulrush, and the threatened Puritan tiger beetle, northeastern beach tiger beetle, flat-spired three-toothed (=Cheat) snail, Chittenango ovate amber snail, bog turtle (northern population), American hart's-tongue fern, Knieskern's beaked-rush, and Virginia sneezeweed.

A 5-year review is based on the best scientific and commercial data available at the time of the review. We are requesting submission of any such information that has become available since the most recent status review for each species.

Why do we conduct 5-year reviews and species status assessments?

Under the ESA (16 U.S.C. 1531 *et seq.*), we maintain Lists of Endangered and Threatened Wildlife and Plants (which we collectively refer to as the List). Listed wildlife and plants can be found at *http://ecos.fws.gov/tess_public/pub/listedAnimals.jsp* and *http://ecos.fws.gov/tess_public/pub/listedPlants.jsp,* respectively. Section 4(c)(2)(A) of the ESA requires us to review each listed species' status at least once every 5 years. Our regulations at 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing species under active review. For additional information about 5-year reviews, refer to our fact sheet at *http://www.fws.gov/endangered/what-we-do/recovery-overview.html.*

What species are under review?

We are initiating 5-year status reviews of the species in table 1.

TABLE 1—SPECIES UNDER REVIEW

Common name	Scientific name	Status	Where listed	Listing date and citation
Animals				
Roseate tern	*Sterna dougallii dougallii*	Endangered	Northeastern North American population (CT, ME, MA, NJ, NY, NC, RI, VA).	52 FR 42064; 11/02/1987.
Roanoke logperch	*Percina rex*	Endangered	Wherever found	54 FR 34468; 08/18/1989.
Virginia big-eared bat	*Corynorhinus (=plecotus) townsendii virginianus.*	Endangered	Wherever found	44 FR 69206; 11/30/1979.
Dwarf wedgemussel	*Alasmidonta heterodon*	Endangered	Wherever found	55 FR 9447; 03/14/1990.
Northern riffleshell	*Epioblasma torulosa rangiana*	Endangered	Wherever found	58 FR 5638; 01/22/1993.
Clubshell	*Pleurobema clava*	Endangered	Wherever found	58 FR 5638; 01/22/1993.
Purple bean	*Villosa perpurpurea*	Endangered	Wherever found	62 FR 1647; 01/10/1997.
Puritan tiger beetle	*Cicindela puritana*	Threatened	Wherever found	55 FR 32088; 08/07/1990.
Northeastern beach tiger beetle.	*Cicindela dorsalis dorsalis*	Threatened	Wherever found	55 FR 32088; 08/07/1990.
Flat-spired three-toothed (=Cheat) snail.	*Triodopsis platysayoides*	Threatened	Wherever found	43 FR 28932; 07/03/1978.
Chittenango ovate amber snail	*Novisuccinea chittenangoensis.*	Threatened	Wherever found	43 FR 28932; 07/03/1978.
Bog turtle	*Glyptemys* [= *Clemmys*] *muhlenbergii.*	Threatened	Northern population (CT, DE, MD, MA, NJ, NY, PA).	62 FR 59605; 11/04/1997.
Plants				
Sandplain gerardia	*Agalinis acuta*	Endangered	Wherever found	53 FR 34701; 09/07/1988.
Peter's Mountain mallow	*Iliamna corei*	Endangered	Wherever found	56 FR 32978; 07/18/1991.
Furbish's lousewort	*Pedicularis furbishiae*	Endangered	Wherever found	51 FR 17343; 05/12/1986.
Northeastern bulrush	*Scirpus ancistrochaetus*	Endangered	Wherever found	56 FR 21091; 05/07/1991.
American hart's-tongue fern	*Asplenium scolopendrium* var. *americanum.*	Threatened	Wherever found	54 FR 29726; 07/14/1989.
Knieskern's beaked-rush	*Rhynchospora knieskernii*	Threatened	Wherever found	56 FR 32978; 07/18/1991.
Virginia sneezeweed	*Helenium virginicum*	Threatened	Wherever found	63 FR 59239; 11/03/1998.

What information do we consider in our 5-year reviews and SSAs?

A 5-year review considers all new information available at the time of the review. In conducting the review, we consider the best scientific and commercial data that have become available since the most recent status review. We are seeking new information specifically regarding:

(1) Species biology, including but not limited to life history and habitat requirements and impact tolerance thresholds;

(2) Historical and current population conditions, including but not limited to population abundance, trends, distribution, demographics, and genetics;

(3) Historical and current habitat conditions, including but not limited to amount, distribution, and suitability;

(4) Historical and current threats, threat trends, and threat projections in relation to the five listing factors (as defined in section 4(a)(1) of the ESA);

(5) Conservation measures for the species that have been implemented or are planned; and

(6) Other new information, data, or corrections, including but not limited to taxonomic or nomenclatural changes, identification of erroneous information contained in the List, and improved analytical methods.

Any new information received will be considered during the 5-year review and will also be useful in evaluating ongoing recovery programs for the species.

Request for New Information

To ensure that 5-year reviews are based on the best available scientific and commercial information, we request new information from all sources. If you submit information, please support it with documentation such as maps, bibliographic references, methods used to gather and analyze the data, and/or copies of any pertinent publications, reports, or letters by knowledgeable sources.

How do I ask questions or provide information?

Please submit your questions, comments, and materials to the appropriate contact in table 2.

Individuals who are hearing impaired or speech impaired may call the Federal Relay Service at 800–877–8339 for TTY assistance.

Public Availability of Comments

Before including your address, phone number, electronic mail address, or other personal identifying information in your submission, you should be aware that your entire submission—including your personal identifying information—may be made publicly available at any time. Although you can request that personal information be withheld from public review, we cannot guarantee that we will be able to do so.

Materials received will be available for public inspection, by appointment, during normal business hours at the offices where the information is submitted.

Contacts

New information on the species covered in this notice should be submitted by mail or electronic mail to the appropriate contact person within the timeframe provided in **DATES**.

TABLE 2—CONTACTS

Species	Contact person, phone, email	Contact address
Roseate tern	Susi von Oettingen, 603–223–2541, extension 22, *susi_vonoettingen@fws.gov*.	U.S. Fish and Wildlife Service, New England Field Office, 70 Commercial Street, Suite 300, Concord, NH 03301.
Chittenango ovate amber snail	Robyn Niver, 607–299–0620, *robyn_niver@fws.gov*.	U.S. Fish and Wildlife Service, New York Field Office, 3817 Luker Road, Cortland, NY 13045.
Roanoke logperch	Sumalee Hoskin, 804–824–2414, *sumalee_hoskin@fws.gov*.	U.S. Fish and Wildlife Service, Virginia Field Office, 6669 Short Lane, Gloucester, VA 23061.
Virginia big-eared bat	Barbara Douglas, 304–636–6586, extension 19, *barbara_douglas@fws.gov*.	U.S. Fish and Wildlife Service, West Virginia Field Office, 694 Beverly Pike, Elkins, WV 26241.
Dwarf wedgemussel	Sandra Doran, 607–753–9334, extension 0586, *sandra_doran@fws.gov*.	U.S. Fish and Wildlife Service, New York Field Office, 3817 Luker Road, Cortland, NY 13045.
Northern riffleshell	Robert Anderson, 814–234–4090, extension 7447, *robert_m_anderson@fws.gov*.	U.S. Fish and Wildlife Service, Pennsylvania Field Office, 110 Radnor Road, Suite 101, State College, PA 16801.
Clubshell	Robert Anderson, 814–234–4090, extension 7447, *robert_m_anderson@fws.gov*.	U.S. Fish and Wildlife Service, Pennsylvania Field Office, 110 Radnor Road, Suite 101, State College, PA 16801.
Purple bean	Jordan Richard, 276–623–1233, extension 15, *jordan_richard@fws.gov*.	U.S. Fish and Wildlife Service, Southwestern Virginia Field Office, 330 Cummings Street, Abingdon, VA 24210.
Puritan tiger beetle	Cherry Keller, 410–573–4532, *cherry_keller@fws.gov*.	U.S. Fish and Wildlife Service, Chesapeake Bay Field Office, 177 Admiral Cochrane Drive, Annapolis, MD 21401.
Northeastern beach tiger beetle	Jennifer Stanhope, 804–824–2408, *Jennifer_stanhope@fws.gov*.	U.S. Fish and Wildlife Service, Virginia Field Office, 6669 Short Lane, Gloucester, VA 23061.
Flat-spired three-toothed snail (Cheat snail).	Barbara Douglas, 304–636–6586, extension 19, *barbara_douglas@fws.gov*.	U.S. Fish and Wildlife Service, West Virginia Field Office, 694 Beverly Pike, Elkins, WV 26241.
Bog turtle	Noelle Rayman-Metcalf, 607–753–9334, *noelle_rayman@fws.gov*.	U.S. Fish and Wildlife Service, New York Field Office, 3817 Luker Road, Cortland, NY 13045.
Sandplain gerardia	Steve Sinkevich, 631–286–0485, *steve_sinkevich@fws.gov*.	U.S. Fish and Wildlife Service, Long Island Field Office, 340 Smith Road, Shirley, NY 11967.
Peter's Mountain mallow	Jennifer Stanhope, 804–824–2408, *jennifer_stanhope@fws.gov*.	U.S. Fish and Wildlife Service, Virginia Field Office, 6669 Short Lane, Gloucester, VA 23061.
Furbish's lousewort	Mark McCollough, 207–902–1570, *mark_mccollough@fws.gov*.	U.S. Fish and Wildlife Service, Maine Fish and Wildlife Service Complex, Maine Field Office, P.O. Box A, East Orland, ME 04431.
Northeastern bulrush	Melinda Turner, 814–234–4090, extension 7449, *melinda_turner@fws.gov*.	U.S. Fish and Wildlife Service, Pennsylvania Field Office, 110 Radnor Road, Suite 101, State College, PA 16801.
American hart's-tongue fern	John Wiley, 607–753–9334, *john_wiley@fws.gov*.	U.S. Fish and Wildlife Service, New York Field Office, 3817 Luker Road, Cortland, NY 13045.
Knieskern's beaked-rush	Ron Popowski, 609–241–7065, *ron_popowski@fws.gov*.	U.S. Fish and Wildlife Service, New Jersey Field Office, 4 East Jimmie Leeds Road, Suite 4, Galloway, NJ 08205.

TABLE 2—CONTACTS—Continued

Species	Contact person, phone, email	Contact address
Virginia sneezeweed	Jennifer Stanhope, 804–824–2408, *jennifer_stanhope@fws.gov*.	U.S. Fish and Wildlife Service, Virginia Field Office, 6669 Short Lane, Gloucester, VA 23061.

Authority

We publish this document under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: July 16, 2018.

Deborah Rocque,

Acting Regional Director, Northeast Region.

[FR Doc. 2018–16931 Filed 8–7–18; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

U.S. Geological Survey

[GX18EB00A181100; OMB Control Number 1028–0085/Renewal]

Agency Information Collection Activities; National Land Remote Sensing Education, Outreach and Research Activity

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the U.S. Geological Survey (USGS) is proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before October 9, 2018.

ADDRESSES: Send your comments on the information collection request (ICR) by mail to the U.S. Geological Survey, Information Collections Clearance Officer, 12201 Sunrise Valley Drive, MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov*. Please reference OMB Control Number 1028–0085 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Sarah Cook by email at *scook@usgs.gov,* or by telephone at 703–648–6136.

SUPPLEMENTARY INFORMATION: We, the U.S. Geological Survey, in accordance with the Paperwork Reduction Act of 1995, provide the general public and other Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are soliciting comments on the proposed ICR described below. We are especially interested in public comment addressing the following issues: (1) Is the collection necessary for the proper functions of the USGS; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the USGS enhance the quality, utility, and clarity of the information to be collected; and (5) how might the USGS minimize the burden of this collection on the respondents, including through the use of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The National Land Remote Sensing Education, Outreach and Research Activity (NLRSEORA) is an effort that involves the development of a U.S. national consortium in building the capability to receive, process and archive remotely sensed data for the purpose of providing access to university and state organizations in a ready-to-use format; and to expand the science of remote sensing through education, research/applications development and outreach in areas such as environmental monitoring to include the effects of climate variability on water availability (or lack thereof) and phenology, natural resource management and disaster analysis. Respondents are submitting proposals to acquire funding for a national (U.S.) program to promote the uses of space-based land remote sensing data and technologies through education and outreach at the state and local level and through university-based and collaborative research projects. The information collected will ensure that sufficient and relevant information is available to evaluate and select a proposal for funding. A panel of USGS Land Resources Mission Area managers and scientists will review each proposal to evaluate the technical merit, requirements, and priorities identified in the call for proposals.

This notice concerns the collection of information that is sufficient and relevant to evaluate and select proposals for funding. We will protect information from respondents considered proprietary under the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2), and under regulations at 30 CFR 250.197, ''Data and information to be made available to the public or for limited inspection.'' Responses are voluntary. No questions of a ''sensitive'' nature are asked. We intend to release the project abstracts and primary investigators for awarded/funded projects only.

Title of Collection: National Land Remote Sensing Education, Outreach and Research Activity (NLRSEORA).

OMB Control Number: 1028–0085.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Public or private institutions of higher education including universities; state and local governments (including county, city, township or special district governments), independent school districts, Native American Tribal governments or oganizations, nonprofit organizations (with or without 501(c)(3) status).

Total Estimated Number of Annual Respondents: Approximately 5 respondents.

Total Estimated Number of Annual Responses: Approximately 5 responses or applications.

Estimated Completion Time per Response: We expect to receive approximately 5 applications per year, taking each applicant approximately 24 hours to complete, totaling 120 burden hours. We anticipate awarding one (1) grant per year. The grantee will be required to submit an interim Annual Progress Report to the designated USGS

Project Officer within 90 days of the end of the project period and a final report on or before 90 working days after the expiration of the agreement.

Total Estimated Number of Annual Burden Hours: 120 hours per year.

Respondent's Obligation: Required to Obtain a Benefit.

Frequency of Collection: Annually.

Total Estimated Annual Non-hour Burden Cost: There are no ''non-hour-cost'' burdens associated with this IC.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authorities for this action are the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*).

Timothy Newman,

Program Coordinator, National Land Imaging Program, U.S. Geological Survey.

[FR Doc. 2018–16986 Filed 8–7–18; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[(LLCAC06000.L13100000.DS0000. LXSIAREV0000.18XL1109AF) MO# 450012099]

Notice of Intent for Potential Amendment to the Resource Management Plan for the Bakersfield Field Office, California, and To Prepare an Associated Supplemental Environmental Impact Statement

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended (NEPA), and the Federal Land Policy and Management Act of 1976, as amended, (FLPMA), the Bureau of Land Management (BLM) Bakersfield Field Office, Bakersfield, California, intends to prepare a supplemental Environmental Impact Statement (EIS) and a potential Resource Management Plan (RMP) amendment for the Bakersfield Field Office Resource Management Plan. The supplemental EIS will analyze the impacts of hydraulic fracturing technology on BLM-administered public land and mineral estate in the Bakersfield Field Office Planning Area exclusive of the California Coastal National Monument and the Carrizo Plain National Monument. This effort is in response to a settlement agreement in case No. 2:15-cv-04378–MWF/JEM, filed with, and approved by, the U.S. District Court for the Central District of California on May 3, 2017. This notice announces the beginning of the scoping process to solicit public comments and identify issues.

DATES: This notice initiates the public scoping process for the Supplemental EIS and potential RMP amendment. Comments on issues may be submitted in writing until September 7, 2018. In order to be included in the analysis, all scoping comments must be submitted in writing and received prior to the close of the 30-day scoping period. We will provide additional opportunities for public participation as appropriate.

ADDRESSES: You may submit comments on issues and planning criteria related to this Supplemental EIS and potential RMP amendment by any of the following methods:

- *Email: blm_ca_bkfo_oil_gas_update@blm.gov.*
- *Mail:* Bakersfield Field Office, Bureau of Land Management, Attn: Bakersfield RMP Hydraulic Fracturing Analysis, 3801 Pegasus Drive, Bakersfield, CA 93308.

Documents pertinent to this proposal may be examined during regular business hours at: Bureau of Land Management, Bakersfield Field Office, 3801 Pegasus Drive, Bakersfield, CA 93308.

FOR FURTHER INFORMATION CONTACT: Carly Summers, Supervisory Natural Resources Specialist, telephone 661–391–6000; address Bureau of Land Management, 3801 Pegasus Drive, Bakersfield, CA 93308; email *blm_ca_bkfo_oil_gas_update@blm.gov.* Contact Ms. Summers to have your name added to our mailing list. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: This document provides notice that the BLM Field Office, Bakersfield, California, intends to prepare a supplemental EIS and potential RMP amendment for the 2014 Bakersfield Field Office RMP Planning Area. Furthermore, this document announces the beginning of the scoping process and seeks public input on issues and planning criteria related to hydraulic fracturing. The planning area is located in Fresno, Kern, Kings, Madera, San Luis Obispo, Santa Barbara, Tulare, and Ventura counties in California and encompasses approximately 400,000 acres of public land and an additional 1.2 million acres of Federal mineral estate (*i.e.,* split estate). The purpose of the supplemental EIS is to analyze the environmental effects of the use of hydraulic fracturing technology in oil and gas development on new leases within the planning area and to determine whether changes are needed to the fluid minerals decisions in the Bakersfield Field Office RMP. The need to develop the supplemental EIS is established by the settlement agreement in case No. 2:15-cv-04378–MWF/JEM, filed with the U.S. District Court for the Central District of California on May 3, 2017. The purpose of the public scoping process is to determine relevant issues that will influence the scope of the environmental analysis, including alternatives if necessary, and guide the planning process. Preliminary issues for the supplemental EIS have been identified by BLM personnel; Federal, State, and local agencies; and other stakeholders. The issues include: Air and atmospheric values; water quality and quantity; seismicity; special status species; mineral resources (oil and gas); and socioeconomics. Preliminary planning criteria include:

1. Only those portions of the existing plan that need to be updated to respond to the issues and management concerns identified in the court order and settlement agreement will be reviewed.

2. The planning process will be completed in compliance with the FLPMA and all other applicable laws.

3. The planning process will include a Supplemental EIS that will comply with NEPA standards.

4. The scope of analysis will be consistent with the level of analysis in approved plans and in accordance with Bureau-wide standards and program guidance.

5. Public comments will be addressed during the planning process.

You may submit comments on issues and planning criteria in writing to the BLM using one of the methods listed in the **ADDRESSES** section above. To be most helpful, you should submit comments by the close of the 30-day scoping period.

The BLM will utilize and coordinate the NEPA scoping process to help fulfill the public involvement process under the National Historic Preservation Act (54 U.S.C. 306108), as provided in 36 CFR 800.2(d)(3). The information about historic and cultural resources within the area potentially affected by the proposed action will assist the BLM in identifying and evaluating impacts to such resources.

The BLM will consult with Indian tribes on a government-to-government

basis in accordance with Executive Order 13175 and other policies. Tribal concerns, including impacts on Indian trust assets and potential impacts to cultural resources, will be given due consideration. Federal, State, and local agencies, along with tribes and other stakeholders that may be interested in or affected by the proposed action that the BLM is evaluating, are invited to participate in the scoping process and, if eligible, may request or be requested by the BLM to participate in the development of the environmental analysis as a cooperating agency.

The BLM will evaluate identified issues to be addressed in the plan, and will place them into one of three categories:

1. Issues to be resolved in the analysis;

2. Issues to be resolved through policy or administrative action; or

3. Issues beyond the scope of the Supplemental EIS and potential RMP amendment.

The BLM will provide an explanation in the Draft Supplemental EIS as to why an issue was placed in category two or three. The public is also encouraged to help identify any management questions and concerns that should be addressed in the plan. The BLM will work collaboratively with interested parties to identify the management decisions that are best suited to local, regional, national needs, and concerns. The BLM will use an interdisciplinary approach to develop the Supplemental EIS and, if necessary, RMP amendment, in order to consider the variety of resource issues and concerns identified. Specialists with expertise in the following disciplines will be involved in the planning process: Hydrology, air, archaeology, paleontology, wildlife biology, oil and gas, geology, sociology and economics.

Before including your address, phone number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so.

Authority: 40 CFR 1501.7 and 43 CFR 1610.2.

Jerome E. Perez,

BLM California State Director.

[FR Doc. 2018–16957 Filed 8–7–18; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLIDB00100 L17110000.PH0000 LXSS024D0000 45001222254]

Notice of Public Meeting, Boise District Resource Advisory Council, Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976, the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Boise District Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Boise District RAC will meet September 13, 2018. The meeting will begin at 8:00 a.m. and end at 4:00 p.m. The public comment period will take place from 8:00 a.m. to 8:30 a.m.

ADDRESSES: The Boise District RAC will meet at the BLM Boise District Office, 3948 Development Avenue, Boise, Idaho 83705.

FOR FURTHER INFORMATION CONTACT: Michael Williamson, BLM Boise District, Idaho, 3948 Development Avenue, Boise, Idaho 83705, 208–384–3393, email *mwilliamson@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may contact Mr. Williamson by calling the Federal Relay Service (FRS) at (800) 877–8339. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with Mr. Williamson. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The 15-member RAC advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in Idaho. During the September 13, 2018 meeting, the Boise District RAC will have a briefing on the Boise District's wild horse program, Tri-State fuel breaks project, travel management planning, and other Field Office updates. Additional topics may be added and will be included in local media announcements.

RAC meetings are open to the public. The public may present written comments to the Council at the address provided above. Each formal Council meeting will also have time allocated for hearing public comments. Depending on the number of persons wishing to comment and time available, the time for individual oral comments may be limited.

Before including your address, phone number, email address, or other personal identifying information in your comments, please be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Individuals who plan to attend and need special assistance, such as sign language interpretation, tour transportation or other reasonable accommodations, should contact the BLM as provided above.

(Authority: 43 CFR 1784.4–2)

Lara Douglas,

District Manager.

[FR Doc. 2018–16968 Filed 8–7–18; 8:45 am]

BILLING CODE 4310–AK–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0025952; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Binghamton University, State University of New York, Binghamton, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Binghamton University has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Binghamton University. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary

objects should submit a written request with information in support of the request to the Binghamton University at the address in this notice by September 7, 2018.

ADDRESSES: Nina M. Versaggi, Public Archaeology Facility, Binghamton University, P.O. Box 6000, Binghamton, NY 13902–6000, telephone (607) 777–4786, email *nversagg@binghamton.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Binghamton University, Binghamton, NY. The human remains and associated funerary objects were removed from Chenango County, NY.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Binghamton University professional staff in consultation with representatives of the Cayuga Nation; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin); Oneida Indian Nation (previously listed as the Oneida Nation of New York); Onondaga Nation; Saint Regis Mohawk Tribe (previously listed as the St. Regis Band of Mohawk Indians of New York); Seneca Nation of Indians (previously listed as the Seneca Nation of New York); Seneca-Cayuga Nation (previously listed as the Seneca-Cayuga Tribe of Oklahoma); Stockbridge Munsee Community, Wisconsin; Tonawanda Band of Seneca (previously listed as the Tonawanda Band of Seneca Indians of New York); and Tuscarora Nation.

History and Description of the Remains

Sometime before 1975, human remains representing, at minimum, three individuals were removed from an unknown site in Chenango County, NY, possibly the Bates Site. An unknown individual donated the human remains to the Greene Middle School in the Town of Greene, Chenango County, NY in 1975. According to the teacher interviewed, the human remains came from an area that is near (or overlaps) the previously recorded Bates site, a Late Woodland settlement. The Greene Middle School gave the human remains to Binghamton University. No known individuals were identified. There are no associated funerary objects.

A bioarchaeologist and archaeologist from Binghamton University determined that the human remains were Native American. Archeological information from the Bates site includes Canandaigua Phase (Sackett Corded) pottery and radiocarbon dates that cluster around A.D. 1190.

Haudenosaunee oral tradition states that, as The People of the Long House, they are affiliated culturally, spiritually, biologically, and personally to the ancestors located within their traditional aboriginal territories. This connection is also based upon cultural practices, language, and the philosophy of respect for those ancestors that have passed. This evidence supports a relationship of shared group identity which can reasonably be traced between the Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin); Oneida Indian Nation (previously listed as the Oneida Nation of New York); Onondaga Nation; and Tuscarora Nation and the human remains removed from Chenango County, as this location is within the traditional aboriginal territory of the Oneida, Onondaga, and Tuscarora Nations.

Determinations Made by the Binghamton University

Officials of the Binghamton University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin); Oneida Indian Nation (previously listed as the Oneida Nation of New York); Onondaga Nation; and Tuscarora Nation.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Nina M. Versaggi, Public Archaeology Facility, Binghamton University, P.O. Box 6000, Binghamton, NY 13902–6000, telephone (607) 777–4786, email *nversagg@binghamton.edu,* by September 7, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin); Oneida Indian Nation (previously listed as the Oneida Nation of New York); Onondaga Nation; and Tuscarora Nation may proceed.

The Binghamton University is responsible for notifying the Cayuga Nation; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin); Oneida Indian Nation (previously listed as the Oneida Nation of New York); Onondaga Nation; Saint Regis Mohawk Tribe (previously listed as the St. Regis Band of Mohawk Indians of New York); Seneca Nation of Indians (previously listed as the Seneca Nation of New York); Seneca-Cayuga Nation (previously listed as the Seneca-Cayuga Tribe of Oklahoma); Stockbridge Munsee Community, Wisconsin; Tonawanda Band of Seneca (previously listed as the Tonawanda Band of Seneca Indians of New York); and Tuscarora Nation that this notice has been published.

Dated: July 9, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–16922 Filed 8–7–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0025953; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Binghamton University, State University of New York, Binghamton, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Binghamton University has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any

Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Binghamton University. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Binghamton University at the address in this notice by September 7, 2018.

ADDRESSES: Nina M. Versaggi, Public Archaeology Facility, Binghamton University, P.O. Box 6000, Binghamton, NY 13902–6000, telephone (607) 777–478, email *nversagg@binghamton.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Binghamton University, Binghamton, NY. The human remains and associated funerary objects were removed from Thomas Lucky Site (SUBi-888), Town of Ashland, Chemung County, NY.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Binghamton University professional staff in consultation with representatives of the Cayuga Nation; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin); Oneida Indian Nation (previously listed as the Oneida Nation of New York); Onondaga Nation; Saint Regis Mohawk Tribe (previously listed as the St. Regis Band of Mohawk Indians of New York); Seneca Nation of Indians (previously listed as the Seneca Nation of New York); Seneca-Cayuga Nation (previously listed as the Seneca-Cayuga Tribe of Oklahoma); Stockbridge Munsee Community, Wisconsin; Tonawanda Band of Seneca (previously listed as the Tonawanda Band of Seneca Indians of New York); and Tuscarora Nation.

History and Description of the Remains

In 1994–1995, following consultation with a chief from the Onondaga Nation, human remains representing two individuals were removed from the Thomas Lucky site in Town of Elmira, Chemung County, NY, by the Binghamton University field school. One associated funerary object, a broken white bone bead, was found with the human remains.

A bioarcheologist and archeologist from Binghamton University determined that the human remains were Native American. No known individuals were identified. Archeological information shows that two longhouses were present at the site, one with AMS dates extending from A.D. 1300 to 1450 and one with dates extending into the A.D. 1600s. Pottery at the site supports this continuous span of land use. This region was home to Delaware communities during the eighteenth century, and both the Delaware and Seneca engaged in Revolutionary War battles fought nearby as part of the Sullivan-Clinton campaign.

Haudenosaunee oral tradition states that, as The People of the Long House, they are affiliated culturally, spiritually, biologically, and personally to the ancestors located within their traditional aboriginal territories. This connection is also based upon cultural practices, language, and the philosophy of respect for those ancestors that have passed. This evidence supports a relationship of shared group identity which can reasonably be traced between the Cayuga Nation of New York; Seneca Nation of New York; Seneca-Cayuga Tribe of Oklahoma; and Tonawanda Band of Seneca Indians of New York and the human remains removed from the Thomas Luckey site, as this location is within the traditional aboriginal territory of the Cayuga Nation; Seneca Nation of Indians (previously listed as the Seneca Nation of New York); Seneca-Cayuga Nation (previously listed as the Seneca-Cayuga Tribe of Oklahoma); and Tonawanda Band of Seneca (previously listed as the Tonawanda Band of Seneca Indians of New York). Similarly, the Delaware Nation, Oklahoma and Delaware Tribe of Indians recognize that they have a territorial connection to, and cultural affiliation with, sites located in Chemung County in New York.

Determinations Made by the Binghamton University

Officials of the Binghamton University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of two individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the one object described in this notice is reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and Cayuga Nation; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Seneca Nation of Indians (previously listed as the Seneca Nation of New York); Seneca-Cayuga Nation (previously listed as the Seneca-Cayuga Tribe of Oklahoma); and Tonawanda Band of Seneca (previously listed as the Tonawanda Band of Seneca Indians of New York).

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Nina M. Versaggi, Public Archaeology Facility, Binghamton University, P.O. Box 6000, Binghamton, NY 13902–6000, telephone (607) 777–478, email *nversagg@binghamton.edu,* by September 7, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to Cayuga Nation; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Seneca Nation of Indians (previously listed as the Seneca Nation of New York); Seneca-Cayuga Nation (previously listed as the Seneca-Cayuga Tribe of Oklahoma); and Tonawanda Band of Seneca (previously listed as the Tonawanda Band of Seneca Indians of New York) may proceed.

The Binghamton University is responsible for notifying the Cayuga Nation; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin); Oneida Indian Nation (previously listed as the Oneida Nation of New York); Onondaga

Nation; Saint Regis Mohawk Tribe (previously listed as the St. Regis Band of Mohawk Indians of New York); Seneca Nation of Indians (previously listed as the Seneca Nation of New York); Seneca-Cayuga Nation (previously listed as the Seneca-Cayuga Tribe of Oklahoma); Stockbridge Munsee Community, Wisconsin; Tonawanda Band of Seneca (previously listed as the Tonawanda Band of Seneca Indians of New York); and Tuscarora Nation that this notice has been published.

Dated: July 9, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–16924 Filed 8–7–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0025950; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Binghamton University, State University of New York, Binghamton, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Binghamton University has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Binghamton University. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Binghamton University at the address in this notice by September 7, 2018.

ADDRESSES: Nina M. Versaggi, Public Archaeology Facility, Binghamton University, P.O. Box 6000, Binghamton, NY 13902–6000, telephone (607) 777–478, email *nversagg@binghamton.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Binghamton University, Binghamton, NY. The human remains and associated funerary objects were removed from Comfort Site, Town of Chenango, Broome County, NY.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Binghamton University professional staff in consultation with representatives of the Cayuga Nation; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin); Oneida Indian Nation (previously listed as the Oneida Nation of New York); Onondaga Nation; Saint Regis Mohawk Tribe (previously listed as the St. Regis Band of Mohawk Indians of New York); Seneca Nation of Indians (previously listed as the Seneca Nation of New York); Seneca-Cayuga Nation (previously listed as the Seneca-Cayuga Tribe of Oklahoma); Stockbridge Munsee Community, Wisconsin; Tonawanda Band of Seneca (previously listed as the Tonawanda Band of Seneca Indians of New York); and Tuscarora Nation.

History and Description of the Remains

In 1971, human remains representing a minimum of nine individuals were removed from the Comfort site in the Town of Chenango, Broome County, NY. The site was excavated by professional and avocational archeologists during construction of a rest area associated with I–81. No known individuals were identified. The 143 associated funerary objects include: 22 pieces of shell, one cord-marked unidentified body sherd, one plain unidentified body sherd, seven pieces of shell, one chert knife, seven chert waste flakes, one retouched chert flake, one Sackett corded rim sherd, four bear teeth, 20 pieces of shell, one chert waste flake, one chert chunk, 21 shell beads, one crinoid fossil bead, three copper cones, one incised rim sherd, one piece of shell, one shell bead, one piece of wood, three chert waste flakes, one chert flake, one clay pipe bowl fragment, one bone awl, two hammerstones, one chert chunk, two chert waste flakes, one retouched/utilized flake, three eroded pottery sherds, two pieces of unworked bird bone, 22 pieces of shell, one worked animal bone, and seven pieces of animal bone.

A bioarcheologist and archeologist from Binghamton University determined that the human remains were Native American. No known individuals were identified. Archaeological information includes a radiocarbon date obtained from charred plant material from one burial which produced a date of A.D. 1130, plus or minus 150 years. Additional archeological information from the pottery showed that the dates could range from A.D. 1070–1400 and recent radiometric dating of material from non-burial features indicates a date range of A.D. 1250 through A.D. 1400. Historically, the Comfort site was part of the eighteenth century string of villages known as *Otsiningo,* an Oneida and Onondaga community that later accepted Native American refugees.

Haudenosaunee oral tradition states that, as The People of the Long House, they are affiliated culturally, spiritually, biologically, and personally to the ancestors located within their traditional aboriginal territories. This connection is also based upon cultural practices, language, and the philosophy of respect for those ancestors that have passed. This evidence supports a relationship of shared group identity which can reasonably be traced between the Oneida, Onondaga, and Tuscarora Nations and the human remains and associated funerary objects, removed from the Comfort site as this location is within the traditional aboriginal territory of the Oneida, Onondaga, and Tuscarora Nations. Similarly, the Delaware Nation, Oklahoma and the Delaware Tribe of Indians recognize that they have a territorial connection to, and cultural affiliation with, sites located in Broome County, New York.

Determinations Made by the Binghamton University

Officials of the Binghamton University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of nine individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 166 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and Delaware Nation, Oklahoma; Delaware Tribe of Indians; Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin); Oneida Indian Nation (previously listed as the Oneida Nation of New York); Onondaga Nation; and Tuscarora Nation.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Nina M. Versaggi, Public Archaeology Facility, Binghamton University, P.O. Box 6000, Binghamton, NY 13902–6000, telephone (607) 777–478, email *nversagg@binghamton.edu,* by September 7, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to Delaware Nation, Oklahoma; Delaware Tribe of Indians; Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin); Oneida Indian Nation (previously listed as the Oneida Nation of New York); Onondaga Nation; and Tuscarora Nation may proceed.

The Binghamton University is responsible for notifying the Cayuga Nation; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin); Oneida Indian Nation (previously listed as the Oneida Nation of New York); Onondaga Nation; Saint Regis Mohawk Tribe (previously listed as the St. Regis Band of Mohawk Indians of New York); Seneca Nation of Indians (previously listed as the Seneca Nation of New York); Seneca-Cayuga Nation (previously listed as the Seneca-Cayuga Tribe of Oklahoma); Stockbridge Munsee Community, Wisconsin; Tonawanda Band of Seneca (previously listed as the Tonawanda Band of Seneca Indians of New York); and Tuscarora Nation that this notice has been published.

Dated: July 9, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–16925 Filed 8–7–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0025915;PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Albuquerque Museum, Albuquerque, NM

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Albuquerque Museum has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Albuquerque Museum. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Albuquerque Museum at the address in this notice by September 7, 2018.

ADDRESSES: Deb Slaney, History Curator, Albuquerque Museum, 2000 Mountain Road NW, Albuquerque, NM 87104 telephone (505) 243–7255, email *dslaney@cabq.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Albuquerque Museum, Albuquerque, NM. The human remains and associated funerary objects were removed from Mesa Prieta, King Ranch, Rio Puerco Valley, Sandoval County, NM; the Deming, Luna County, NM; and Jemez Pueblo, Sandoval County, NM.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Albuquerque Museum professional staff in consultation with representatives of the Pueblo of Acoma, New Mexico; Pueblo of Cochiti, New Mexico; and Pueblo of Santa Clara, New Mexico. The Kewa Pueblo, New Mexico (previously listed as the Pueblo of Santo Domingo); Ohkay Owingeh, New Mexico (previously listed as the Pueblo of San Juan); Pueblo of Isleta, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Laguna, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Picuris, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Felipe, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Sandia, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Taos; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; Ysleta del Sur Pueblo (previously listed as the Ysleta Del Sur Pueblo of Texas); and Zuni Tribe of the Zuni Reservation, New Mexico were contacted and invited to consult, but did not participate.

History and Description of the Remains

In 1967–1968, human remains representing, at minimum, three individuals were removed from Prieta Vista Pueblo in Sandoval County, NM. The human remains were excavated by Eastern New Mexico University in collaboration with the Albuquerque Archaeological Society in 1967–1968, and donated by the AAS to the Albuquerque Museum in 1977. Burial #1, PC1977.34.73, belongs to a two to four year old child, who was buried (with associated lithic debris) under a

sandstone slab. The human remains are fragmentary and consist of a portion of the skull and rib cage. Burial #2, PC1977.34.74, belongs to a 10 to 11 year old child, and represents either a disturbed or a secondary burial. The human remains are fragmentary and were found with associated lithic debris. Burial #3, PC1977.34.75, belongs to an approximately 20-year-old adult female, who was buried with associated lithic debris and one lot of 4 St. Johns Polychrome potsherds. The human remains are fragmentary. No known individuals are identified. The 14 lots of associated funerary objects, PC1977.34.73–75, are 12 lots of lithic debris from Burials #1–3; one rectangular sandstone slab numbered AS3/270 associated with Burial #1, 30.3″ X 24.4″ X .7″; and one lot of St. Johns Polychrome potsherds associated with Burial #3.

The human remains were published in Richard A. Bice and William M. Sundt, *Prieta Vista, A Small Pueblo II Ruin in North Central New Mexico.* (Albuquerque: Albuquerque Archaeological Society, 1972). The cultural affiliation of the human remains and associated funerary objects is based upon geographical, kinship, biological, archeological, linguistic, folklore, oral tradition, historic evidence, other information, and expert opinion. Primary information sources include reviews of our accession and catalogue records conducted by museum staff and consultant Dena Lewis between 1991 and 2015, a review of archeological publications on Prieta Vista Pueblo, and consultation with Indian tribe officials and traditional religious leaders. The Pueblo of Acoma Review Committee participated in an on-site review of the human remains and associated funerary objects, the Committee declined to view them, but indicated that the people of Prieta Vista Pueblo could be of Keres or Tanoan affiliation, and they would consult with other pueblos regarding repatriation. The Pueblo of Cochiti Review Committee consulted the inventory on site but did not participate in a physical review of the human remains and associated funerary objects. The Committee indicated that it would consult with the Pueblos of Zuni, Acoma, Hopi, and Zia regarding the cultural affiliation of the human remains. The Pueblo of Santa Clara Review Committee reviewed the human remains and associated funerary objects, but did not provide a cultural attribution for them. The geographical location of Prieta Vista Pueblo is consistent with the historically documented territory of the Keres people. Bice and Sundt (1972:200) conclude that the site is most likely affiliated with the Pueblo of Zia or a Tewa-speaking pueblo, and Dena Lewis (1991:111) concludes that the site is most likely affiliated with the Pueblo of Zia.

At a date prior to 1974, human remains representing, at minimum, one individual were removed from an unknown location in the vicinity of Deming, Luna Co., NM. The human remains were donated to the Museum by a New Mexico collector in 1974. The remains, PC1974.9.29, belong to a cremation. The age and sex of the remains are unknown. The one associated funerary object, PC1974.9.29, is a small Three Circle Neck Corrugated clay jar.

The remains are dated C.E. 900 to 1000 based on the date of the jar. The cultural affiliation of the human remains and associated funerary objects is based upon geographical, kinship, biological, archeological, linguistic, folklore, oral tradition, historic evidence, other information, and expert opinion. Primary information sources include reviews of our accession and catalogue records conducted by museum staff and consultant Dena Lewis between 1991 and 2015, and consultation Indian tribe officials and traditional religious leaders. The geographical location of Deming, NM, is consistent with the historically documented territory of the Mimbres people. The cremation was identified as Mimbres by Dr. Cynthia Bettison, Director, Western New Mexico University Museum. The Pueblo of Acoma Review Committee participated in an on-site review of the human remains and associated funerary objects, but did not review or confirm the cultural affiliation of the remains and jar. The Pueblo of Cochiti Review Committee consulted the inventory while on site but did not participate in a physical review of the human remains and associated funerary objects. The Committee indicated it would consult with the Pueblos of Zuni, Acoma, Hopi, and Zia regarding cultural affiliation of the remains. The Pueblo of Santa Clara Review Committee reviewed the human remains and associated funerary objects, but declined to provide a cultural attribution for them.

At a date prior to 1974, human remains representing, at minimum, one individual was removed from an unknown location in the vicinity of the Pueblo of Jemez, Sandoval County, NM. The human remains, PC1976.83, were collected near the Pueblo of Jemez by the Albuquerque High School Archeology Club, and donated to the Albuquerque Museum in 1974. The age and sex of the human remains are unknown. No known individuals were identified. The 10 associated funerary objects, PC1976.83, are one bird bone flute, and nine samples of worked and unworked animal bone.

The human remains belong to an inhumation and include cranial bones. The date of the human remains and associated funerary objects is unknown. Cultural affiliation of the human remains and associated funerary objects is based upon geographical, kinship, biological, archeological, linguistic, folklore, oral tradition, historic evidence, other information, and expert opinion. Primary information sources include reviews of our accession and catalogue records conducted by museum staff and consultant Dena Lewis between 1991 and 2015, and consultation with Indian tribe officials and traditional religious leaders. The proximity of the collection location is geographically consistent with the historically documented territory of Jemez Pueblo. The Pueblo of Acoma Review Committee participated in an on-site review of the human remains and associated funerary objects, but did not review or confirm the cultural affiliation of the remains and associated funerary objects. The Pueblo of Cochiti Review Committee consulted the inventory while on site, but did not participate in a physical review of the human remains and associated funerary objects. The Committee indicated that it would consult with the Pueblos of Zuni, Acoma, Hopi, and Zia regarding the cultural affiliation of the remains. The Pueblo of Santa Clara Review Committee reviewed the human remains and associated funerary objects, but declined to identify a cultural affiliation for them.

At a date prior to 1974, human remains representing, at minimum, one individual were removed from an unknown location in the vicinity of Deming, Luna County, NM. The human remains, UA146.1, were likely collected by the Albuquerque High School Archeology Club and donated to the Albuquerque Museum in 1974. The age and sex of the human remains is unknown.

The human remains and associated funerary objects are believed to be collected by the AHS Archeology Club because ''AHS'' was written on the box in which they were contained. No known individuals were identified. The nine associated funerary objects, UA146.1, are one bone awl and eight bone beads of unknown species and date. Cultural affiliation of the human

remains and associated funerary objects listed is based upon geographical, kinship, biological, archeological, linguistic, folklore, oral tradition, historic evidence, other information, and expert opinion. Primary information sources include reviews of our accession and catalogue records conducted by museum staff and consultant Dena Lewis between 1991 and 2015, a review of archaeological publications on Prieta Vista Pueblo and Tonque Pueblo, and consultation with Indian tribe officials and traditional religious leaders. The location where the human remains are believed to have been collected lies within the historically documented territory of Jemez Pueblo. The Pueblo of Acoma Review Committee participated in an on-site review of the human remains and associated funerary objects, but declined to view them or identify a cultural affiliation of the remains and associated funerary objects. The Pueblo of Cochiti Review Committee consulted the inventory while on site, but did not participate in a physical review of the human remains and associated funerary objects. The Committee indicated that it would consult with the Pueblos of Zuni, Acoma, Hopi, and Zia regarding the cultural affiliation of the remains, and that the human remains and associated funerary objects should be stored separately from the other collections. The Pueblo of Santa Clara Review Committee reviewed the human remains and associated funerary objects, and offered to consult with other Pueblos regarding repatriation.

Determinations Made by the Albuquerque Museum

Officials of the Albuquerque Museum have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of six individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 34 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Hopi Tribe of Arizona; Kewa Pueblo, New Mexico (previously listed as the Pueblo of Santo Domingo); Ohkay Owingeh, New Mexico (previously listed as the Pueblo of San Juan); Pueblo of Acoma, New Mexico; Pueblo of Cochiti, New Mexico; Pueblo of Isleta, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Laguna, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Felipe, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Sandia, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Santa Clara, New Mexico; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; and Zuni Tribe of the Zuni Reservation, New Mexico (hereafter referred to as ''The Tribes'').

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Deb Slaney, History Curator, Albuquerque Museum, 2000 Mountain Road NW, Albuquerque, NM 87104, telephone (505) 243–7255, email *dslaney@cabq.gov,* by September 7, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

The Albuquerque Museum is responsible for notifying The Tribes that this notice has been published.

Dated: June 29, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–16926 Filed 8–7–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0025951; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Binghamton University, State University of New York, Binghamton, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Binghamton University has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Binghamton University. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Binghamton University at the address in this notice by September 7, 2018.

ADDRESSES: Nina M. Versaggi, Public Archaeology Facility, Binghamton University, P.O. Box 6000, Binghamton, NY 13902–6000, telephone (607) 777–478, email *nversagg@binghamton.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Binghamton University, Binghamton, NY. The human remains and associated funerary objects were removed from the following four sites: Roundtop (SUBi-365), Village of Endicott, Broome County, NY; Steen Topsoil Removal Plant, Town of Owego, Tioga County, NY; Cottage (SUBi-220), Town of Owego, Tioga County, NY; and Owego Sewage Plant Site (SUBi-336), Town of Owego, Tioga County, NY.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Binghamton University professional staff in consultation with representatives of the Cayuga Nation; Delaware Nation, Oklahoma; Delaware Tribe of Indians; Oneida Nation (previously listed as the Oneida Tribe of Indians of Wisconsin); Oneida Indian Nation (previously listed as the Oneida Nation of New York); Onondaga Nation; Saint Regis Mohawk

Tribe (previously listed as the St. Regis Band of Mohawk Indians of New York); Seneca Nation of Indians (previously listed as the Seneca Nation of New York); Seneca-Cayuga Nation (previously listed as the Seneca-Cayuga Tribe of Oklahoma); Stockbridge Munsee Community, Wisconsin; Tonawanda Band of Seneca (previously listed as the Tonawanda Band of Seneca Indians of New York); and Tuscarora Nation (hereafter referred to as ''The Consulted Tribes'').

History and Description of the Remains

The Roundtop site (SUBi-365): In 1965, a burial containing the human remains of two individuals was excavated at the Roundtop site in the Village of Endicott, Broome County, NY, by a Binghamton University field school. Subsequently, the human remains were transferred to the control of the New York State Museum. This site was also excavated by amateurs as well as the New York State Museum. Much has been published on the site, including data showing it was a multicomponent site dating between circa A.D. 1000 and 1600. No known individuals are associated with that burial. The human remains and some associated funerary objects (AFOs) have been under the control of the New York State Museum since their excavation; the remainder of the AFOs are under the control of the University. The 197 AFOs under the control of Binghamton University are: Six chert decortification flakes, one chert shatter, three chert blocks, 14 chert waste flakes, one large chert waste flake, three chert blocks, eight chert shatter, six chert decortification flakes, 52 chert waste flakes, seven utilized chert flakes, 18 chert waste flakes, one chert decortification flake, two chert shatter, one possible utilized flake, eight chert shatter, five chert decortification flakes, one fire-reddened jasper waste flake, six chert chunks, four utilized chert flakes, one retouched chert flake, and 49 chert waste flakes. Roundtop site is located within the traditional territories of the Delaware Nation, Oklahoma; Delaware Tribe, Oklahoma; and Onondaga Nation of New York.

Steen Topsoil Removal Plant site: During the early 1980s, human remains representing, at minimum, three individuals were removed from a back dirt pile at this mining site in the Town of Owego, Tioga County, NY. They were dropped off at Binghamton University anonymously. There were no associated funerary objects included in the donation. A bioarcheologist and archeologist from Binghamton University determined that the human remains were Native American. No known individuals are associated with that burial. The site is located within the traditional territories of the Delaware Nation, Oklahoma; Delaware Tribe, Oklahoma; and the Onondaga Nation, New York.

Cottage site (SUBi-220): In 1973, human remains representing two individuals were donated to Binghamton University by a local collector who removed items from this site located in the Town of Owego, Tioga County, NY. There were no associated funerary objects included in the donation. A bioarcheologist and archeologist from Binghamton University determined that the human remains were Native American. No known individuals are associated with that burial. The site is located within the traditional territories of the Delaware Nation, Oklahoma; Delaware Tribe, Oklahoma; and the Onondaga Nation, New York.

Owego Sewage Plant site (SUBi-336): In 1965, human remains representing, at minimum, one individual were removed from this site in the Town of Owego, Tioga County, NY. A Binghamton University faculty member and the Triple Cities Chapter of the New York State Archaeological Association conducted salvage excavations when cultural material was uncovered. A bioarcheologist and archeologist from Binghamton University determined that the human remains were Native American. No known individuals are associated with that burial. The site is located within the traditional territories of the Delaware Nation, Oklahoma; Delaware Tribe, Oklahoma; and the Onondaga Nation, New York.

Haudenosaunee oral tradition states that they are affiliated culturally, spiritually, biologically, and personally to the ancient ancestors located within their traditional aboriginal territories. This connection is based upon Haudenosaunee oral history, cultural practices, language, and the philosophy of respect for those ancestors that have passed. The Haudenosaunee assert this affiliation to all Native American ancestors located within their extended aboriginal territory based on their cultural and spiritual beliefs as The People of the Long House. Therefore, they argue that this evidence supports a relationship of shared group identity which can be reasonably traced from the Onondaga Nation to the Roundtop site, Steen Topsoil Removal site, Cottage site, and Owego Sewage Plant site. Similarly, the Delaware Nation and Delaware Tribe recognize that they have a territorial connection to, and cultural affiliation with, these sites located in Broome and Tioga Counties, NY.

Determinations Made by the Binghamton University

Officials of the Binghamton University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of eight individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 197 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Delaware Nation, Oklahoma; Delaware Tribe of Indians; and Onondaga Nation.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Nina M. Versaggi, Public Archaeology Facility, Binghamton University, P.O. Box 6000, Binghamton, NY 13902–6000, telephone (607) 777–478, email *nversagg@binghamton.edu,* by September 7, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Delaware Nation, Oklahoma; Delaware Tribe of Indians; and Onondaga Nation may proceed.

The Binghamton University is responsible for The Consulted Tribes that this notice has been published.

Dated: July 9, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–16923 Filed 8–7–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA– NPS0025916; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: San Diego Museum of Man, San Diego, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The San Diego Museum of Man has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the San Diego Museum of Man. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the San Diego Museum of Man at the address in this notice by September 7, 2018.

ADDRESSES: Ben Garcia, Deputy Director, San Diego Museum of Man, 1350 El Prado, San Diego, CA 92101, telephone (619) 239–2001 ext. 17, email *bgarcia@museumofman.org*.

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the San Diego Museum of Man. The human remains and associated funerary objects were removed from San Diego, San Diego County, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the San Diego Museum of Man professional staff in consultation with representatives of Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California; Capitan Grande Band of Diegueno Mission Indians of California (Barona Group of Capitan Grande Band of Mission Indians of the Barona Reservation, California); Viejas (Baron Long) Group of Capitan Grande Band of the Mission Indians of the Viejas Reservation, California; Ewiiaapaayp Band of Kumeyaay Indians, California; Iipay Nation of Santa Ysabel, California (previously listed as the Santa Ysabel Band of Diegueno Mission Indians of the Santa Ysabel Reservation); Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California; Jamul Indian Village of California; La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California; Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California; Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California; San Pasqual Band of Diegueno Mission Indians of California; and Sycuan Band of the Kumeyaay Nation (hereafter referred to as ''The Tribes'').

History and Description of the Remains

In 1929, human remains representing, at minimum, two individuals were recovered by Malcom J. Rogers from CA–SDI–694 (W–99 and W–99A), a site located on the north side of Bataquitos Lagoon. During consultation, it was determined that CA–SDI–694 is a cemetery and that, based on traditional Kumeyaay burial practices, all objects excavated from this site are associated funerary objects. No known individuals were identified. The 163 associated funerary objects are: One unmodified faunal bone, one chipped stone biface, one projectile point, 15 chipped stone cores, 23 chipped stone core tools, 27 chipped stone unworked flakes, 37 chipped stone utilized flakes, eight groundstone manos, five groundstone metates, 19 stone ecofacts, five lots unmodified shell, five lots of soil, and 16 battered stones.

In 1929, human remains representing, at minimum, one individual were recovered by Malcom J. Rogers from CA–SDI–691/693/6867 (W–98, W–101, W–101B, and W–102), a site complex located on the north side of Bataquitos Lagoon. During consultation, it was determined that this site complex is a cemetery and that, based on traditional Kumeyaay burial practices, all objects excavated from this site are associated funerary objects. No known individuals were identified. The 125 associated funerary objects are: One undecorated ceramic body sherd, 14 lots of unmodified faunal bones, six chipped stone cores, 10 chipped stone core tools, one chipped stone knife, one chipped stone unifacial tool, 11 lots of unworked flakes, 27 utilized flakes, seven manos, one metate, one groundstone fishing or netting weight, two steatite pendants, one groundstone, two pestle fragments, 10 lots of ecofacts, 10 unmodified shells, eight lots of unmodified shells, three soil samples, six battered stones, two lots of fire affected stone, and one lot of charcoal.

In 1929, human remains representing, at minimum, two individuals were recovered by Malcom J. Rogers from CA–SDI–8195, CA–SDI–4860, and CA–SDI–4847 (W–108, W–109, W–109A, W–110), a cluster of sites north of Bataquitos Lagoon. During consultation, it was determined that these sites comprise one cemetery and that, based on traditional Kumeyaay burial practices, all objects excavated from these sites are associated funerary objects. No known individuals were identified. The 233 associated funerary objects are: Four lots of unmodified faunal bones, two decorated ceramic sherds, one ceramic undecorated rim sherd, four lots of mixed ceramic sherds, one chipped stone biface, 16 chipped stone cores, 87 chipped stone core tools, three stone spear points, four chipped stones, three stone scrapers, seven projectile points, one unworked flake, three lots of unworked flakes, one stone crescentic, 54 utilized flakes, 14 manos, one metate, one groundstone, two stone pestles, one stone ecofact, three lots of ecofacts, one modified shell pendant, three lots of unmodified shell, one soil sample, and 15 battered stones.

In 1929, human remains representing, at minimum, one individual were recovered by Malcom J. Rogers from CA–SDI–4548, 4990 (W–92), a site south of Bataquitos Lagoon. Based on traditional Kumeyaay burial practices, all objects excavated from this site are associated funerary objects. No known individuals were identified. The 241 associated funerary objects are: One chipped stone biface, 11 cores, 45 core tools, one projectile point, one scraper, four lots of unworked flakes, 162 utilized flakes, eight manos, one lot of ecofacts, one olivella shell bead, two lots of unworked shell, one soil sample, two battered stones, and one lot of unmodified faunal bone.

In 1929, human remains representing, at minimum, one individual were recovered by Malcom J. Rogers from CA–SDI–630 (W–141 and W–141B), a site east of Buena Vista Lagoon along Buena Vista Creek. Based on traditional

Kumeyaay burial practices, all objects excavated from this sites are associated funerary objects. No known individuals were identified. The 44 associated funerary objects are: One decorated ceramic sherd, one undecorated ceramic sherd, one lot of undecorated ceramic sherds, one biface, seven stone choppers, one crescentic fragment, 13 stone scrapers, three lots of unworked flakes, two manos, one mortar, one heating stone, one arrow shaft straightener, one olivella shell bead, one shell pendant, five lots of unmodified shell, two soil samples, one battered stone, and one lot of unmodified faunal bone.

At an unknown date prior to 1949, human remains representing, at minimum, one individual were donated to the San Diego Museum of Man by H.E. Ellery. Other than their association to W–146, no additional information exists about the date of collection or collector. Based on traditional Kumeyaay burial practices, all objects excavated from this site are associated funerary objects to this individual. No known individuals were identified. The 24 associated funerary objects are: One mixed lot of faunal bone and shell, two lots unmodified faunal bone, one lot of undecorated ceramics sherds, one chipped stone biface, one core tool, three scrapers, four lots of unworked flakes, two manos, one abrader, one ecofact, five unmodified shells, one soil sample, and one hammerstone.

At an unknown date prior to 1949, human remains representing, at minimum, one individual were donated to the San Diego Museum of Man by John Kelley. Mr. Kelley collected this burial following a heavy flood and landslide on his property in 1916, also known as W–148. Based on traditional Kumeyaay burial practices, all objects removed from this site are associated funerary objects to this individual. No known individuals were identified. The eight associated funerary objects are: one battered stone, one stone scraper, one unworked flake, one rim sherd, one unmodified faunal bone, one oyster shell, one lot miscellaneous shell, and one soil sample.

In 1929, human remains representing, at minimum, two individuals were recovered by Malcom J. Rogers from CA–SDI–8797, CA–SDI–10671, CA–SDI–6132, and CA–10673 (W–116, W–118, W–119, and W–129), a cluster of sites south of Agua Hedionda Lagoon. During consultation, it was determined that these site comprise one cemetery and that, based on traditional Kumeyaay burial practices, all objects excavated from these sites are associated funerary objects. No known individuals were identified. The 149 associated funerary objects are: Three lots of ceramic sherds, five lots of unmodified faunal bone, one heating stone, five stone cores, 25 chipped stone core tools, two chipped stone bifaces, eight scrappers, three unworked flakes, 11 lots of unworked flakes, 39 utilized flakes, nine manos, one metate, six groundstones, six lots of ecofacts, six lots of shell, one unmodified shell, one olivella bead, four soil samples, six battered stones, one chopper, four hammerstones, one fire-affected rock, and one stone bead.

In 1929, human remains representing, at minimum, one individual were recovered by Malcom J. Rogers from CA–SDI–6134 (W–121), a site south of Agua Hedionda Lagoon. During consultation, it was determined that this site is a cemetery and that, based on traditional Kumeyaay burial practices, all objects excavated from this site are associated funerary objects. No known individuals were identified. The 64 associated funerary objects are: One bone awl, seven lots unmodified faunal bone, one undecorated ceramic body sherd, one chipped stone biface fragment, one chipped stone core, 25 chipped stone scrapers, 10 lots of chipped stone unworked flakes, one chipped stone utilized flake, one mano, one hematite ''charm stone'', one steatite doughnut stone fragment, one sandstone grinding slab fragment, one modified wood piece, one ecofact, six lots of unmodified shell, two soil samples, and three battered stones.

In 1929, human remains representing, at minimum, one individual were recovered by Malcom J. Rogers from W–124, a site south of Agua Hedionda Lagoon. During consultation, it was determined that this site is a cemetery and that, based on traditional Kumeyaay burial practices, all objects excavated from this site are associated funerary objects. No known individuals were identified. The 20 associated funerary objects are: One lot of undecorated ceramic body sherds, one chipped stone flaking and battering fragment, 11 chipped stone scrapers, three lots of chipped stone unworked flakes, one lot unmodified shell, and three battered stones.

The excavations at the above sites by Rogers and the other individuals were often conducted at the behest of the San Diego Museum of Man. These sites are all located within well-known and documented territories occupied by the Kumeyaay Nation. Based on archeological evidence, geographic location, ethnographic information, and oral history evidence, these remains have been identified as Native American.

Determinations Made by the San Diego Museum of Man

Officials of the San Diego Museum of Man have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 13 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 1,071 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Ben Garcia, Deputy Director, San Diego Museum of Man, 1350 El Prado, San Diego, CA 92101, telephone (619) 239–2001 ext. 17, email *bgarcia@museumofman.org,* by September 7, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

The San Diego Museum of Man is responsible for notifying The Tribes that this notice has been published.

Dated: June 29, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–16921 Filed 8–7–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0025914; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: New York University College of Dentistry, New York City, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The New York University (NYU) College of Dentistry has completed an inventory of human remains, in consultation with the

appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the NYU College of Dentistry. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the NYU College of Dentistry at the address in this notice by September 7, 2018.

ADDRESSES: Dr. Louis Terracio, NYU College of Dentistry, 345 East 24th Street, New York, NY 10010, telephone (212) 998–9717, email *louis.terracio@nyu.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the NYU College of Dentistry, New York City, NY. The human remains were removed from Shinnecock Hills, Suffolk County, Long Island, NY.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the NYU College of Dentistry professional staff in consultation with representatives of the Delaware Nation, Oklahoma; Delaware Tribe of Indians; Shinnecock Indian Nation; and Stockbridge Munsee Community, Wisconsin.

History and Description of the Remains

At an unknown date, human remains representing, at minimum, one individual were removed from an unknown site in Shinnecock Hills, Suffolk County, NY. In 1926, the town of Southampton donated the human remains, which consist of the cranial fragments of one adult, to the Museum of the American Indian, Heye Foundation. They were accessioned into the collection of the Department of Physical Anthropology of the Museum of the American Indian, Heye Foundation that same year. In 1956, the human remains were transferred to Dr. Theodore Kazamiroff, NYU College of Dentistry. No known individuals were identified. No associated funerary objects are present. The age of the human remains cannot be determined from the available information. Forensic examination revealed diagnostic features of an individual with Native American ancestry. Without any information about the site or age of the remains, no identifiable earlier group can be determined.

Shinnecock Hills, which lies near the northeastern end of Long Island, is not included in any treaties, Acts of Congress, or Executive Orders that establish aboriginal land. The area is, however, within territory that was long recognized by the tribe, the town of Southampton, and the state of New York as Shinnecock land. In 1703, the Shinnecock and town of Southampton reached an agreement in which the Shinnecock held a 1,000 year lease of approximately 3,500 acres, including Shinnecock Hills. The area was subsequently referred to as the Shinnecock Reservation in various state and local documents. The Shinnecock renegotiated their lease in 1859 and relinquished the lands at Shinnecock Hills in exchange for fee title to the land at Shinnecock Neck. The current Shinnecock Reservation, which no longer includes Shinnecock Hills, was placed into trust after the tribe was federally recognized in 2010. The Department of Interior proposed finding on the Shinnecock petition for federal recognition identifies Shinnecock Hills as part of the pre-1859 Shinnecock Reservation.

Determinations Made by the NYU College of Dentistry

Officials of the NYU College of Dentistry have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on diagnostic cranial features observed during forensic examination.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- Authoritative governmental documents, including the Shinnecock Indian Nation's federal recognition decision, state agreements, and local property records indicate that the land from which the Native American human remains were removed is the aboriginal land of the Shinnecock Indian Nation.
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to the Shinnecock Indian Nation.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Dr. Louis Terracio, NYU College of Dentistry, 345 East 24th Street, New York, NY 10010, telephone (212) 998–9717, email *louis.terracio@nyu.edu,* by September 7, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Shinnecock Indian Nation may proceed.

The NYU College of Dentistry is responsible for notifying the Shinnecock Indian Nation that this notice has been published.

Dated: June 29, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–16920 Filed 8–7–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Clinical Supplies Management Holdings, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before September 7, 2018. Such persons may also file a written request for a hearing on the application on or before September 7, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be

sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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 1301.34(a), this is notice that on June 29, 2018, Clinical Supplies Management Holdings, Inc., 342 42nd Street South, Fargo, North Dakota 58103–1132 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to import the listed controlled substances to manufacture bulk controlled substances for use in clinical trials only.

Dated: July 31, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–16939 Filed 8–7–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: AndersonBrecon Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before September 7, 2018. Such persons may also file a written request for a hearing on the application on or before September 7, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. Comments and requests for hearings on applications to import narcotic 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 1301.34(a), this is notice that on May 2, 2018, AndersonBrecon Inc., 5775 Logistics Parkway, Rockford, Illinois 61109 applied to be registered as an importer of the following basic class of controlled substance:

Controlled substance	Drug code	Schedule
Tetrahydrocannabinols	7370	I

The company plans to import the listed controlled substances for clinical trial only. Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2).

Authorization will not extend to the import of FDA approved or non-approved finished dosage forms for commercial sale.

Dated: July 31, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–16937 Filed 8–7–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Registration

ACTION: Notice of registration.

SUMMARY: Registrants listed below have applied for and been granted registration by-the Drug Enforcement Administration (DEA) as importers of various classes of schedule I or II controlled substances.

SUPPLEMENTARY INFORMATION: The companies listed below applied to be registered as importers of various basic classes of controlled substances. Information on previously published notices is listed in the table below. No comments or objections were submitted and no requests for hearing were submitted for these notices.

Company	FR docket	Published
Restek Corporation	83 FR 27634	June 13, 2018.
Bellwyck Clinical Services	83 FR 27633	June 13, 2018.
Cambrex Charles City	83 FR 27633	June 13, 2018.

The Drug Enforcement Administration (DEA) has considered the factors in 21 U.S.C. 823, 952(a) and 958(a) and determined that the registration of the listed registrants to import the applicable basic classes of schedule I or II controlled substances is consistent with the public interest and with United States obligations under international treaties, conventions, or protocols in effect on May 1, 1971. The DEA investigated each company's maintenance of effective controls against diversion by inspecting and testing each company's physical security systems, verifying each company's compliance with state and local laws, and reviewing each company's background and history.

Therefore, pursuant to 21 U.S.C. 952(a) and 958(a), and in accordance with 21 CFR 1301.34, the DEA has granted a registration as an importer for schedule I or II controlled substances to the above listed companies.

Dated: July 31, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–16941 Filed 8–7–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Euticals Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before October 9, 2018.

ADDRESS: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152.

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 25, 2018, Euticals, Inc., 2460 W Bennett Street, Springfield, Missouri 65807–1229 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
Phenylacetone	8501	II
Methadone	9250	II
Methadone intermediate	9254	II
Oripavine	9330	II
Tapentadol	9780	II

The company plans to manufacture the above-listed controlled substances in bulk for distribution to its customers.

Dated: July 31, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–16942 Filed 8–7–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Chattem Chemicals, Inc.

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before September 7, 2018. Such persons may also file a written request for a hearing on the application on or before September 7, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. Comments and requests for hearings on applications to import narcotic 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 1301.34(a), this is notice that on August 16, 2017, Chattem Chemicals, Inc., 3801 St. Elmo Avenue, Chattanooga, Tennessee 37409 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Methamphetamine	1105	II
4-Anilino-N-phenethyl-4-piperidine (ANPP).	8333	II
Phenylacetone	8501	II

Controlled substance	Drug code	Schedule
Opium, raw	9600	II
Poppy Straw Concentrate.	9670	II
Tapentadol	9780	II

The company plans to import the listed controlled substances to manufacture bulk controlled substances for sale to its customers. The company plans to import an intermediate form of tapentadol (9780), to bulk manufacture tapentadol for distribution to its customers.

Dated: July 31, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–16940 Filed 8–7–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Importer of Controlled Substances Application: Myoderm

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before September 7, 2018. Such persons may also file a written request for a hearing on the application on or before September 7, 2018.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All request for hearing should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DRW, 8701 Morrissette Drive, Springfield, Virginia 22152. Comments and requests for hearings on applications to import narcotic 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 1301.34(a), this is notice that on October 5, 2017, Myoderm, 48 East Main St., Norristown, Pennsylvania 19401 applied to be registered as an importer of the following basic classes of controlled substances:

Controlled substance	Drug code	Schedule
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Nabilone	7379	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Morphine	9300	II
Oxymorphone	9652	II
Fentanyl	9801	II

The company plans to import controlled substances commercially packaged in dosage form only for clinical trials purposes, research, and analytical purposes only.

Dated: July 31, 2018.

John J. Martin,

Assistant Administrator.

[FR Doc. 2018–16938 Filed 8–7–18; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; State Apprenticeship Expansion (SAE) Grants Research Study

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of Labor (DOL), Employment and Training Administration (ETA) is soliciting comments concerning a new request for the authority to conduct the information collection request (ICR) titled, ''State Apprenticeship Expansion (SAE) Grants Research Study.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by October 9, 2018.

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 by contacting Gloribel Nieves-Cartagena by telephone at (202) 693–2771, TTY 1–877–889–5627 (these are not toll free numbers), or by email at *Nieves-Cartagena.Gloribel@dol.gov.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration, Office of Policy Development and Research, Room N–5641, 200 Constitution Avenue NW, Washington, DC 20210; by email: *Nieves-Cartagena.Gloribel@dol.gov;* or by Fax at (202) 693–2766.

FOR FURTHER INFORMATION CONTACT: Gloribel Nieves-Cartagena by telephone at (202) 693–2771, TYY 1–877–889–5627 (these are not toll-free numbers) or by email at *Nieves-Cartagena.Gloribel@dol.gov*.

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: The DOL, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents is properly assessed.

The information collection activities described in this notice will provide data for a qualitative study of Apprenticeship SAE grants and related apprenticeship expansion activities.

Through grant and contract vehicles, DOL is seeking to expand opportunities related to Registered Apprenticeships, expand programs to new industries and occupations, increase the number of apprentices, and to promote the diversity and inclusion of apprentices.

First, in September 2016, DOL awarded $20.4 million through 10 National Industry Partner contracts and four National Equity Partner contracts to increase apprenticeships in particular industries and focus on diversity and inclusion in apprenticeships, respectively. In November 2016, DOL awarded a total of $50.5 million in grants to 36 states and one territory to expand apprenticeships throughout the country. In 2017, 10 contracts were renewed for a second contract year.

This information collection covers an evaluation study, which will address six key research questions related to the SAE grants and national industry and equity partner contracts: (1) How are grantees' and contractors' implementation activities progressing around efforts to drive apprenticeship expansion and diversity, (2) What partnerships have been developed as a result of these activities, (3) What factors have affected implementation, (4) How are funds being used, (5) What state policies exist or are in development to support expansion, and (6) What promising models or lessons have emerged? In addition, through a national survey of states and U.S. territories, the study will address the question: What is the current status of states' efforts to grow apprenticeship programs and opportunities?

The National Apprenticeship Act of 1937 (29 U.S.C. 50) authorizes this information collection.

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 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* CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of final ICR. In order to help ensure appropriate consideration, comments should mention control number 1205–XXXX.

Submitted comments will also be a matter of public record for this ICR and posted on the internet without redaction. The DOL encourages commenters not to include personally identifiable information, in any comments.

The DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance 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–ETA.

Type of Review: NEW.

Title of Collection: State Apprenticeship Expansion (SAE) Grants Research Study.

Forms: 1. State Apprenticeship Expansion Grant administrator protocol; 2. National Industry Partner contractor protocol; 3. National Equity Partner contractor protocol; and 4. State Registered Apprenticeship administrator survey.

OMB Control Number: 1205–XXXX.

Affected Public: Staff of state government agencies, for-profit entities, and not-for-profit entities. ''Respondent groups identified include (1) administrators of State apprenticeship expansion grants, (2) representatives for industry and equity partner contracts, and (3) State Registered Apprenticeship staff.

Estimated Number of Respondents: 95.

Frequency: Once.

Total Estimated Annual Responses: 48.

Estimated Average Time per Response: Varies.

Estimated Total Annual Burden Hours: 55.

Estimated Total Annual Other Cost Burden: $1,873.85.

Rosemary Lahasky,

Deputy Assistant Secretary for Employment and Training Administration.

[FR Doc. 2018–16930 Filed 8–7–18; 8:45 am]

BILLING CODE 4510–FT–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (18–060)]

NASA Advisory Council; Human Exploration and Operations Committee; Meeting.

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Human Exploration and Operations Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC.

DATES: Monday, August 27, 2018, 10:00 a.m.–5:00 p.m.; and Tuesday, August 28, 2018, 8:00 a.m.–2:45 p.m., PDT. Joint meeting with the NAC Science Committee on August 28, 2018.

ADDRESSES: NASA Ames Research Center, NASA Ames Conference Center, Building 3, 500 Severyns Road, Ballroom Meeting Room, Moffett Field, CA 94035.

FOR FURTHER INFORMATION CONTACT: Dr. Bette Siegel, Designated Federal Officer, Human Exploration and Operations Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–2245, or *bette.siegel@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. This meeting is also available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the USA toll free conference call number 1–888–324–9238 or toll access number 1–517–308–9132, passcode 3403297, followed by the # sign to participate in this meeting by telephone. The WebEx link is *https://nasa.webex.com/,* the meeting number is 996 163 984, and the password is Exploration@2018 (case sensitive).

The agenda for the meeting includes the following topics:

—Status of Human Exploration and Operations
—International Space Station
—Exploration Systems Development
—Commercial Crew and Launch Readiness Process
—Gateway and Cis-Lunar Activities
—Transformative Lunar Science

For NASA Ames Research Center visitor access, please go through the Main Gate and show a valid government-issued identification (*i.e.,*

driver's license, passport, etc.) to the security guard. Inform the security guard that you are attending a meeting in Building 3. Attendees will also be required to sign a register prior to entering the meeting room. It is imperative that the meeting be held on these dates to the scheduling priorities of the key participants.

Carol J. Hamilton,

Acting Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2018–16967 Filed 8–7–18; 8:45 am]

BILLING CODE 4510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (18–063)]

NASA Advisory Council; Technology, Innovation and Engineering Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Technology, Innovation and Engineering Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC.

DATES: Tuesday, August 28, 2018, 8:00 a.m.–5:00 p.m., PDT.

ADDRESSES: NASA Ames Research Center, NASA Ames Conference Center, Building 3, 500 Severyns Road, Mezzanine Room, Moffett Field, CA 94035.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Green, Designated Federal Officer, Space Technology Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–4710, or *g.m.green@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. This meeting is also available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the toll free access number 1–844–467–6272, passcode 102421, followed by the # sign to participate in the meeting by telephone. The WebEx link is *https://nasa.webex.com/,* the meeting number is 990 564 469, and the password is ''N@CTIE0818'' (case sensitive). NOTE: If dialing in, please ''mute'' your telephone. The agenda for the meeting includes the following topics:

—Space Technology Mission Directorate Update and Discussion
—Autonomous Systems Capability Overview
—Solar Electric Propulsion Update
—Office of the Chief Technologist Update
—Annual Ethics Training Briefing
—In-Space Robotic Manufacturing and Assembly Projects Update
—Center for the Utilization of Biological Engineering for Space (CUBES) Update

For NASA Ames Research Center visitor access, please go through the Main Gate and show a valid government-issued identification (*i.e.,* driver's license, passport, etc.) to the security guard. Inform the security guard that you are attending a meeting in Building 3. Attendees will also be required to sign a register prior to entering the meeting room. It is imperative that the meeting be held on these dates to the scheduling priorities of the key participants.

Carol J. Hamilton,

Acting Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2018–16964 Filed 8–7–18; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (18–059)]

NASA Advisory Council; Aeronautics Committee; Meeting.

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Aeronautics Committee of the NASA Advisory Council (NAC). This meeting will be held for the purpose of soliciting, from the aeronautics community and other persons, research and technical information relevant to program planning.

DATES: Tuesday, August 28, 2018, 10:00 a.m.–5:00 p.m., PDT.

ADDRESSES: NASA Ames Research Center, NASA Ames Conference Center, Building 3, 500 Severyns Road, North Wing Room, Moffett Field, CA 94035

FOR FURTHER INFORMATION CONTACT: Ms. Irma Rodriguez, Designated Federal Officer, Aeronautics Research Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–0984, or *irma.c.rodriguez@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the capacity of the room. This meeting is also available telephonically and online via Adobe Connect. You must use a touch-tone phone to participate in this meeting. Any interested person may dial the USA toll-free conference number 1–844–467–6272, passcode: 592382, followed by the # sign to participate in this meeting by telephone. The Adobe Connect link is *https://ac.arc.nasa.gov/aero.* Enter as a guest and type your name. NOTE: If dialing in, please ''mute'' your telephone. The agenda for the meeting includes the following topics:

—Urban Air Mobility (UAM) Strategy
—Unmanned Air Systems (UAS) Update
—Low Boom Flight Demonstrator (LBFD) Update

For NASA Ames Research Center visitor access, please go through the Main Gate and show a valid government-issued identification (*i.e.,* driver's license, passport, etc.) to the security guard. Inform the security guard that you are attending a meeting in Building 3. Attendees will also be required to sign a register prior to entering the meeting room. It is imperative that the meeting be held on these dates to the scheduling priorities of the key participants.

Carol J. Hamilton,

Acting Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2018–16966 Filed 8–7–18; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (18–061)]

NASA Advisory Council; Science Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Science Committee of the NASA Advisory Council (NAC). The meeting will be held for the purpose of soliciting, from the scientific community and other persons, scientific and technical information relevant to program planning. This Committee reports to the NAC.

DATES: Monday, August 27, 2018, 8:00 a.m.–5:00 p.m.; and Tuesday, August 28, 2018, 8:00 a.m.–2:45 p.m., PDT. Joint meeting with the NAC Human Exploration and Operations Committee on August 28, 2018.

ADDRESSES: NASA Ames Research Center, NASA Ames Conference Center, Building 3, 500 Severyns Road, Moffett Field, CA 94035.

FOR FURTHER INFORMATION CONTACT: Ms. KarShelia Henderson, Science Mission Directorate, NASA Headquarters, Washington, DC 20546, (202) 358–2355, fax (202) 358–2779, or *khenderson@nasa.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. This meeting is also available telephonically and by WebEx. You must use a touch-tone phone to participate in this meeting. For August 27, please use the following information: the Science Committee meeting will be held in the Showroom. Any interested person may dial the toll free number 1–888–324–2680 or toll access number 1–517–308–9418, passcode: 8870080, followed by the # sign to participate in the meeting by telephone. The WebEx link is *https://nasa.webex.com/;* the meeting number is 995 388 125 and the password is SC@Aug2018 (case sensitive). For August 28, please use the following information: the joint Science Committee/Human Exploration and Operations Committee meeting will be held in the Ballroom. Any interested person may dial the toll free number 1–888–324–9238 or toll access number 1–517–308–9132, passcode: 3403297, followed by the # sign to participate in the meeting by telephone. The WebEx link is *https://nasa.webex.com/,* the meeting number is 996 163 984, and the password is Exploration@2018 (case sensitive). NOTE: If dialing in, please ''mute'' your telephone.

The agenda for the meeting includes the following topics:

—Lunar Exploration Science
—Science Mission Directorate Overview
—Research and Analysis Charge
—Big Data

For NASA Ames Research Center visitor access, please go through the Main Gate and show a valid government-issued identification (*i.e.,* driver's license, passport, etc.) to the security guard. Inform the security guard that you are attending a meeting in Building 3. Attendees will also be required to sign a register prior to entering the meeting room. It is imperative that the meeting be held on these dates to the scheduling priorities of the key participants.

Carol J. Hamilton,

Acting Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2018–16965 Filed 8–7–18; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (18–062)]

NASA Advisory Council; Ad Hoc Task Force on STEM Education; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Ad Hoc Task Force on Science, Technology, Engineering and Mathematics (STEM) of the NASA Advisory Council (NAC). This Task Force reports to the NAC.

DATES: Tuesday, August 28, 2018, 9:30 a.m.–2:30 p.m., PDT.

FOR FURTHER INFORMATION CONTACT: Dr. Beverly Girten, Designated Federal Officer, Office of Education, NASA Headquarters, Washington, DC 20546, (202) 358–0212, or *beverly.e.girten@nasa.gov.*

SUPPLEMENTARY INFORMATION: This meeting will be virtual and will be available telephonically and by WebEx only. You must use a touch tone phone to participate in this meeting. Any interested person may dial the toll free access number 1–844–467–6272 or toll access number 1–720–259–6462, passcode: 634012, followed by the # sign to participate in the meeting by telephone. To join via WebEx, the link is *https://nasa.webex.com/,* the meeting number is 993 201 922 and the password is NAC2018$ (case sensitive.) NOTE: If dialing in, please ''mute'' your telephone. The agenda for the meeting will include the following:

—Opening Remarks by Chair
—Update on New Task Force Members
—Transition Update and STEM Engagement
—Business and Administrative Systems Office Implementation and STEM Engagement Strategic Plan
—STEM Education Advisory Panel
—Status on Federal Five-Year Strategic Plan
—Performance and Evaluation Update
—Space STEM Forum and 50th Anniversary Plans
—Findings and Recommendations to the NAC
—Other Related Topics

For NASA Ames Research Center visitor access, please go through the Main Gate and show a valid government-issued identification (*i.e.,* driver's license, passport, etc.) to the security guard. Inform the security guard that you are attending a meeting in Building 3. Attendees will also be required to sign a register prior to entering the meeting room. It is imperative that the meeting be held on these dates to the scheduling priorities of the key participants.

Carol J. Hamilton,

Acting Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2018–16963 Filed 8–7–18; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2018–052]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when agencies no longer need them for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives of the United States and to destroy, after a specified period, records lacking administrative, legal, research, or other value. NARA publishes notice in the **Federal Register** for records schedules in which agencies propose to destroy records they no longer need to conduct agency business. NARA invites public comments on such records schedules.

DATES: NARA must receive requests for copies in writing by September 7, 2018. Once NARA finishes appraising the records, we will send you a copy of the schedule you requested. We usually prepare appraisal memoranda that contain additional information concerning the records covered by a proposed schedule. You may also

request these. If you do, we will also provide them once we have completed the appraisal. You have 30 days after we send to you these requested documents in which to submit comments.

ADDRESSES: You may request a copy of any records schedule identified in this notice by contacting Records Appraisal and Agency Assistance (ACRA) using one of the following means:

Mail: NARA (ACRA); 8601 Adelphi Road, College Park, MD 20740–6001.

Email: request.schedule@nara.gov.

FAX: 301–837–3698.

You must cite the control number, which appears in parentheses after the name of the agency that submitted the schedule, and a mailing address. If you would like an appraisal report, please include that in your request.

FOR FURTHER INFORMATION CONTACT: Margaret Hawkins, Director, by mail at Records Appraisal and Agency Assistance (ACRA); National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001, by phone at 301–837–1799, or by email at *request.schedule@nara.gov.*

SUPPLEMENTARY INFORMATION: NARA publishes notice in the **Federal Register** for records schedules they no longer need to conduct agency business. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

Each year, Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing records retention periods and submit these schedules for NARA's approval. These schedules provide for timely transfer into the National Archives of historically valuable records and authorize the agency to dispose of all other records after the agency no longer needs them to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

The schedules listed in this notice are media neutral unless otherwise specified. An item in a schedule is media neutral when an agency may apply the disposition instructions to records regardless of the medium in which it creates or maintains the records. Items included in schedules submitted to NARA on or after December 17, 2007, are media neutral unless the item is expressly limited to a specific medium. (See 36 CFR 1225.12(e).)

Agencies may not destroy Federal records without Archivist of the United States' approval. The Archivist approves destruction only after thoroughly considering the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value.

In addition to identifying the Federal agencies and any subdivisions requesting disposition authority, this notice lists the organizational unit(s) accumulating the records (or notes that the schedule has agency-wide applicability when schedules cover records that may be accumulated throughout an agency); provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction); and includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it also includes information about the records. You may request additional information about the disposition process at the addresses above.

Schedules Pending

1. Department of Agriculture, Foreign Agricultural Service (DAA–0166–2018–0028, 2 items, 2 temporary items). Documentation and amendments to marketing plans, cooperator annual progress reports, cooperator contribution reports, and related correspondence.

2. Department of Agriculture, Forest Service (DAA–0095–2018–0007, 1 item, 1 temporary item). General correspondence, memos, and mailing lists related to cooperative fire protection programs.

3. Department of Agriculture, Forest Service (DAA–0095–2018–0008, 1 item, 1 temporary item). General correspondence, studies, and reports related to fire suppression assistance.

4. Department of Agriculture, Forest Service (DAA–0095–2018–0009, 1 item, 1 temporary item). General correspondence, studies, analysis, and reports related to cooperative wildfire programs.

5. Department of Agriculture, Forest Service (DAA–0095–2018–0010, 1 item, 1 temporary item). General correspondence, memos, and training documentation related to forestry assistance programs.

6. Department of Agriculture, Forest Service (DAA–0095–2018–0011, 1 item, 1 temporary item). Correspondence, memos, minutes, and guidance publications related to forest management assistance.

7. Department of Agriculture, Forest Service (DAA–0095–2018–0012, 1 item, 1 temporary item). General correspondence, policies, procedures, administrative studies, and testing sheets related to cooperative nursery production.

8. Department of Agriculture, Forest Service (DAA–0095–2018–0024, 1 item, 1 temporary item). General program administration and correspondence records related to the land exchange program, including unconsummated cases.

9. Department of Agriculture, Forest Service (DAA–0095–2018–0025, 1 item, 1 temporary item). General program administration and correspondence records related to the partial land interest program, including unconsummated cases.

10. Department of Agriculture, Forest Service (DAA–0095–2018–0026, 1 item, 1 temporary item). General program administration and correspondence records related to the rights-of-way acquisition program, including unconsummated cases.

11. Department of Agriculture, Forest Service (DAA–0095–2018–0027, 1 item, 1 temporary item). General program administration and correspondence records related to the sale and granting of land through special acts, including unconsummated cases.

12. Department of Agriculture, Forest Service (DAA–0095–2018–0028, 1 item, 1 temporary item). Management records of the aviation program to include aircraft policy and procedure records, oversight, and evaluation records.

13. Department of Agriculture, Forest Service (DAA–0095–2018–0034, 1 item, 1 temporary item). Reports, indexes, logs, and inventories used in tracking and control of agency records.

14. Department of Agriculture, Forest Service (DAA–0095–2018–0099, 5 items, 5 temporary items). General administrative records relating to equipment development throughout the Equipment Development Centers, including budget files, correspondence, progress reports, and administrative project files.

15. Department of Homeland Security, Bureau of Customs and Border Protection (DAA–0568–2017–0010, 3 items, 3 temporary items). Records related to human resources processes not covered in General Records Schedules.

16. Department of Transportation, National Highway Traffic Safety Administration (DAA–0416–2015–0009, 1 item, 1 temporary item). Master files of an electronic information system used to track fuel economy data for vehicles and manufacturers.

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2018–16913 Filed 8–7–18; 8:45 am]

BILLING CODE 7515–01–P

PENSION BENEFIT GUARANTY CORPORATION

Solicitation of Nominations for Appointment to the Advisory Committee of the Pension Benefit Guaranty Corporation

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) is soliciting nominations for appointment to the Advisory Committee of the PBGC.

DATES: Nominations must be received on or before September 24, 2018. Please allow three weeks for regular mail delivery to PBGC.

ADDRESSES: Nominations must be submitted to Judith Larsen, Office of the Director, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026, or as email attachments to *OfficeOfTheDirector@pbgc.gov*. If sending electronically, please use an attachment in Word or pdf format.

SUPPLEMENTARY INFORMATION: The Pension Benefit Guaranty Corporation (PBGC or the Corporation) administers the pension plan termination insurance program under Title IV of the Employee Retirement Income Security Act of 1974 (ERISA). Section 4002(h) of ERISA provides for the establishment of an Advisory Committee to the Corporation. The Advisory Committee consists of seven members appointed by the President from among individuals recommended by the PBGC Board of Directors, which consists of the Secretaries of Labor, Treasury, and Commerce. The Advisory Committee members are as follows:

- Two representatives of employee organizations;
- Two representatives of employers who maintain pension plans; and
- Three representatives of the general public.

No more than four members of the Committee shall be members of the same political party. Anyone currently subject to federal registration requirements as a lobbyist is not eligible for appointment.

Advisory Committee members must have experience with employee organizations, employers who maintain defined benefit pension plans, the administration or advising of pension plans, or in related fields. Appointments are for three-year terms. Some of the appointments may serve unexpired terms that have less than three years remaining. Reappointments are possible but are subject to the appointment process.

The Advisory Committee's prescribed duties include advising the Corporation as to its policies and procedures relating to investment of moneys, and other issues as the Corporation may request or as the Advisory Committee determines appropriate. The Advisory Committee meets at least six times each year. At least one meeting is a joint meeting with the PBGC Board of Directors.

By February 19, 2019, the terms of all of the Advisory Committee members will have expired. Therefore, PBGC is seeking nominations for all of the seats.

PBGC is committed to equal opportunity in the workplace and seeks a broad-based and diverse Advisory Committee.

If you or your organization wants to nominate one or more people for appointment to the Advisory Committee to represent any of the interest groups specified above, you may submit nominations to PBGC. Nominations may be in the form of a letter, resolution or petition, signed by the person making the nomination or, in the case of a nomination by an organization, by an authorized representative of the organization. PBGC encourages you to include additional supporting letters of nomination. PBGC will not consider self-nominees who have no supporting letters. Please do not include any information that you do not want publicly disclosed.

Nominations, including supporting letters, should:

- State the person's qualifications to serve on the Advisory Committee (including any specialized knowledge or experience relevant to the nominee's proposed Advisory Committee position);
- State that the candidate will accept appointment to the Advisory Committee if offered;
- Include which of the positions (representing interest group) the candidate is being nominated to fill;
- Include the nominee's full name, work affiliation, mailing address, phone number, and email address;
- Include the nominator's full name, mailing address, phone number, and email address; and
- Include the nominator's signature, whether sent by email or otherwise.

PBGC will contact nominees for information on their political affiliation and their status as registered lobbyists. Nominees should be aware of the time commitment for attending meetings and actively participating in the work of the Advisory Committee. Historically, this has meant a commitment of at least 15 days per year. PBGC has a process for vetting nominees under consideration for appointment.

Issued in Washington, DC.

William Reeder,

Director, Pension Benefit Guaranty Corporation.

[FR Doc. 2018–16958 Filed 8–7–18; 8:45 am]

BILLING CODE 7709–02–P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service

AGENCY: U.S. Office of Personnel Management (OPM).

ACTION: Notice.

SUMMARY: This notice identifies Schedule A, B, and C appointing authorities applicable to a single agency that were established or revoked from March 1, 2018 to March 31, 2018.

FOR FURTHER INFORMATION CONTACT: Senior Executive Resources Services, Senior Executive Services and Performance Management, Employee Services, (202) 606–2246.

SUPPLEMENTARY INFORMATION: In accordance with 5 CFR 213.103, Schedule A, B, and C appointing authorities available for use by all agencies are codified in the Code of Federal Regulations (CFR). Schedule A, B, and C appointing authorities applicable to a single agency are not codified in the CFR, but the U.S. Office of Personnel Management (OPM) publishes a notice of agency-specific authorities established or revoked each month in the **Federal Register** at *www.gpo.gov/fdsys/*. OPM also publishes an annual notice of the consolidated listing of all Schedule A, B, and C appointing authorities, current as of June 30, in the **Federal Register**.

Schedule A

No schedule A Authorities to report during March 2018.

Schedule B

No schedule B Authorities to report during March 2018.

Schedule C

The following Schedule C appointing authorities were approved during March 2018.

Agency name	Organization name	Position title	Authorization No.	Effective date
Department of Agriculture	Office of Forest Service	Senior Advisor	DA180127	03/08/2018
	Office of Farm Service Agency	State Executive Director—Delaware.	DA180140	03/23/2018
	Office of Rural Housing Service	Confidential Assistant	DA180150	03/28/2018
	Office of the Secretary	Director of Advance	DA180151	03/28/2018
		Staff Assistant	DA180143	03/29/2018
	Office of Communications	Advance Lead	DA180152	03/29/2018
Department of Commerce	Office of the Director	Chief of Congressional Affairs	DC180090	03/12/2018
	Office of the Chief of Staff	Confidential Assistant	DC180104	03/19/2018
	Office of Patent and Trademark	Chief Communications Officer	DC180114	03/20/2018
	Office of the Under Secretary	Senior Advisor	DC180100	03/29/2018
Department of Defense	Office of the Assistant Secretary of Defense (Legislative Affairs).	Director of Strategic Communications for Legislative Affairs.	DD180067	03/16/2018
		Special Assistant (Legislative Affairs).	DD180074	03/22/2018
	Office of the Secretary	Director of Communications	DD180072	03/29/2018
	Office of the Under Secretary of Defense (Acquisition, Technology, and Logistics) Office of the Under Secretary of Defense (Policy).	Director of Operations for Research and Engineering.	DD180065	03/16/2018
		Special Assistant for Homeland Defense and Defense Support of Civil Authorities.	DD180066	03/19/2018
	Office of Washington Headquarters Services.	Defense Fellow (2)	DD180060	03/16/2018
			DD180076	03/28/2018
Department of the Air Force	Office of the Secretary	Special Assistant and Speechwriter	DF180016	03/29/2018
Department of the Navy	Office of the Under Secretary of the Navy.	Special Assistant for Financial Management and Comptroller.	DN180014	03/16/2018
Department of Energy	Office of Public Affairs	Associate Deputy Press Secretary	DE170191	03/01/2018
	Office of Economic Impact and Diversity.	Special Advisor	DE180033	03/12/2018
	Assistant Secretary for Fossil Energy.	Senior Advisor	DE180060	03/23/2018
Environmental Protection Agency	Office of the Associate Administrator for Congressional and Intergovernmental Relations.	Special Advisor	EP180026	03/01/2018
Federal Trade Commission	Office of the Chairman	Director, Office of Policy Planning	FT180001	03/29/2018
		Director, Office of Public Affairs	FT180002	03/29/2018
General Services Administration	Office of the Administrator	Confidential Assistant	GS180023	03/13/2018
Department of Health and Human Services.	Office of Administration for Children and Families.	Policy Advisor	DH180059	03/06/2018
	Office of Center for Consumer Information and Insurance Oversight.	Policy Advisor	DH180082	03/08/2018
	Office of Centers for Medicare and Medicaid Services.	Senior Advisor for Medicare	DH180064	03/06/2018
		Special Assistant	DH180088	03/23/2018
	Office of Indian Health Service	Senior Advisor	DH180054	03/06/2018
	Office for Civil Rights	Senior Advisor for Conscience Protection.	DH180065	03/06/2018
	Office of the Assistant Secretary for Health.	Executive Director, President's Council on Fitness, Sports, and Nutrition.	DH180057	03/06/2018
		Advisor	DH180086	03/08/2018
		Senior Policy Advisor	DH180103	03/29/2018
	Office of the Assistant Secretary for Legislation.	Senior Advisor	DH180084	03/22/2018
	Office of the Assistant Secretary for Public Affairs.	Director of Communications	DH180072	03/19/2018
		Assistant Speechwriter	DH180078	03/27/2018
	Office of the Secretary	Advisor	DH180095	03/29/2018
Department of Homeland Security	Office of the Under Secretary for National Protection and Programs Directorate.	Director of Public Affairs	DM180097	03/06/2018
	Office of the Chief of Staff	Deputy White House Liaison	DM180109	03/13/2018
	Office of Countering Weapons of Mass Destruction.	Director for Countering Weapons of Mass Destruction Policy and Plans.	DM180119	03/16/2018
	Office of the Assistant Secretary for Public Affairs.	Press Assistant	DM180124	03/16/2018

Agency name	Organization name	Position title	Authorization No.	Effective date
Department of Housing and Urban Development.	Office of Congressional and Intergovernmental Relations.	Advisor for Intergovernmental Relations.	DU180042	03/13/2018
		Deputy Assistant Secretary for Congressional Relations.	DU180051	03/19/2018
	Office of Public Affairs	Director of Speechwriting for Program and Policy.	DU180043	03/27/2018
Department of the Interior	Secretary's Immediate Office	Speechwriter	DI180034	03/01/2018
	Secretary's Immediate Office	Deputy White House Liaison	DI180035	03/08/2018
	Office of Bureau of Ocean Energy Management.	Advisor	DI180032	03/23/2018
Department of Justice	Office of Legislative Affairs	General Attorney (2)	DJ180058	03/08/2018
			DJ180059	03/08/2018
	Office of the Attorney General	Senior Policy Advisor	DJ180071	03/22/2018
	Office of Justice Programs	Senior Advisor	DJ180042	03/23/2018
	Office of Public Affairs	Program Event Press Specialist	DJ180061	03/28/2018
Department of Labor	Office of Public Affairs	Senior Advisor for Digital Strategy	DL180054	03/22/2018
		Press Assistant	DL180057	03/27/2018
	Office of Public Liaison	Special Assistant	DL180053	03/27/2018
Office of Management and Budget	Office of General Counsel	Confidential Assistant	BO180011	03/19/2018
Office of National Drug Control Policy.	Office of Public Affairs	Public Affairs Specialist (Program Support).	QQ180004	03/22/2018
Office of Personnel Management	Office of the Director	Special Assistant	PM180017	03/22/2018
	Congressional, Legislative, and Intergovernmental Affairs.	Legislative Director	PM180015	03/27/2018
Small Business Administration	Office of Congressional and Legislative Affairs.	Special Advisor	SB180021	03/16/2018
Social Security Administration	Office of the Commissioner	Confidential Assistant	SZ180022	03/01/2018
Department of State	Office of the Chief of Protocol	Assistant Chief of Protocol for Ceremonials.	DS180025	03/01/2018
		Chief of Staff	DS180034	03/01/2018
	Bureau of International Organizational Affairs.	Senior Advisor	DS180035	03/06/2018
	Office of Policy Planning	Senior Advisor	DS180031	03/08/2018
	Bureau of Economic and Business Affairs.	Special Assistant	DS180033	03/20/2018
	Office of Global Women's Issues	Special Assistant	DS180039	03/27/2018
Department of Transportation	Office of Chief Information Officer	Special Assistant	DT180037	03/15/2018
	Office of the Administrator	Director of Governmental Affairs	DT180009	03/23/2018
	Office of the Assistant Secretary for Budget and Programs.	Special Assistant	DT180032	03/23/2018
	Office of the Secretary	Special Assistant	DT180034	03/23/2018
		Special Assistant for Advance (2)	DT180035	03/23/2018
			DT180036	03/23/2018
Department of Veterans Affairs	Office of the Secretary and Deputy	Senior Advisor for Investigations	DV180022	03/05/2018

The following Schedule C appointing authorities were revoked during March 2018.

Agency name	Organization name	Title	Request No.	Date vacated
Department of Agriculture	Office of the Assistant Secretary for Congressional Relations.	Confidential Assistant	DA180019	03/03/2018
Department of Commerce	Office of Assistant Secretary for Global Markets.	Special Advisor for Select United States of America.	DC170147	03/17/2018
	Office of International Trade Administration.	Confidential Assistant	DC170118	03/03/2018
	Office of Scheduling and Advance	Deputy Director of Advance	DC170079	03/02/2018
	Office of the Chief of Staff	Scheduler	DC170146	03/03/2018
		Scheduling Assistant	DC170139	03/03/2018
		Confidential Assistant	DC170062	03/31/2018
	Office of the General Counsel	Senior Counsel to the General Counsel.	DC170095	03/31/2018
	Office of the Under Secretary	Senior Advisor for Advance	DC180004	03/17/2018
	Office of Patent and Trademark Office.	Deputy Chief Communications Officer for Strategic Communications.	DC170077	03/31/2018
		Senior Advisor	DC170088	03/31/2018

Agency name	Organization name	Title	Request No.	Date vacated
Office of the Secretary of Defense	Office of the Assistant Secretary of Defense (Legislative Affairs).	Special Assistant to the Assistant Secretary of Defense (Legislative Affairs) for Installations, Environment, and Energy.	DD170153	03/03/2018
Department of Education	Office of Communications and Outreach.	Communications Director	DB170122	03/03/2018
Department of Energy	Office of the Assistant Secretary for Electricity Delivery and Energy Reliability.	Senior Advisor	DE170090	03/02/2018
	Office of Public Affairs	Press Assistant	DE170125	03/03/2018
Department of Health and Human Services.	Office of the Assistant Secretary of Health.	Liaison to the Veterans Administration.	DH170137	03/16/2018
		Special Advisor	DH170277	03/17/2018
	Office of Indian Health Service	Senior Advisor to the Director, Indian Health Service.	DH170299	03/17/2018
	Office of the General Counsel	Advisor and Legal Counsel	DH170334	03/17/2018
	Office of the Secretary	Policy Advisor for Health Policy	DH170262	03/17/2018
		Special Assistant	DH170244	03/17/2018
	Centers for Medicare and Medicaid Services.	Director of Strategic Communications.	DH180025	03/18/2018
	Office of the Assistant Secretary for Legislation.	Advisor	DH180007	03/30/2018
Department of State	Office of the Chief of Protocol	Senior Protocol Officer	DS170177	03/03/2018
Department of the Treasury	Department of the Treasury	Speechwriter	DY170067	03/03/2018
Environmental Protection Agency	Office of the Administrator	Senior Advisor to the Administrator for Agriculture Policy.	EP180001	03/04/2018
	Office of the Associate Administrator for Congressional and Intergovernmental Relations.	Special Assistant to the Office of Congressional and Intergovernmental Relations.	EP170078	03/17/2018
General Services Administration	Office of the Administrator	Senior Advisor for Administrative Services.	GS170025	03/30/2018
National Aeronautics and Space Administration.	Office of Communications	Social Media Specialist	NN180004	03/17/2018
Small Business Administration	Office of Congressional and Legislative Affairs.	Legislative Assistant	SB170011	03/17/2018

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR, 1954–1958 Comp., p. 218.

U.S. Office of Personnel Management.

Jeff T.H. Pon,

Director.

[FR Doc. 2018–16927 Filed 8–7–18; 8:45 am]

BILLING CODE 6325–39–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83765; File No. SR–NYSEArca–2018–55]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To List and Trade Shares of the GraniteShares Gold MiniBAR Trust

August 2, 2018.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 19, 2018, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade shares of GraniteShares Gold MiniBAR Trust under NYSE Arca Rule 8.201–E (''Commodity-Based Trust Shares''). The proposed change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade shares (''Shares'') of the GraniteShares Gold MiniBAR Trust under NYSE Arca Rule 8.201–E.[4] Under NYSE Arca Rule 8.201–E, the Exchange may propose to list and/or trade pursuant to unlisted trading privileges (''UTP'') ''Commodity-Based Trust Shares.'' [5]

The Trust will not be registered as an investment company under the

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Trust has filed a registration statement on Form S–1 under the Securities Act of 1933 (15 U.S.C. 77a), dated July 2, 2018 (File No. 333–226034) (the ''Registration Statement''). The description of the operation of the Trust and the Shares herein is based, in part, on the Registration Statement.

[5] Commodity-Based Trust Shares are securities issued by a trust that represents investors' discrete identifiable and undivided beneficial ownership interest in the commodities deposited into the Trust.

Investment Company Act of 1940, as amended.[6] The Trust is not a commodity pool for purposes of the Commodity Exchange Act, as amended.[7]

The sponsor of the Trust is GraniteShares LLC (''Sponsor''). The ''Trustee'' is The Bank of New York Mellon and the ''Custodian'' is ICBC Standard Bank Plc.

The Commission has previously approved listing on the Exchange under NYSE Arca Rules 5.2–E(j)(5) and 8.201–E of other precious metals and gold-based commodity trusts, including the GraniteShares Gold Trust; [8] Merk Gold Trust; [9] ETFS Gold Trust,[10] ETFS Platinum Trust [11] and ETFS Palladium Trust (collectively, the ''ETFS Trusts''); [12] APMEX Physical-1 oz. Gold Redeemable Trust; [13] Sprott Gold Trust; [14] SPDR Gold Trust (formerly, streetTRACKS Gold Trust); iShares Silver Trust; [15] iShares COMEX Gold Trust; [16] Long Dollar Gold Trust; [17] Euro Gold Trust, Pound Gold Trust and Yen Gold Trust; [18] and the Gold Trust.[19]

[6] 15 U.S.C. 80a–1.

[7] 17 U.S.C. 1.

[8] Securities Exchange Act Release No. 81077 (July 5, 2017) (SR–NYSEArca–2017–55) (order approving listing and trading shares of the GraniteShares Gold Trust under NYSE Arca Equities Rule 8.201).

[9] Securities Exchange Act Release No. 71378 (January 23, 2014), 79 FR 4786 (January 29, 2014) (SR–NYSEArca–2013–137).

[10] Securities Exchange Act Release No. 59895 (May 8, 2009), 74 FR 22993 (May 15, 2009) (SR–NYSEArca–2009–40).

[11] Securities Exchange Act Release No. 61219 (December 22, 2009), 74 FR 68886 (December 29, 2009) (SR–NYSEArca–2009–95).

[12] Securities Exchange Act Release No. 61220 (December 22, 2009), 74 FR 68895 (December 29, 2009) (SR–NYSEArca–2009–94).

[13] Securities Exchange Act Release No 66930 (May 7, 2012), 77 FR 27817 (May 11, 2012) (SR–NYSEArca–2012–18)

[14] Securities Exchange Act Release No. 61496 (February 4, 2010), 75 FR 6758 (February 10, 2010) (SR–NYSEArca–2009–113).

[15] *See* Securities Exchange Act Release No. 58956 (November 14, 2008), 73 FR 71074 (November 24, 2008) (SR–NYSEArca–2008–124) (approving listing on the Exchange of the iShares Silver Trust)).

[16] *See* Securities Exchange Act Release No.56224 (August 8, 2007), 72 FR 45850 (August 15, 2007) (SR–NYSEArca-2007–76) (approving listing on the Exchange of the street TRACKS Gold Trust); Securities Exchange Act Release No. 56041 (July 11, 2007), 72 FR 39114 (July 17, 2007) (SR–NYSEArca–2007–43) (order approving listing on the Exchange of iShares COMEX Gold Trust).

[17] *See* Securities Exchange Act Release No. 79518 (December 9, 2016), 81 FR 90876 (December 15, 2016) (SR–NYSEArca–2016–84) (order approving listing and trading of shares of the Long Dollar Gold Trust).

[18] *See* Securities Exchange Act Release No. 80840 (June 17, 2017) (SR–NYSEArca-2017–33) (order approving listing and trading of shares of the Euro Gold Trust, Pound Gold Trust, and the Yen Gold Trust under NYSE Arca Equities Rule 8.201).

[19] *See* Securities Exchange Act Release No.81918 (October 23, 2017), 82 FR 49884 (October 27, 2017) (SR–NYSEArca–2017–98) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, to List and Trade Shares of The Gold Trust under NYSE Arca Rule 8.201–E).

Prior to their listing on the Exchange, the Commission approved listing of the streetTRACKS Gold Trust on the New York Stock Exchange (''NYSE'') [20] and listing of iShares COMEX Gold Trust and iShares Silver Trust on the American Stock Exchange LLC.[21] In addition, the Commission has approved trading of the streetTRACKS Gold Trust and iShares Silver Trust on the Exchange pursuant to UTP.[22]

The Exchange represents that the Shares satisfy the requirements of NYSE Arca Rule 8.201–E and thereby qualify for listing on the Exchange.[23]

Operation of the Trust [24]

The investment objective of the Trust will be for the Shares to reflect the performance of the price of gold, less the expenses and liabilities of the Trust. The Trust will issue Shares which represent units of fractional undivided beneficial interest in and ownership of the Trust.

The Trust will not trade in gold futures, options or swap contracts on any futures exchange or over the counter (''OTC''). The Trust will not hold or trade in commodity futures contracts, ''commodity interests'', or any other instruments regulated by the Commodities Exchange Act. The Trust will take delivery of physical gold that complies with the London Bullion Markets Association (''LBMA'') gold delivery rules.

The Shares are intended to constitute a simple and cost-effective means of making an investment similar to an investment in gold. Although the Shares are not the exact equivalent of an investment in gold, they are intended to provide investors with an alternative that allows a level of participation in the gold market through the securities market.

[20] *See* Securities Exchange Act Release No. 50603 (October 28, 2004), 69 FR 64614 (November 5, 2004) (SR–NYSE–2004–22) (order approving listing of street TRACKS Gold Trust on NYSE).

[21] *See* Securities Exchange Act Release Nos. 51058 (January 19, 2005), 70 FR 3749 (January 26, 2005) (SR-Amex-2004–38) (order approving listing of iShares COMEX Gold Trust on the American Stock Exchange LLC); 53521 (March 20, 2006), 71 FR 14967 (March 24, 2006) (SR–Amex–2005–72) (approving listing on the American Stock Exchange LLC of the iShares Silver Trust).

[22] *See* Securities Exchange Act Release Nos. 53520 (March 20, 2006), 71 FR 14977 (March 24, 2006) (SR–PCX–2005–117) (approving trading on the Exchange pursuant to UTP of the iShares Silver Trust); 51245 (February 23, 2005), 70 FR 10731 (March 4, 2005) (SR–PCX–2004–117) (approving trading on the Exchange of the streetTRACKS Gold Trust pursuant to UTP).

[23] With respect to the application of Rule 10A–3 (17 CFR 240.10A–3) under the Act, the Trust relies on the exemption contained in Rule 10A–3(c)(7).

[24] The description of the operation of the Trust, the Shares and the gold market contained herein is based, in part, on the Registration Statement. *See* note 4, *supra.*

Operation of the Gold Market

The global trade in gold consists of OTC transactions in spot, forwards, and options and other derivatives, together with exchange-traded futures and options.

The OTC gold market includes spot, forward, and option and other derivative transactions conducted on a principal-to-principal basis. While this is a global, nearly 24-hour per day market, its main centers are London, New York, and Zurich.

According to the Registration Statement, most OTC market trades are cleared through London. The LBMA plays an important role in setting OTC gold trading industry standards. A London Good Delivery Bar (as described below), which is acceptable for settlement of any OTC transaction, will be acceptable for delivery to the Trust in connection with the issuance of Baskets.

The most significant gold futures exchange in the U.S. is COMEX, operated by Commodities Exchange, Inc., a subsidiary of New York Mercantile Exchange, Inc., and a subsidiary of the Chicago Mercantile Exchange Group (the ''CME Group''). Other commodity exchanges include the Tokyo Commodity Exchange (''TOCOM''), the Multi Commodity Exchange Of India (''MCX''), the Shanghai Futures Exchange, ICE Futures US (the ''ICE''), and the Dubai Gold & Commodities Exchange.

The London Gold Bullion Market

According to the Registration Statement, most trading in physical gold is conducted on the OTC market, predominantly in London. LBMA coordinates various OTC-market activities, including clearing and vaulting, acts as the principal intermediary between physical gold market participants and the relevant regulators, promotes good trading practices and develops standard market documentation. In addition, the LBMA promotes refining standards for the gold market by maintaining the ''London Good Delivery List,'' which identifies refiners of gold that have been approved by the LBMA. In the OTC market, gold bars that meet the specifications for weight, dimensions, fineness (or purity), identifying marks (including the assay stamp of an LBMA-acceptable refiner) and appearance described in ''The Good Delivery Rules for Gold and Silver Bars'' published by the LBMA are referred to

as ''London Good Delivery Bars.'' A London Good Delivery Bar (typically called a ''400 ounce bar'') must contain between 350 and 430 fine troy ounces of gold (1 troy ounce = 31.1034768 grams), with a minimum fineness (or purity) of 995 parts per 1000 (99.5%), be of good appearance and be easy to handle and stack. The fine gold content of a gold bar is calculated by multiplying the gross weight of the bar (expressed in units of 0.025 troy ounces) by the fineness of the bar. A London Good Delivery Bar must also bear the stamp of one of the refiners identified on the London Good Delivery List.

Following the enactment of the Financial Markets Act 2012, the Prudential Regulation Authority of the Bank of England is responsible for regulating most of the financial firms that are active in the bullion market, and the Financial Conduct Authority is responsible for consumer and competition issues.

Creation and Redemption of Shares

According to the Registration Statement, the Trust will create and redeem Shares on a continuous basis in one or more blocks of 50,000 Shares (a block of 50,000 Shares is called a ''Basket''). As described below, the Trust will issue Shares in Baskets to certain authorized participants (''Authorized Participants'') on an ongoing basis. Baskets of Shares will only be issued or redeemed in exchange for an amount of gold determined by the Trustee on each day that the Exchange is open for regular trading. No Shares will be issued unless the Custodian has allocated to the Trust's account the corresponding amount of gold. Initially, a Basket will require delivery of 500 fine ounces of gold. The amount of gold necessary for the creation of a Basket, or to be received upon redemption of a Basket, will decrease over the life of the Trust, due to the payment or accrual of fees and other expenses or liabilities payable by the Trust.

Baskets may be created or redeemed only by Authorized Participants. Orders must be placed by 3:59 p.m. Eastern Time (''E.T.''). The day on which the Trust receives a valid purchase or redemption order is the order date.

Each Authorized Participant must be a registered broker-dealer, a participant in Depository Trust Corporation, have entered into an agreement with the Trustee (the ''Authorized Participant Agreement'') and be in a position to transfer gold to, and take delivery of gold from, the Custodian through one or more gold accounts. The Authorized Participant Agreement provides the procedures for the creation and redemption of Baskets and for the delivery of gold in connection with such creations or redemptions.

According to the Registration Statement, Authorized Participants may surrender Baskets of Shares in exchange for the corresponding Basket Amount announced by the Trustee. Upon surrender of such Shares and payment of the Trustee's applicable fee and of any expenses, taxes or charges (such as stamp taxes or stock transfer taxes or fees), the Trustee will deliver to the order of the redeeming Authorized Participant the amount of gold corresponding to the redeemed Baskets.

Before surrendering Baskets of Shares for redemption, an Authorized Participant must deliver to the Trustee a written request indicating the number of Baskets it intends to redeem and the location where it would like to take delivery of the gold represented by such Baskets. The date the Trustee receives that order determines the Basket Amount to be received in exchange. However, orders received by the Trustee after 3:59 p.m. Eastern Time (''E.T.'') will not be accepted.

The redemption distribution from the Trust will consist of a credit to the redeeming Authorized Participant's unallocated account representing the amount of the gold held by the Trust evidenced by the Shares being redeemed as of the date of the redemption order.

Net Asset Value

According to the Registration Statement, the net asset value of the Trust will be obtained by subtracting the Trust's expenses and liabilities on any day from the value of the gold owned by the Trust on that day; the net asset value (''NAV'') per Share will be obtained by dividing the net asset value of the Trust on a given day by the number of Shares outstanding on that day. On each day on which the Exchange is open for regular trading, the Trustee will determine the net asset value of the Trust and the NAV per Share as promptly as practicable after 4:00 p.m. (E.T.). The Trustee will value the Trust's gold on the basis of LBMA Gold Price PM. If there is no LBMA Gold Price PM on any day, the Trustee is authorized to use the LBMA Gold Price AM announced on that day. If neither price is available for that day, the Trustee will value the Trust's gold based on the most recently announced LBMA Gold Price PM or LBMA Gold Price AM. If the Sponsor determines that such price is inappropriate to use, the Sponsor will identify an alternate basis for evaluation to be employed by the Trustee. Further, the Sponsor may instruct the Trustee to use on an on-going basis a different publicly available price which the Sponsor determines to fairly represent the commercial value of the Trust's gold.

Availability of Information Regarding Gold

Currently, the Consolidated Tape Plan does not provide for dissemination of the spot price of a commodity such as gold over the Consolidated Tape. However, there will be disseminated over the Consolidated Tape the last sale price for the Shares. In addition, there is a considerable amount of information about gold and gold markets available on public websites and through professional and subscription services.

Investors may obtain gold pricing information on a 24-hour basis based on the spot price for an ounce of Gold from various financial information service providers, such as Reuters and Bloomberg.

Reuters and Bloomberg, for example, provide at no charge on their websites delayed information regarding the spot price of Gold and last sale prices of Gold futures, as well as information about news and developments in the gold market. Reuters and Bloomberg also offer a professional service to subscribers for a fee that provides information on Gold prices directly from market participants. Complete real-time data for Gold futures and options prices traded on the COMEX are available by subscription from Reuters and Bloomberg. There are a variety of other public websites providing information on gold, ranging from those specializing in precious metals to sites maintained by major newspapers. In addition, the LBMA Gold Price is publicly available at no charge at *www.lbma.org.uk.*

Availability of Information

The intraday indicative value (''IIV'') per Share for the Shares will be disseminated by one or more major market data vendors. The IIV will be calculated based on the amount of gold held by the Trust and a price of gold derived from updated bids and offers indicative of the spot price of gold.[25]

The website for the Trust (*www.graniteshares.com*) will contain the following information, on a per Share basis, for the Trust: (a) The mid-point of the bid-ask price[26] at the close

[25] The IIV on a per Share basis disseminated during the Core Trading Session should not be viewed as a real-time update of the NAV, which is calculated once a day.

[26] The bid-ask price of the Shares will be determined using the highest bid and lowest offer

of trading (''Bid/Ask Price''), and a calculation of the premium or discount of such price against such NAV; and (b) data in chart format displaying the frequency distribution of discounts and premiums of the Bid/Ask Price against the NAV, within appropriate ranges, for each of the four previous calendar quarters. The website for the Trust will also provide the Trust's prospectus. Finally, the Trust's website will provide the last sale price of the Shares as traded in the U.S. market. In addition, information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers.

Criteria for Initial and Continued Listing

The Trust will be subject to the criteria in NYSE Arca Rule 8.201–E(e) for initial and continued listing of the Shares.

A minimum of two Baskets or 100,000 Shares will be required to be outstanding at the start of trading, which is equivalent to 1,000 fine ounces of gold or about $1.24 million as of July 18, 2018. The Exchange believes that the anticipated minimum number of Shares outstanding at the start of trading is sufficient to provide adequate market liquidity.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Trust subject to the Exchange's existing rules governing the trading of equity securities. Trading in the Shares on the Exchange will occur in accordance with NYSE Arca Rule 7.34–E(a). The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in NYSE Arca Rule 7.6–E, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00 for which the MPV for order entry is $0.0001.

Further, NYSE Arca Rule 8.201–E sets forth certain restrictions on ETP Holders acting as registered Market Makers in the Shares to facilitate surveillance. Under NYSE Arca Rule 8.201–E(g), an ETP Holder acting as a registered Market Maker in the Shares is required to provide the Exchange with information relating to its trading in the underlying gold, related futures or options on futures, or any other related derivatives. Commentary .04 of NYSE Arca Rule 11.3–E requires an ETP Holder acting as a registered Market Maker, and its affiliates, in the Shares to establish, maintain and enforce written policies and procedures reasonably designed to prevent the misuse of any material nonpublic information with respect to such products, any components of the related products, any physical asset or commodity underlying the product, applicable currencies, underlying indexes, related futures or options on futures, and any related derivative instruments (including the Shares).

As a general matter, the Exchange has regulatory jurisdiction over its ETP Holders and their associated persons, which include any person or entity controlling an ETP Holder. A subsidiary or affiliate of an ETP Holder that does business only in commodities or futures contracts would not be subject to Exchange jurisdiction, but the Exchange could obtain information regarding the activities of such subsidiary or affiliate through surveillance sharing agreements with regulatory organizations of which such subsidiary or affiliate is a member.

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. Trading on the Exchange in the Shares may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which conditions in the underlying gold market have caused disruptions and/or lack of trading, or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. In addition, trading in Shares will be subject to trading halts caused by extraordinary market volatility pursuant to the Exchange's ''circuit breaker'' rule.[27] The Exchange will halt trading in the Shares if the NAV of the Trust is not calculated or disseminated daily. The Exchange may halt trading during the day in which an interruption occurs to the dissemination of the IIV, as described above. If the interruption to the dissemination of the IIV persists past the trading day in which it occurs, the Exchange will halt trading no later than the beginning of the trading day following the interruption.

Surveillance

The Exchange represents that trading in the Shares will be subject to the existing trading surveillances administered by the Exchange, as well as cross-market surveillances administered by the Financial Industry Regulatory Authority (''FINRA'') on behalf of the Exchange, which are designed to detect violations of Exchange rules and applicable federal securities laws.[28] The Exchange represents that these procedures are adequate to properly monitor Exchange trading of the Shares in all trading sessions and to deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.

The surveillances referred to above generally focus on detecting securities trading outside their normal patterns, which could be indicative of manipulative or other violative activity. When such situations are detected, surveillance analysis follows and investigations are opened, where appropriate, to review the behavior of all relevant parties for all relevant trading violations.

The Exchange or FINRA, on behalf of the Exchange, or both, will communicate as needed regarding trading in the Shares with other markets and other entities that are members of the Intermarket Surveillance Group (''ISG''), and the Exchange or FINRA, on behalf of the Exchange, or both, may obtain trading information regarding trading in the Shares from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.[29]

Also, pursuant to NYSE Arca Rule 8.201–E(g), the Exchange is able to obtain information regarding trading in the Shares and the underlying gold, gold futures contracts, options on gold futures, or any other gold derivative, through ETP Holders acting as registered Market Makers, in connection with such ETP Holders' proprietary or customer trades through ETP Holders which they effect on any relevant market.

In addition, the Exchange also has a general policy prohibiting the

on the Consolidated Tape as of the time of calculation of the closing day NAV.

[27] *See* NYSE Arca Rule 7.12–E.

[28] FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[29] For a list of the current members of ISG, *see www.isgportal.org.*

distribution of material, non-public information by its employees.

All statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange listing rules specified in this rule filing shall constitute continued listing requirements for listing the Shares of the Trust on the Exchange.

The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Trust to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor for compliance with the continued listing requirements. If the Trust is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

Information Bulletin

Prior to the commencement of trading, the Exchange will inform its ETP Holders in an Information Bulletin of the special characteristics and risks associated with trading the Shares. Specifically, the Information Bulletin will discuss the following: (1) The procedures for purchases and redemptions of Shares in Baskets (including noting that Shares are not individually redeemable); (2) NYSE Arca Rule 9.2–E(a), which imposes a duty of due diligence on its ETP Holders to learn the essential facts relating to every customer prior to trading the Shares; (3) how information regarding the IIV is disseminated; (4) the requirement that ETP Holders deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; (5) the possibility that trading spreads and the resulting premium or discount on the Shares may widen as a result of reduced liquidity of gold trading during the Core and Late Trading Sessions after the close of the major world gold markets; and (6) trading information. For example, the Information Bulletin will advise ETP Holders, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Trust. The Exchange notes that investors purchasing Shares directly from the Trust will receive a prospectus. ETP Holders purchasing Shares from the Trust for resale to investors will deliver a prospectus to such investors.

In addition, the Information Bulletin will reference that the Trust is subject to various fees and expenses as will be described in the Registration Statement. The Information Bulletin will also reference the fact that there is no regulated source of last sale information regarding physical gold, that the Commission has no jurisdiction over the trading of gold as a physical commodity, and that the Commodity Futures Trading Commission has regulatory jurisdiction over the trading of gold futures contracts and options on gold futures contracts.

The Information Bulletin will also discuss any relief, if granted, by the Commission or the staff from any rules under the Act.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5) [30] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in NYSE Arca Rule 8.201–E. The Exchange has in place surveillance procedures that are adequate to properly monitor trading in the Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. The Exchange may obtain information via the ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that there is a considerable amount of gold price and gold market information available on public websites and through professional and subscription services. Investors may obtain on a 24-hour basis gold pricing information based on the spot price for an ounce of gold from various financial information service providers. Investors may obtain gold pricing information based on the spot price for an ounce of gold from various financial information service providers. Current spot prices also are generally available with bid/ask spreads from gold bullion dealers. In addition, the Trust's website will provide pricing information for gold spot prices and the Shares. Market prices for the Shares will be available from a variety of sources including brokerage firms, information websites and other information service providers. The NAV of the Trust will be published by the Sponsor on each day that the NYSE Arca is open for regular trading and will be posted on the Trust's website. The IIV relating to the Shares will be widely disseminated by one or more major market data vendors at least every 15 seconds during the Core Trading Session. In addition, the LBMA Gold Price is publicly available at no charge at *www.lbma.org.uk.* The Trust's website will also provide the Trust's prospectus, as well as the two most recent reports to stockholders. In addition, information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers.

The proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of an additional type of exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding gold pricing.

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 Exchange believes the proposed rule change will enhance competition by accommodating Exchange trading of an additional exchange-traded product relating to physical gold.

[30] 15 U.S.C. 78f(b)(5).

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

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.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEArca–2018–55 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2018–55. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2018–55, and should be submitted on or before August 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Eduardo A. Aleman,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83763; File No. SR–CHX–2018–001]

Self-Regulatory Organizations; Chicago Stock Exchange, Inc.; Notice of Withdrawal of a Proposed Rule Change To Adopt the Route QCT Cross Routing Option

August 2, 2018.

On March 6, 2018, the Chicago Stock Exchange, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt the Route QCT Cross routing option. The proposed rule change was published for comment in the **Federal Register** on March 20, 2018.[3] On May 1, 2018, pursuant to Section 19(b)(2) of the Exchange Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On June 13, 2018, the Commission instituted proceedings under Section 19(b)(2)(B) of the Exchange Act[6] to determine whether to approve or disapprove the proposed rule change.[7] The Commission received one comment letter on the proposed rule change.[8]

On July 26, 2018, the Exchange withdrew the proposed rule change (SR–CHX–2018–001).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–16889 Filed 8–7–18; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–83767; File No. SR–FICC–2018–006]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Proposed Rule Change To Codify the Processing of Conditional Prepayment Rate Claims in the MBSD Rules and Make Other Changes

August 2, 2018.

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 July 26, 2018, Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of amendments to the FICC Mortgage-Backed Securities Division (''MBSD'') Clearing Rules (''MBSD Rules'') in order to (i) add terms governing MBSD's

[31] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 82870 (March 14, 2018), 83 FR 12214.

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 83143, 83 FR 20123 (May 7, 2018).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 83425, 83 FR 28477 (June 19, 2018).

[8] *See* letter from Tracy Richardson, Tribal Technology Trade Inc., dated June 14, 2018, available at *https://www.sec.gov/comments/sr-chx-2018-001/chx2018001.htm.*

[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

processing of conditional prepayment rate (''CPR'') claims to the MBSD Rules and (ii) make certain clarifications and corrections in the MBSD Rules, as described in greater detail below.[3]

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FICC is proposing to amend the MBSD Rules in order to (i) add terms governing MBSD's processing of CPR claims to the MBSD Rules and (ii) make certain clarifications and corrections in the MBSD Rules.

(i) Background

As discussed in more detail below, the submission of CPR claims is an established process that occurs today pursuant to FICC's procedures. FICC is proposing to add provisions to the MBSD Rules to formalize this process in the MBSD Rules.

Mortgage pools[4] are often traded in To-Be-Announced (TBA) trades, which are trades for which the actual identities of and/or the number of pools underlying each trade are unknown at the time of trade execution. MBSD guidelines provide that two business days prior to the established settlement date of the TBA settlement obligations, the Clearing Member that has an obligation to deliver pools for the TBA transaction (*i.e.,* the ''seller'') must allocate the pools to be delivered.[5] Pursuant to the MBSD Rules, Clearing Members may substitute an underlying pool after it has been allocated with respect to a pool deliver obligation by providing instructions to FICC.[6]

CPR is the percentage of the outstanding loan balance for a pool that is expected to be repaid over a one year period.[7] For instance, a 10% CPR means that 10% of a pool's outstanding loan balance is expected to be repaid in the next year. A CPR claim arises when an underlying TBA pool is allocated or substituted with a pool that pays down at a faster rate (*i.e.,* has a higher CPR) than the average pay down rate for pools of the same type as the underlying pool being replaced.[8] The result is that the buyer is receiving a pool with less value than anticipated based on the TBA terms.

The industry currently has a process pursuant to which a buyer may make a CPR claim against the seller as set forth in the SIFMA Guidelines.[9] The CPR claim process is intended to compensate the buyer for the excess amount that it is paying for the pool being delivered.[10] Pursuant to SIFMA Guidelines, an entity is entitled to make a CPR claim if (i) the allocation or substitution giving rise to the CPR claim occurred after the factor release date[11] following the scheduled contractual settlement date relating to the trade, (ii) the pools involved in the claim meet the criteria for fast paying pools in accordance with SIFMA Guidelines, (iii) the amount of the CPR claim is $10,000 or greater, or, in the case that an entity is submitting a re-transmittal[12] of a CPR claim, the CPR claim is $500 or greater, and (iv) 90% of the buyer's claimable unit has settled.[13]

FICC currently processes CPR claims that it receives from Clearing Members in a manner consistent with SIFMA Guidelines, except that (i) FICC currently uses a different definition of ''claimable unit'' as discussed below and (ii) for re-transmittals, FICC's current procedures provide a minimum threshold of $5,000 (rather than $500 as set forth in the SIFMA Guidelines). FICC is proposing to codify its existing CPR claims process in the MBSD Rules, including adding a provision providing that a Clearing Member's cash settlement obligations would include the positive or negative amount of any valid CPR claim. The proposed MBSD CPR claims process would generally follow the CPR claims process set forth in the SIFMA Guidelines and MBSD's current CPR claims process, with the following exceptions:

(A) Definition of Claimable Unit

FICC is proposing to add to the MBSD Rules two definitions of ''claimable unit,'' the use of which would depend on the type of transaction. Pursuant to SIFMA Guidelines and FICC's current process, CPR claims are based on a ''claimable unit'' which defines the pool or group of pools that are included in a particular CPR claim.[14] Pursuant to SIFMA Guidelines a claimable unit is based on all pools allocated for a trade between factor release dates that have the same underlying TBA characteristics, such as product, coupon, trade date, settlement date and price.[15]

FICC currently processes CPR claims using a different definition of claimable unit than the SIFMA definition. FICC's CPR claims process currently uses a definition of claimable unit based on characteristics of pools after MBSD Pool Netting[16] takes place rather than based on underlying TBA characteristics. The

[3] Capitalized terms used herein and not otherwise defined shall have the meaning assigned to such terms in the MBSD Rules, *available at http://www.dtcc.com/legal/rules-and-procedures.*

[4] A pool is a collection of mortgage loans or other collateral assembled by an originator or master services as collateral for a mortgaged-back security.

[5] *See* Section 1 of MBSD Rule 7, *supra* note 3, which provides that ''[i]n order for the Corporation to process data for Pool Comparison, the Corporation must receive data from the long and short sides of the allocated pool submission in the format and within the timeframes specified in guidelines issued by the Corporation from time to time.''

[6] Section 5 of MBSD Rule 8, *supra* note 3. Section 5 of MBSD Rule 8 provides that substitutions may be made pursuant to the communication links, formats, timeframes and deadlines established by FICC and that a Clearing Member with a pool receive obligation (*i.e.,* the ''buyer'') must accept the substituted pool in accordance with FICC's procedures. *Id.*

[7] *See* definition of ''CPR'' in Chapter 2 of the SIFMA Guidelines. SIFMA Guidelines refer generally to the guidelines for good delivery of mortgage-backed securities as promulgated from time to time by The Securities Industry and Financial Markets Association (''SIFMA''), an industry trade group. *See* definition of ''SIFMA Guidelines'' in MBSD Rule 1, *supra* note 3. The SIFMA Guidelines, *located at https://www.sifma.org/resources/general/tba-market-governance/* under ''Uniform Practices Manual,'' are trading, clearing and settlement guidelines prepared by SIFMA intended to reflect common industry practices relating to confirming, comparing and settling mortgage-backed securities.

[8] *See* Section A.16 of Chapter 8 of the SIFMA Guidelines, *supra* note 7.

[9] *See id.*

[10] *See* Section A.16.d of Chapter 8 of the SIFMA Guidelines, *supra* note 7.

[11] The term ''factor release date'' means, with respect to a pool, the date on which the Federal National Mortgage Association (''Fannie Mae''), the Federal Home Loan Mortgage Corporation (''Freddie Mac'') or the Government National Mortgage Association (''Ginnie Mae''), as applicable, release the ''factor'' that represents the percentage of the agency's original balance of the pool that remains outstanding as of such date.

[12] A re-transmittal of a CPR claim occurs when a party with the pool deliver obligation passes the CPR claims it received to the entities that sent it the pools it used for delivery.

[13] *See* Section A.16 of Chapter 8 of the SIFMA Guidelines, *supra* note 7.

[14] *See* Section A.16.b of Chapter 8 of the SIFMA Guidelines, *supra* note 7.

[15] *See* Section A.16.f(i)(7) of Chapter 8 of the SIFMA Guidelines, *supra* note 7.

[16] Pursuant to the MBSD Rules, the term ''Pool Netting'' means the service provided to Clearing Members, as applicable, and the operations carried out by FICC in the course of providing such service in accordance with MBSD Rule 8. MBSD Rule 1, *supra* note 3.

Pool Netting process generally reduces the number of pool settlements by aggregating and matching offsetting allocated pools submitted by Clearing Members to arrive at a single net position per counterparty in a particular pool number. If a pool obligation is a result of Pool Netting, FICC is unable to track the pool obligation to an original TBA trade or trades and would be unable to group pool obligations for CPR claims based on TBA characteristics as provided in SIFMA Guidelines.

FICC is proposing to use the same definition of claimable unit for CPR claims as SIFMA Guidelines if the pool obligations upon which the CPR claims are based have not been through MBSD Pool Netting, as provided in subsection (1) below. FICC is proposing to use a different definition of claimable unit for CPR claims if the pool obligations upon which the CPR claims are based have been through the MBSD Pool Netting process, as described in subsection (2) below.

(1) Proposed Definition of Claimable Unit Consistent With SIFMA Guidelines for CPR Claims That *Are Not* a Result of Pool Netting

FICC is proposing to use the same definition of claimable unit used in the SIFMA Guidelines for CPR claims based on pool obligations that *are not* a result of Pool Netting. This definition would be used for pool allocations or substitutions for pool obligations that have been allocated after the factor release date because pool obligations allocated after the factor release date do not go through the Pool Netting process. As a result, FICC would be able to track the pool obligation to an original TBA trade, which would allow FICC to group the pool obligation with other pool obligations based on TBA characteristics. This proposed definition would be the same as the definition used in the SIFMA Guidelines but would be different from the definition used in FICC's existing CPR claims process.

(2) Proposed Definition of Claimable Unit Different From SIFMA Guidelines for CPR Claims That *Are* a Result of Pool Netting

FICC is proposing to use a different definition of a claimable unit from the SIFMA Guidelines definition for CPR claims based on pool obligations that *are* a result of Pool Netting. FICC is proposing to define a claimable unit for such pool obligations based on pool characteristics after Pool Netting, rather than based on the original TBA pool characteristics. This definition would be used for substitutions for pool obligations that are a result of Pool Netting because FICC would be unable to track the pool obligation to an original TBA trade and thus unable to group such pool obligation with other pool obligations based on TBA characteristics. This proposed definition would be different than the definition used in the SIFMA Guidelines but would be the same as the definition currently used in FICC's existing CPR claims process.

(B) Re-Transmittal Threshold

FICC is proposing to add to the MBSD Rules two minimum thresholds ($500 and $5,000) for re-transmittals [17] of CPR claims, the use of which would depend on the type of transaction. The minimum threshold for a re-transmittal of a CPR claim under SIFMA Guidelines is $500.[18] FICC's current process provides that the minimum threshold for re-transmittals is $5,000. FICC is proposing to use the $500 re-transmittal minimum threshold for allocations (and related substitutions) where the allocations were made after the applicable factor release date. This $500 proposed minimum threshold would be the same as the minimum threshold in the SIFMA Guidelines but different from FICC's existing CPR claims process. FICC is proposing to use a $5,000 re-transmittal threshold for substitutions relating to allocations that were made prior to the factor release date following the contractual settlement date. This $5,000 proposed minimum threshold would be different than the minimum threshold in the SIFMA Guidelines but would be the same as the minimum threshold used in FICC's existing CPR claims process.

FICC is proposing to change its current practice and add a proposed $500 re-transmittal threshold for certain allocations described above in the MBSD Rules in order to be more consistent with SIFMA Guidelines and established industry practice. FICC is proposing to use a higher $5,000 threshold, which is consistent with its current process, for re-transmittals for certain substitutions described above to avoid having to process multiple smaller transactions, which FICC believes would likely be administratively burdensome.

(ii) Proposed MBSD Rule Changes

To codify the CPR claims process as described above, the proposed rule change would add a description of the CPR claim process in a new Section 10 of MBSD Rule 9, including a defined term for ''CPR Claim.'' In addition, the proposed rule change would specify the validation process for CPR claims, which, as described above, would codify existing FICC practices relating to CPR claims and provide that the process for CPR claims is consistent with SIFMA Guidelines, in each case, with the exceptions noted above in Items II(A)1(i)(A) and (B).

Specifically, the proposed rule change would specify that CPR claims submitted would be reviewed by FICC to validate the following: (i) The claimable unit with respect to the CPR claim meets the criteria for fast paying pools as set forth in SIFMA Guidelines, (ii) the CPR claim amount is $10,000 or greater, unless the CPR claim is a re-transmittal of a CPR claim, in which case, (a) if the CPR claim relates to an allocation of a pool effected after the factor release date following the contractual settlement date and/or substitution of related pools, the amount is $500 or greater or (b) if the CPR claim relates to a substitution of a pool that was allocated prior to the factor release date following the contractual settlement date, the amount is $5,000 or greater and (iii) 90% of the Clearing Member's claimable unit has settled. Consistent with FICC's current CPR claims process, the proposed rule change would also specify that (1) FICC maintains the right to process CPR claims with no minimum denomination, (2) CPR claims may be apportioned to more than one participant, (3) CPR claims may be comprised of both debits and credits, (4) FICC would process all CPR claims on the Class ''B'' settlement date in the month following the transmittal month and (5) FICC would notify the Clearing Member that the CPR claim has been rejected if the CPR claim is determined to be invalid. In addition, the proposed rule change would specify that FICC shall not guaranty CPR claim payments, and any credit to be received with respect to a CPR claim would be reduced to the extent the corresponding debit in connection with a CPR claim is not paid.

To ensure that Clearing Members understand the potential credits and debits relating to CPR claims, the proposed rule change would add credits and debits relating to CPR claims in Section 7 of MBSD Rule 11 as items for end of day cash balance computations.

To further describe the CPR claims process as set forth above, a cross-reference for the defined term ''CPR Claim'' and new defined terms ''Claimable Unit'' and ''Factor Release Date'' would be added to MBSD Rule 1, which are consistent with existing FICC

[17] *See supra* note 10.

[18] *See* Section A.16.f(i)(6) of Chapter 8 of the SIFMA Guidelines, *supra* note 7.

practices relating to CPR claims and with SIFMA Guidelines, in each case, with the exceptions noted above in Items II(A)1(i)(A) and (B).

The definitions for Fannie Mae, Freddie Mac and Ginnie Mae would be corrected in MBSD Rule 1 to be consistent with industry practice and with their usage throughout the MBSD Rules. In addition, the definition of ''SIFMA Guidelines'' would be clarified by adding a link identifying the location of the SIFMA Guidelines on the SIFMA website.

2. Statutory Basis

Section 17A(b)(3)(F) of the Act [19] requires, in part, that the MBSD Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions.

FICC believes that the proposed changes to add the MBSD's CPR claims process to the MBSD Rules are consistent with Section 17A(b)(3)(F) of the Act.[20] The proposed rule changes to add the CPR claims process to the MBSD Rules would provide a standard and efficient mechanism in the MBSD Rules to compensate a buyer that receives faster paying pools that is consistent with accepted industry standards as set forth in the SIFMA Guidelines. While FICC provides a process for CPR claims pursuant to its existing procedures, the proposed changes would codify such procedures in the MBSD Rules and would make MBSD's CPR claims process more consistent with SIFMA Guidelines, with the exceptions noted above in Items II(A)1(i)(A) and (B). Having the CPR claims process stated in the MBSD Rules would enable Clearing Members to understand how CPR claims would be validated and processed through FICC's facilities and how FICC's CPR claims process would differ from SIFMA Guidelines with respect to the definition of claimable unit and the re-transmittal minimum threshold as set forth above. Therefore, allowing Clearing Members to make and receive CPR claims through the use of FICC facilities in a manner that is consistent with industry standards and that is clearly stated in the MBSD Rules would promote the prompt and accurate clearance and settlement of securities transactions, consistent with the requirements of Section 17A(b)(3)(F) of the Act.[21]

FICC believes that the proposed changes correcting the definitions of Fannie Mae, Freddie Mac and Ginnie Mae are consistent with Section 17A(b)(3)(F) of the Act [22] because the corrections would update such terms to reflect usage in the industry and current usage in the MBSD Rules. As such, the proposed changes would enable Clearing Members to have a better understanding of the MBSD Rules and the usage of such terms therein, and thereby assist in promoting the prompt and accurate clearance and settlement of securities transactions, consistent with the requirements of Section 17A(b)(3)(F) of the Act.[23]

FICC believes that the proposed change clarifying the definition of SIFMA Guidelines by adding a link identifying the location of the SIFMA Guidelines on the SIFMA website is consistent with Section 17A(b)(3)(F) of the Act [24] because the proposed change would enhance clarity of the MBSD Rules by providing Clearing Members with an easier method of finding the SIFMA Guidelines that are referenced in the MBSD Rules. Providing clarity in the location of the SIFMA Guidelines would enable Clearing Members to more quickly locate the SIFMA Guidelines when such Clearing Members are reading MBSD Rules that reference the SIFMA Guidelines, thus making it easier for such Clearing Members to review such MBSD Rules and understand their rights and obligations thereunder. As such, the proposed change would assist in promoting the prompt and accurate clearance and settlement of securities transactions, consistent with the requirements of Section 17A(b)(3)(F) of the Act.[25]

Rule 17Ad–22(e)(23)(ii) under the Act [26] requires FICC to establish, implement, maintain and enforce written policies and procedures reasonably designed to provide sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency. The proposed rule changes to add CPR claims and corresponding credits and debits in Section 7 of MBSD Rule 11 as items for end of day cash balance computations are consistent with this provision and would help ensure that the charges relating to CPR claims are clear to Clearing Members. Having clear provisions in this regard would enable Clearing Members to better understand the operation of the pool settlement charges by providing sufficient information for Clearing Members to identify potential debits and credits that may be incurred with respect to CPR claims. As such, FICC believes the proposed rule change is consistent with Rule 17Ad–22(e)(23)(ii) of the Act.[27]

(B) Clearing Agency's Statement on Burden on Competition

FICC believes that the proposed rule changes to add the CPR claims process in the MBSD Rules as described above could have an impact on competition because the CPR claims process would result in CPR claim charges for Clearing Members against whom CPR claims are processed. Specifically, FICC believes this proposed rule change could burden competition by negatively affecting such Clearing Members' operating costs. While such Clearing Members may experience increases in their charges as a result of CPR claims processed through FICC, FICC does not believe such change would in and of itself mean that the burden on competition is significant. Regardless of whether the burden on competition is deemed significant, FICC believes any burden on competition that is created by the proposed rule changes to add the proposed CPR claims process would be necessary and appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.[28]

FICC believes the proposed rule changes to include the MBSD CPR claims process in the MBSD Rules would be necessary in furtherance of the purposes of the Act.[29] FICC believes that allocations or substitutions by sellers of TBA pool transactions with a pool that pays down at a faster rate than the average pay down rate for pools of the same type as the underlying pool being replaced can create uncertainty regarding the value of pools being received by the buyer. Persistent delivery of faster paying pools could create market inefficiencies, increase credit risk for market participants and heighten overall systemic risk. The proposed rule changes to add the CPR claims process to the MBSD Rules would mitigate against this systemic risk by (i) describing the types of CPR claims that FICC would process and thereby discouraging allocations or substitutions using faster paying pools that may give rise to CPR claims and (ii) providing a clear process in the MBSD Rules to compensate a buyer that receives such faster paying pools. Therefore, FICC believes the proposed

[19] 15 U.S.C. 78q–1(b)(3)(F).

[20] *Id.*

[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] 17 CFR 240.17Ad–22(e)(23)(ii).

[27] *Id.*

[28] 15 U.S.C. 78q–1(b)(3)(I).

[29] *Id.*

rule changes to add the MBSD CPR claims process to the MBSD Rules would be necessary in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.[30]

FICC also believes any burden on competition that is created by the proposed rule changes to add the MBSD CPR claims process in the MBSD Rules would be appropriate in furtherance of the purposes of the Act.[31] Under the proposal, the MBSD CPR claims process would be consistent, with the exceptions noted above in Items II(A)1(i)(A) and (B), with SIFMA Guidelines, which represent the current accepted industry practice with respect to CPR claims. Therefore, the MBSD CPR claims process would provide a mechanism by which Clearing Members could make and receive CPR claims that would be consistent with accepted industry practice. In addition, CPR claims would be imposed upon Clearing Members that choose to allocate or substitute using faster paying pools and no Clearing Members would be disproportionally impacted. As such, FICC believes the proposed rule changes to add the CPR claims process that is consistent, to the extent practicable and appropriate, with SIFMA Guidelines would be appropriate in furtherance of the purposes of the Act, as permitted by Section 17A(b)(3)(I) of the Act.[32]

FICC does not believe there would be an impact on competition with the proposed rule changes that would update the definitions of Fannie Mae, Freddie Mac, Ginnie Mae and SIFMA Guidelines.[33] These changes would provide enhanced clarity to the MBSD Rules and would not affect Clearing Members' rights and obligations. As such, FICC believes that these proposed rule changes would not have any impact on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

FICC has not received or solicited any written comments relating to this proposal. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FICC–2018–006 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE Washington, DC 20549.

All submissions should refer to File Number SR–FICC–2018–006. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of FICC and on DTCC's website (*http://dtcc.com/legal/sec-rule-filings.aspx*). All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FICC–2018–006 and should be submitted on or before August 29, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–16901 Filed 8–7–18; 8:45 am]

BILLING CODE 8011–01–P

[30] *Id.*

[31] *Id.*

[32] *Id.*

[33] *Id.*

[34] 17 CFR 200.30–3(a)(12).

SOCIAL SECURITY ADMINISTRATION

[Docket No. SSA–2018–0036]

Notice of Senior Executive Service Performance Review Board Membership

AGENCY: Social Security Administration.

ACTION: Notice of Senior Executive Service Performance Review Board Membership.

Title 5, U.S. Code, 4314 (c)(4), requires that the appointment of Performance Review Board members be published in the **Federal Register** before service on said Board begins.

The following persons will serve on the Performance Review Board which oversees the evaluation of performance appraisals of Senior Executive Service members of the Social Security Administration:

Bonnie Doyle
Stephen Evangelista *
Joanne Gasparini
Erik Hansen
John Lee
Joseph Lytle
Dan Parry
Van Roland *
Patrice Stewart
* New Member

Marianna LaCanfora,

Deputy Commissioner for Human Resources.

[FR Doc. 2018–16945 Filed 8–7–18; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF STATE

[Public Notice: 10492]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: Exhibition of Two Roman-Era Objects

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that two objects to be

exhibited in the Arms and Armor Department of The Metropolitan Museum of Art, 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 Metropolitan Museum of Art, New York, New York, from on or about August 6, 2018, until on or about September 30, 2021, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Elliot Chiu, Attorney-Adviser, 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 Delegation of Authority No. 236–11 of July 27, 2018.

Jennifer Z. Galt,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–16929 Filed 8–7–18; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 10491]

Notice of Determinations; Culturally Significant Objects Imported for Exhibition—Determinations: ''Animal-Shaped Vessels From the Ancient World: Feasting With Gods, Heroes, and Kings'' Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects to be included in the exhibition ''Animal-Shaped Vessels from the Ancient World: Feasting with Gods, Heroes, and Kings,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to loan agreements with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at the Harvard Art Museums, Cambridge, Massachusetts, from on or about September 16, 2018, until on or about January 13, 2019, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Elliot Chiu, Attorney-Adviser, 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 Delegation of Authority No. 236–11 of July 27, 2018.

Jennifer Z. Galt,

Principal Deputy Assistant Secretary for Educational and Cultural Affairs, Department of State.

[FR Doc. 2018–16928 Filed 8–7–18; 8:45 am]

BILLING CODE 4710–05–P

SUSQUEHANNA RIVER BASIN COMMISSION

Commission Meeting

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: The Susquehanna River Basin Commission will hold its regular business meeting on September 7, 2018, in Binghamton, New York. Details concerning the matters to be addressed at the business meeting are contained in the Supplementary Information section of this notice.

DATES: The meeting will be held on Friday, September 7, 2018, at 9 a.m.

ADDRESSES: The meeting will be held at the DoubleTree by Hilton Binghamton, North Riverside Room, 225 Water Street, Binghamton, NY 13901.

FOR FURTHER INFORMATION CONTACT: Gwyn Rowland, Manager, Governmental & Public Affairs, 717–238–0423, ext. 1316.

SUPPLEMENTARY INFORMATION: The business meeting will include actions or presentations on the following items: (1) Informational presentation of interest to the upper Susquehanna River region; (2) release of proposed rulemaking and policies for public comment; (3) revisions to financial instruments and policies; (4) ratification/approval of contracts/grants; (5) a report on delegated settlements; (6) a proposed consumptive use mitigation project located in Conoy Township, Lancaster County, Pa.; and (7) Regulatory Program projects.

Regulatory Program projects and the consumptive use mitigation project listed for Commission action are those that were the subject of a public hearing conducted by the Commission on August 2, 2018, and identified in the notice for such hearing, which was published in 83 FR 31439, July 5, 2018.

The public is invited to attend the Commission's business meeting. Comments on the Regulatory Program projects and the consumptive use mitigation project were subject to a deadline of August 13, 2018. Written comments pertaining to other items on the agenda at the business meeting may be mailed to the Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, Pennsylvania 17110–1788, or submitted electronically through *http://www.srbc.net/pubinfo/publicparticipation.htm.* Such comments are due to the Commission on or before August 31, 2018. Comments will not be accepted at the business meeting noticed herein.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.,* 18 CFR parts 806, 807, and 808.

Dated: August 3, 2018.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2018–16980 Filed 8–7–18; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Release From Federal Surplus Property and Grant Assurance Obligations at Daniel K. Inouye International Airport (HNL), Honolulu, Hawaii

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of request to release airport land.

SUMMARY: The Federal Aviation Administration (FAA) proposes to rule and invites public comment on the

application for a release of approximately 9.34 acres of airport property at the Daniel K. Inouye International Airport (HNL), Honolulu, Hawaii from all federal obligations contained in the Quitclaim Deed, dated April 18, 2000, and Grant Assurances because the portion of land is not needed for airport purposes. The land requested to be released is located approximately one mile east of the airport completely separated by a lagoon and the Sand Island Access Road, a major public roadway. The release will allow the State of Hawaii (State) to transfer the property from the State Airports Division at fair market value to the State Highways and Harbors Divisions, thereby benefiting the Airport and serving the interest of civil aviation. The proposed use of the land after the transfer of jurisdiction will be compatible with the airport and will not interfere with the airport or its operation.

DATED: Comments must be received on or before September 7, 2018.

FOR FURTHER INFORMATION CONTACT: Comments on the request may be mailed or delivered to the FAA at the following address: Mr. Gordon Wong, Manager, Federal Aviation Administration, Honolulu Airports District Office, **Federal Register** Comment, 300 Ala Moana Boulevard, Honolulu, HI 96850–0001. In addition, one copy of the comment submitted to the FAA must be mailed or delivered to Jade T. Butay, Director of Transportation, State of Hawaii, Department of Transportation, 869 Punchbowl Street, Honolulu, HI 96813–5097.

SUPPLEMENTARY INFORMATION: In accordance with the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR 21), Public Law 106–181 (Apr. 5, 2000; 114 Stat. 61), this notice must be published in the **Federal Register** 30 days before the Secretary may waive any condition imposed on a federally obligated airport by surplus property conveyance deeds or grant agreements.

The following is a brief overview of the request:

The State of Hawaii requested a release from public airport purposes and grant assurance obligations for approximately 9.34 acres of airport land from the 11.34-acre site to allow for its sale and a land-use change to use for other than aeronautical purposes on the remaining approximately 2.0 acres of airport property. In 1989, Congress authorized conveying the 11.34 acres land to the State of Hawaii under Public Law 101–189, Section 2814, *Land Conveyances, Kapalama Military Reservation, Hawaii.* Under Governor's Executive Order No. 4454 dated April 25, 2014, the 11.34-acre parcel was set aside to the State of Hawaii, Department of Transportation for public airport purposes. The land is located approximately one mile east of the airfield, outside of the airport, separated by the Keehi Lagoon, and the Sand Island Access Road. The land has been utilized for industrial warehouse operations during most of the past ten years and is currently vacant. The land no longer serves an airport purpose.

The State of Hawaii will transfer the Airports Division's jurisdiction of approximately 8.37 acres parcel to the State Harbors Division and approximately 0.97 acres of property to the State Highways Division totaling approximately 9.34 acres for fair market value compensation. The Airports Division will retain and lease the remaining 2.0 acres of the land for fair market rental value for non-aeronautical revenue producing purposes.

The sales proceeds and rental income will be devoted to airport operations and capital projects. The reuse of the property will not interfere with the airport or its operation; thereby, serve the interests of civil aviation.

Issued in Honolulu, Hawaii, on July 30, 2018.

Gordon Wong,

Manager, Honolulu Airports District Office, Western-Pacific Region.

[FR Doc. 2018–16971 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Meetings; A Notice by the Federal Aviation Administration

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

ACTION: Notice of meeting.

SUMMARY: The Federal Aviation Administration (FAA) is announcing the upcoming meetings of the International Aircraft Materials Fire Test Forum (IAMFTF) and the International Aircraft Systems Fire Protection Forum (IASFPF). The IAMFTF and IASFPF were established to provide a forum for interested parties to review and provide feedback on FAA fire safety research driven by current and emerging aircraft systems fire threats and test methods. This notification provides details of where to find the date, location, and agenda for the upcoming meetings.

Date and Location: The meeting dates and locations are determined based upon the availability of host organizations to provide meeting space. The FAA Fire Safety Branch website (*https://www.fire.tc.faa.gov/Meetings/meetings.asp*) contains all information for upcoming meetings and meeting registration. The meetings are open to the public but due to limited capacity, registration is mandatory.

FOR FURTHER INFORMATION CONTACT: April Horner, Meeting Coordinator, William J. Hughes Technical Center, Building 287, Atlantic City International Airport, NJ 08405, telephone: (609) 485–4471, email: *april.ctr.horner@faa.gov*.

SUPPLEMENTARY INFORMATION: The IAMFTF and IASFPF began in the early 1990's as forums to discuss aircraft fire safety research.

The IAMFTF began in 1991 to provide a forum for discussion of aircraft materials fire test methods, and to enable interested parties to contribute to improvement of those test methods through research. The IAMFTF also provides a setting to share research information generated by the FAA as well as other entitites. Topics include tests to assess flammability properties of thermal/acoustic insulation, composite structure, electrical wiring and non-tradtional metal alloys. The meetings typically occur 3 times per year in the spring, summer and fall, and are facilitated by the Fire Safety Branch at the FAA's William J. Hughes Technical Center.

The IASFPF began as a forum to discuss research and development (R&D) on replacements of Halon fire extguishing agents in October 1993. The IASFPF originally focused on R&D into minimum performance standards and test methodologies for non-halon aircraft fire suppression agents/systems in cargo compartments, engine nacelles, hand held extinguishers, and lavatory trash receptacles. The IASFPF's focus has expanded to include a forum for R&D for all aircraft system fire protection. The meetings occur twice per year, typically in May and October and are also facilitated by the Fire Safety Branch at the FAA's William J. Hughes Technical Center.

Topics include research into minimum performance standards for aircraft handheld extinguishers, cargo compartment fire suppression systems, and engine nacelles. Halon replacement agents for these areas are also discussed. Additionally, topics such as research on powerplants fire testing, lithium batteries, fuel cells, fuel tank explosion protection (including fuel flammability, nitrogen inerting, other methods of

explosion protection), fire protection in hidden areas of the aircraft, and fire detection R&D are discussed in the IASFPF.

The IAMFTF and IASFPF meetings follow a town hall style format. Neither has a standing membership, nor is an advisory body and do not make recommendations on regulations or policy. Any technical research issues that have future relevance to regulations or policy will be handled through the formal processes in place to include full public participation.

The meetings are open to the public, and are typically attended by the international aviation community including industry, government, and academia with an interest in aircraft fire protection systems. Due to limited capacity, advanced registration is required to attend.

Agenda for the 2018 IAMFTF and IASFPF Meetings

An agenda will be published at least one month in advance of each meeting on the FAA Fire Safety Branch website (*https://www.fire.tc.faa.gov*).

Attendance at the Upcoming Meetings

Interested persons may attend the meeting. Because seating is limited, if you plan to attend please register in advance on the FAA Fire Safety Branch website (*https://www.fire.tc.faa.gov*) so that meeting space may be made to accommodate all attendees.

Record of the Meeting

A meeting summary for the IAMFTF and IASFPF meetings will be posted on the FAA Fire Safety Branch website (*https://www.fire.tc.faa.gov*) after the conclusion of the meeting. Issued on 07/31/2018.

David Blake,

Manager, Fire Safety Branch, ANG–E21.

[FR Doc. 2018–16962 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee; Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Aviation Rulemaking Advisory Committee (ARAC) meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the ARAC.

DATES: The meeting will be held on September 20, 2018, starting at 1:00 p.m. Eastern Standard Time. Arrange oral presentations by September 4, 2018.

ADDRESSES: The meeting will take place at the Federal Aviation Administration, Bessie Coleman Room, 800 Independence Avenue SW, Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: Lakisha Pearson, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, telephone (202) 267–4191; fax (202) 267–5075; email *9-awa-arac@faa.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. 2), we are giving notice of a meeting of the ARAC taking place on September 20, 2018, at the Federal Aviation Administration, Bessie Coleman Room, 800 Independence Avenue SW, Washington, DC 20591.

The Draft Agenda includes:

1. Status Report from the FAA
2. Status Updates:
   a. Active Working Groups
   b. Transport Airplane and Engine (TAE) Subcommittee
3. Recommendation Reports
4. Any Other Business

The Agenda will be published on the FAA Meeting web page (*https://www.faa.gov/regulations_policies/rulemaking/npm/*) once it is finalized.

Attendance is open to the interested public but limited to the space available. Please confirm your attendance with the person listed in the **FOR FURTHER INFORMATION CONTACT** section no later than September 4, 2018. Please provide the following information: Full legal name, country of citizenship, and name of your industry association, or applicable affiliation. If you are attending as a public citizen, please indicate so.

For persons participating by telephone, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section by email or phone for the teleconference call-in number and passcode. Callers are responsible for paying long-distance charges.

The public must arrange by September 4, 2018, to present oral statements at the meeting. The public may present written statements to the Aviation Rulemaking Advisory Committee by providing 25 copies to the Designated Federal Officer, or by bringing the copies to the meeting.

If you are in need of assistance or require a reasonable accommodation for this meeting, please contact the person listed under the heading **FOR FURTHER INFORMATION CONTACT**. Sign and oral interpretation, as well as a listening device, can be made available if requested 10 calendar days before the meeting.

Issued in Washington, DC, on August 2, 2018.

Lirio Liu,

Designated Federal Officer, Aviation Rulemaking Advisory Committee.

[FR Doc. 2018–16961 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2016–0130]

Commercial Driver's License: Application for Exemption; Missouri Department of Revenue (DOR)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for renewal of exemption; request for comments.

SUMMARY: FMCSA announces that it has received an application from the Missouri DOR for a renewal of its exemption from the Agency's commercial driver's license (CDL) regulations. These regulations require a driver to pass the general knowledge test before being issued a Commercial Learner's Permit (CLP). The exemption renewal would allow the Missouri DOR to continue to waive the mandatory knowledge test requirement for qualified veterans who participated in dedicated training in approved military programs. The Missouri DOR states that its goal is to continue to assist qualified veterans in obtaining employment when returning to the civilian workforce, and granting this exemption renewal will assist those veterans who have already been through extensive military training. The Missouri DOR currently holds an exemption for the period of October 27, 2016, through October 29, 2018, and is requesting a 2-year renewal. FMCSA requests public comment on the Missouri DOR's application for exemption.

DATES: Comments must be received on or before September 7, 2018.

ADDRESSES: You may submit comments identified by Federal Docket Management System (FDMS) Number FMCSA–2016–0130 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building,

Ground Floor, Room W12–140, Washington, DC 20590–0001.

- *Hand Delivery or Courier:* West Building, Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 1–202–493–2251.

Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *www.regulations.gov,* including any personal information included in a comment. Please see the *Privacy Act* heading below.

Docket: For access to the docket to read background documents or comments, go to *www.regulations.gov* at any time or visit Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. The on-line FDMS is available 24 hours each day, 365 days each year. If you want acknowledgement that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: For information concerning this notice, contact Mr. Richard Clemente, FMCSA Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards; Telephone: (202) 366–2722. Email: *MCPSD@dot.gov.* If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2016–0130), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to *www.regulations.gov* and put the docket number, ''FMCSA–2016–0130'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *www.regulations.gov* and insert the docket number, ''FMCSA–2016–0130'' in the ''Keyword'' box and click ''Search.'' Next, click ''Open Docket Folder'' button and choose the document listed to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by compliance with the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reason for the grant or denial, and, if granted, the specific person or class of persons receiving the exemption, and the regulatory provision or provisions from which exemption is granted. The notice must also specify the effective period of the exemption (up to 5 years), and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Request for Exemption

The Missouri DOR's initial exemption application from the provisions of 49 CFR 383.71(a)(2)(ii) was submitted in 2016; a copy is in the docket identified at the beginning of this notice. That 2016 application describes fully the nature of the Missouri DOR's request, and the reasons for its request. The Missouri DOR contends that those qualified veterans who participated in dedicated training in approved military programs have already received numerous hours of classroom training, practical skills training, and one-on-one road training that are essential for safe driving. The original exemption was granted on October 27, 2016 (81 FR 74861) and expires on October 29, 2018. Missouri DOR now requests a 2-year renewal of the exemption. The current exemption allows all States to waive the CDL knowledge test for qualified current or former military personnel who participated in training in military heavy-vehicle driving programs, but does not require them to do so.

The Missouri DOR provided several reasons for this renewal of the exemption request, including:

- The proposed regulatory change to 49 CFR parts 383 and 384 for Military Licensing and State Commercial Driver Licensing Reciprocity [82 FR 26894, June 12, 2017] has not yet been posted as a final rulemaking by the Agency;
- The Missouri legislature did not pass the enabling legislation to pursue full implementation during a recent legislative session; and
- Missouri, as well as other State Driver Licensing Agencies (SDLAs) that have implemented or want to pursue implementation of these provisions, must have an exemption renewal in place until such time as the proposed regulatory change is approved and posted as final.

In addition, because the issue concerning the Missouri DOR request could be applicable in each of the States, FMCSA requests public comment on whether the exemption, if granted, should cover all SDLAs.

A copy of the Missouri DOR's application for exemption renewal is available for review in the docket for this notice.

Issued on: July 27, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018–16949 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2018–0008–N–6]

Approved Agency Information Collection Activities

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Notice of Office of Management and Budget (OMB) Approval of Revised Instructions for Form FRA F 6180.57 and Other Recent FRA Information Collection OMB Approvals.

SUMMARY: FRA announces that OMB approved the information collection requests (ICRs) identified below for 3 years.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W33–497, Washington, DC 20590 (telephone: (202) 493–6292) or Ms. Kim Toone, Information Collection Clearance Officer, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W34–212, Washington, DC 20590 (telephone: (202) 493–6132).

SUPPLEMENTARY INFORMATION: On June 6, 2018, OMB approved revised instructions Form FRA F 6180.57, Highway-Rail Grade Crossing Accident/Incident Report, for 3 years under OMB No. 2130–0500 (49 CFR part 225). This latest approval authorizes FRA to capture information concerning post-accident toxicological testing for certain human-factor highway-rail grade crossing accidents and incidents in the narrative block of this form. The newly revised 49 CFR 219.201, effective on June 12, 2017, requires post-accident toxicological testing of railroad employees when at least one of five specific requirements is met for certain human factor categories of highway-rail grade crossing accidents and incidents. Additionally, under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA announces that OMB approved the renewal ICRs identified below for 3 years. These renewal ICRs pertain to 49 CFR parts 213, 217, 218, 224, 227, 228, 229, 231, 232, 234, 237, 238, 239, 241, 242, 243, and 272. Finally, FRA announces that OMB approved two study-related renewal ICRs for 3 years.

The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to display OMB control numbers and inform respondents of their legal significance once OMB approval is obtained. In the past 12 months, OMB approved the following renewal information collections with the following new expiration dates: (1) OMB No. 2130–0500 (49 CFR part 225) (Form FRA F 6180.55/55a/56/57/78/81/98107/150)—June 30, 2021; (2) OMB No. 2130–0545, Passenger Train Emergency Preparedness (49 CFR part 239)—July 31, 2020; (3) OMB No. 2130–0552, Locomotive Cab Sanitation Standards (49 CFR part 229)—July 31, 2020; (4) OMB No. 2130–0564, Locomotive Crashworthiness (49 CFR part 229)—July 31, 2020; (5) OMB No. 2130–0602, Critical Incident Stress Plans (49 CFR part 272)—August 31, 2020; (6) OMB No. 2130–0005, Hours of Service Regulations (49 CFR part 228) (Form FRA F 6180.3)—January 31, 2021; (7) OMB No. 2130–0566, Reflectorization of Freight Rolling Stock (49 CFR part 224) (Form FRA F 6180.113)—November 30, 2020; (8) OMB No. 2130–0594, Railroad Safety Appliance Standards (49 CFR part 231)—October 31, 2020; (9) OMB No. 2130–0035, Railroad Operating Rules (49 CFR parts 217 & 218)—February 28, 2021; (10) OMB No. 2130–0592, Track Safety Standards; Concrete Crossties (49 CFR part 213)—February 28, 2021; (11) OMB No. 2130–0506, Identification of Cars Moved in Accordance with 49 CFR 232.3(d) (Formerly Order 13528) (49 CFR part 232)—March 31, 2021; (12) OMB No. 2130–0556, U.S. Locational Requirement for Dispatching Rail Operations in the United States (49 CFR part 241)—April 30, 2021; (13) OMB No. 2130–0595, Safety and Health Requirements Related to Camp Cars (49 CFR part 228)—April 30, 2021; (14) OMB No. 2130–0597, Training, Qualification, and Oversight for Safety-Related Railroad Employees (49 CFR parts 213 & 243)—April 30, 2021; (15) OMB No. 2130–0571, Occupational Noise Exposure for Railroad Operating Employees (49 CFR part 227)—May 31, 2021; and (16) OMB No. 2130–0596, Conductor Certification (49 CFR part 242)—May 31, 2021.

Additionally, in the last 18 months, OMB approved the following two study-related renewal information collections with the following new expiration dates: (1) OMB No. 2130–0617, Survey of Insular and Tourist Railroads (49 CFR part 237) (email survey)—November 31, 2020; and (2) OMB No. 2130–0622, Cab Technology Integration Lab (CTIL) Head-Up Display Study (Forms FRA F 6180.170a; FRA F 6180.170b)—January 31, 2021.

Persons affected by the above-referenced information collections are not required to respond to any collection of information unless it displays a currently valid OMB control number. These OMB approvals certify FRA has complied with the provisions of the PRA (44 U.S.C. 3501–3520) and with 5 CFR 1320.5(b) informing the public about OMB's approval of the information collection requirements of the above cited forms, studies, and regulations.

Authority: 44 U.S.C. 3501–3520.

Juan D. Reyes III,

Chief Counsel.

[FR Doc. 2018–16881 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2018–0008–N–7]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of Information Collection Request; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA), this notice announces that FRA is forwarding the Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and comment. The ICR describes the information collections and their expected burden. On May 10, 2018, FRA published a notice providing a 60-day period for public comment on the ICR.

DATES: Interested persons are invited to submit comments on or before September 7, 2018.

ADDRESSES: Submit written comments on the ICR to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503,

Attention: FRA Desk Officer. Comments may also be sent via email to OMB at the following address: *oira_submissions@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W33–497, Washington, DC 20590 (telephone: (202) 493–6292); or Ms. Kim Toone, Information Collection Clearance Officer, Office of Administration, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W34–212, Washington, DC 20590 (telephone: (202) 493–6132).

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve an ICR. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8–12. On May 10, 2018, FRA published a 60-day notice in the **Federal Register** soliciting comment on the ICR for which it is now seeking OMB approval. *See* 83 FR 21815 (May 10, 2018). During the comment period, on June 4, 2018, counsel for the Association of American Railroads asked clarifying questions, on behalf of its member railroads, regarding FRA's proposed changes to Section 6 of the Quarterly PTC Progress Report (Form FRA F 6180.165) and Annual PTC Progress Report (Form FRA F 6180.166). Consistent with the abstract below, and FRA's summary in its 60-day notice, FRA confirmed that a host railroad may provide its *approximate* completion dates for interoperability testing with each tenant railroad in Section 6 of the reporting forms. FRA received no written comments in response to the 60-day notice.

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983 (Aug. 29, 1995). OMB believes the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR at 44983. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

Comments are invited on the following ICR regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the information will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Positive Train Control.

OMB Control Number: 2130–0553.

Abstract: Under the Positive Train Control Enforcement and Implementation Act of 2015 (PTCEI Act), each railroad subject to 49 U.S.C. 20157(a) must submit an annual progress report to FRA by March 31, 2016, and annually thereafter, until PTC system implementation is completed. 49 U.S.C. 20157(c)(1). The PTCEI Act specifically requires each railroad to provide certain information in the annual reports regarding its progress toward implementing a PTC system, in addition to any other information FRA requests. *See id.* In addition, 49 U.S.C. 20157(c)(2) requires FRA to conduct compliance reviews at least annually to ensure each railroad is complying with its revised PTC Implementation Plan (PTCIP), including any FRA-approved amendments. The PTCEI Act requires railroads to provide information to FRA that FRA determines is necessary to adequately conduct such compliance reviews. 49 U.S.C. 20157(c)(2).

Under its statutory and regulatory investigative authorities, FRA currently requires, and seeks to continue requiring, each subject railroad to submit Quarterly PTC Progress Reports (Form FRA F 6180.165) and Annual PTC Progress Reports (Form FRA F 6180.166) on its PTC system implementation progress. *See* 49 U.S.C. 20157(c)(1)–(2); *see also* 49 U.S.C. 20107; 49 CFR 236.1009(h).

Specifically, in addition to the Annual PTC Progress Report (Form FRA F 6180.166) due each March 31 under 49 U.S.C. 20157(c)(1), railroads must provide quarterly progress reports covering the preceding three-month period and submit the forms to FRA on the dates in the following table until full PTC system implementation is completed:

	Coverage priod	Due dates for quarterly reports
Q1	January 1–March 31	April 30.
Q2	April 1–June 30	July 31.
Q3	July 1–September 30	October 31.
Q4	October 1–December 31	January 31.

Each railroad must submit its Quarterly PTC Progress Reports on Form FRA F 6180.165 and its Annual PTC Progress Reports on Form FRA F 6180.166 on FRA's Secure Information Repository at *https://sir.fra.dot.gov.*

II. Proposed Revisions to the Quarterly and Annual PTC Progress Report Forms

On August 15, 2017, OMB approved the Quarterly PTC Progress Report (Form FRA F 6180.165) and Annual PTC Progress Report (Form FRA F 6180.166) for a period of one year, expiring on August 31, 2018. The current Quarterly PTC Progress Report Form and Annual PTC Progress Report Form, as approved through August 31, 2018, can be accessed and downloaded in FRA's eLibrary at: *https://www.fra.dot.gov/eLib/details/L17365* and *https://www.fra.dot.gov/eLib/details/L17366,* respectively. These versions of the forms took into account the Association of American Railroads' written comments on behalf of itself and its member railroads; the American Public Transportation Association's written comments on behalf of Northeast Illinois Commuter Rail System, the Utah Transit Authority, the Tri-County Metropolitan Transportation District of Oregon, and the Fort Worth Transportation Authority; and industry stakeholders' comments during FRA's public meeting on April 19, 2016. FRA published minutes from the meeting on *www.regulations.gov* under Docket No. FRA–2016–0002. For a summary of the

oral and written comments and FRA's responses to the comments, please see 81 FR 28140, May 9, 2016.

Following the above cited 60-day public comment period, FRA is now requesting OMB's re-approval of the forms, with the five changes described below. First, in Section 1 of the Quarterly PTC Progress Report Form (FRA F 6180.165), FRA proposes revising the row ''Territories Where Revenue Service Demonstration Has Been Initiated'' to state ''Territories in Revenue Service Demonstration or in PTC Operation'' for clarity, based on additional feedback from the industry following OMB's approval of the form on August 15, 2017. FRA intended this row to include any and all territories where a railroad had initiated revenue service demonstration (RSD), even if a railroad subsequently obtained PTC System Certification from FRA and is operating its PTC system in revenue service. The purpose of this row is to collect information regarding a railroad's progress toward meeting the statutory criteria under 49 U.S.C. 20157(a)(3)(B)(vi)–(vii), if applicable. Based on feedback from the industry, FRA proposes clarifying the language in this row in Section 1 so railroads understand that a railroad can include in this row the number of territories where its PTC system is in RSD or in operation. This proposed change does not result in any additional reporting burden as it is only a clarifying change.

Second, in footnotes 4 and 6 of the Quarterly PTC Progress Report Form (FRA F 6180.165), FRA proposes adding a hyperlink to Appendix A. The footnotes currently state: ''If a particular category listed in this table does not apply to the railroad's technology, please indicate 'N/A.' A railroad may add categories or subcategories if it wants to provide more detail.'' FRA proposes adding the phrase ''in Appendix A'' to the second sentence with a hyperlink to that appendix to the form, as it will help direct railroads to the available section of the PDF where they can provide additional information. A hyperlink to Appendix A was in the corresponding footnotes in the prior version of the Quarterly PTC Progress Report Form that OMB approved through June 30, 2017, but the hyperlink was omitted in error from the current version of the form. This proposed change (*i.e.,* adding a hyperlink to an existing appendix) does not result in any additional reporting burden as it is only a formatting change.

Third, in Section 4 (entitled ''Installation/Track Segment Progress—Current Status'') of both the quarterly form and the annual form, FRA proposes replacing the ''Testing'' option in the drop-down menu with two more precise options—*i.e.,* ''Field Testing'' and ''Revenue Service Demonstration.'' This modification will help ensure clearer and more accurate reporting, without imposing an additional reporting burden.

Fourth, with respect to only the Annual PTC Progress Report Form (FRA F 6180.166), FRA proposes to delete a now inapplicable instruction from footnote 7 in Section 4, which stated,

> Please note: For the Annual PTC Progress Report due by March 31, 2017, this mandatory geographic requirement (that must be satisfied by either completing Column 5 in Section 4 or submitting a GIS shapefile as described above) is due to FRA by April 30, 2017. Every other part of this form must be completed and submitted to FRA by March 31, 2017. This limited extension applies only in 2017.

FRA delayed the due date for submitting that specific information in 2017 only, per OMB's request, to ensure railroads had sufficient time to compile and provide the information. FRA proposes removing that note from footnote 7 as it is no longer applicable or necessary. By statute, a railroad's Annual PTC Progress Report is due by March 31st each year until it completes PTC system implementation. 49 U.S.C. 20157(c)(1).

Fifth, with respect to both the quarterly form and the annual form, FRA proposes making certain changes to Section 6 (entitled ''Update on Interoperability Progress''). FRA proposes removing the portion of the instruction that states a host railroad must provide information about the status of each tenant railroad's rolling stock ''if the tenant does not have a separate PTCIP on file.'' FRA proposes removing this limiting instruction because FRA needs to know the PTC implementation status of any tenant railroad that operates on the host railroad's property, except any tenant railroad that is subject to an exception under 49 CFR 236.1006(b). In addition, before the final column in the table in Section 6, FRA proposes adding a column entitled, ''Scheduled Completion Date for Interoperability Testing.'' This information is necessary for FRA to understand the progress a host railroad and each of its required tenant railroads are jointly making toward testing and achieving PTC system interoperability, consistent with host railroad's PTC Implementation Plan and/or PTC Safety Plan. FRA estimates the additional burden for a host railroad to complete this new reporting requirement would be, on average, approximately 2.5 hours for Class I railroads and large passenger railroads; 1.25 hours for Class II and medium passenger railroads; and thirty minutes for Class III, terminal, and small passenger railroads.

III. Overview of Information Collection

The associated collection of information is summarized below.

Title: Positive Train Control (Quarterly Positive Train Control Progress Report and Annual Positive Train Control Progress Report).

Type of Request: Extension with change of a currently approved information collection.

Affected Public: Businesses (railroads).

Form(s): FRA F 6180.165 and FRA F 6180.166.

Respondent Universe: 41 Railroad Carriers.

Frequency of Submission: On occasion.

Total Estimated Annual Responses: 147,526.

Total Estimated Annual Burden: 2,728,528 hours.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Juan D. Reyes III,

Chief Counsel.

[FR Doc. 2018–16880 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Reports, Forms, and Record Keeping Requirements Agency Information Collection Activity Under OMB Review

AGENCY: National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces the Information Collection Request (ICR) abstracted below will be submitted to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected burden. A **Federal Register** Notice with a 60-day comment period soliciting public comments on the following information collection was published on May 18, 2018 (83 FR

23336). NHTSA did not receive any public comments in response to the 60-day notice.

DATES: Comments must be received on or before September 7, 2018.

ADDRESSES: You may submit comments, within 30 days, to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington DC 20503, Attention NHTSA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Dr. Kathy Sifrit, Office of Behavioral Safety Research (NPD–320), National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, W46–472, Washington, DC 20590. Dr. Sifrit's phone number is (202) 366–0868 and her email address is *kathy.sifrit@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: Hazard Perception and Distracted Driving Training Intervention for Teens

Type of Request: New information collection requirement.

Abstract: The National Highway Traffic Safety Administration (NHTSA) proposes to collect information from newly-licensed teen drivers for a one-time voluntary study to evaluate Risk Awareness and Perception Training (RAPT), a hazard perception and distracted driving training intervention to improve novice driver safety. NHTSA proposes to collect information from a sample of newly-licensed teen drivers in two States to determine (1) their eligibility to participate in a study to evaluate RAPT hazard perception training; (2) their hazard perception performance before and after they complete RAPT or placebo training, and again six months after training; and (3) their driving exposure via driving logs to account for potential differences across participants. In addition, participants will agree to allow researchers to access their crash and citation records for six months to support analyses of the effects of RAPT training on crash and citation rates. NHTSA will invite an estimated 20,000 newly licensed drivers ages 16 through 19 in two States to participate, with the goal of recruiting 10,000 volunteers—7,500 from a first State and 2,500 from a second State for validation. Participation will be voluntary and solicited through the distribution of recruiting letters at Department of Motor Vehicle locations (DMVs) when new drivers obtain their license. Once obtaining consent from the teen and their guardian(s) through an informed consent agreement, study participants will be randomly assigned within age and sex categories to either participation in the RAPT or the placebo condition. Participants in the RAPT condition will complete the training protocol; those in the placebo condition will view a vehicle maintenance video. A subsample of 2,000 participants will also be asked to complete a week-long trip log to record driving exposure during the study period. The 7,500 participants in the first State will be invited to complete a six-month follow-up test to see whether they retained the RAPT training; these participants will also be asked questions about any crashes or traffic tickets during their first six months of driving to capture any unreported crashes or incidents. NHTSA will use the information to produce a technical report that presents the results of the study. The technical report will provide aggregate (summary) statistics and tables as well as the results of statistical analysis of the information, but it will not include any personal information. The technical report will be shared with State Highway Safety Offices as well as other stakeholders interested in improving the safety of novice teen drivers. The total estimated burden for recruitment (2,000 hours), the initial training (7,500 hours), the trip log (1,167 hours) and the follow-up data collection (1,875 hours) is 12,542 hours.

Comments are invited on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the Department's estimate of the burden of the proposed information collection;

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

(iv) Ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

A comment to OMB is most effective if OMB receives it within 30 days of publication of this notice.

Authority: 44 U.S.C. Section 3506(c)(2)(A).

Issued in Washington, DC, on August 3, 2018.

Jeff Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2018–16951 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2018–0076]

Drugs That Impair Safe Driving; Request for Comments; Correction

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice; correction.

SUMMARY: NHTSA published a document in the **Federal Register** of July 17, 2017, concerning request for comments on drugs that impair safe driving. The document had an incorrect docket number.

FOR FURTHER INFORMATION CONTACT: Richard Compton, 202–366–2699.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of July 17, 2018, in FR Doc. 2018–15209, on page 33305 in the second column, correct the ''Docket No.'' to read:

[Docket No. NHTSA–2018–0076]

July 19, 2018

Authority: 44 U.S.C. Section 3506(c)(2)(A).

Issued in Washington, DC, on August 3, 2018.

Jeff Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2018–16952 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Reports, Forms, and Record Keeping Requirements Agency Information Collection Activity Under OMB Review

AGENCY: National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces the Information Collection Request (ICR) abstracted below will be submitted to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected burden. A **Federal Register** Notice with a 60-day comment period soliciting public comments on the following information collection

was published on May 17, 2018 (83 FR 23040). NHTSA did not receive any public comments in response to the 60-day notice.

DATES: Comments must be received on or before September 7, 2018.

ADDRESSES: You may submit comments, within 30 days, to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503, Attention NHTSA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Dr. Kathy Sifrit, Office of Behavioral Safety Research (NPD–320), National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, W46–472, Washington, DC 20590. Dr. Sifrit's phone number is (202) 366–0868 and her email address is *kathy.sifrit@dot.gov.*

SUPPLEMENTARY INFORMATION:

Title: In-Vehicle Drowsiness Detection and Alerting.

Type of Request: New information collection requirement.

Abstract: The National Highway Traffic Safety Administration (NHTSA) is seeking approval to collect information from licensed young drivers for a one-time voluntary driving simulator study of the effectiveness of in-vehicle drowsiness detection and alerting systems that aim to reduce drowsy driving. NHTSA proposes to collect information from licensed young drivers to determine (1) their eligibility to participate in a study evaluating systems designed to detect and mitigate drowsy driving, (2) their driving performance during a simulated driving task to measure drowsiness mitigation system effectiveness, and (3) their opinions about the safety systems and their perceptions of the benefits. NHTSA will collect information about age, sex, driver license status, sleep and caffeine habits, and driving habits from an estimated 120 young drivers through a one-time, voluntary telephone interview to determine their eligibility for this study. NHTSA will then invite 85 qualified young drivers to report to the simulator to complete an informed consent form and other screening activities including a ten-minute practice drive in the simulator and an assessment of propensity for simulator sickness. NHTSA expects that 75 young drivers will pass the screening and will report for the overnight study, which includes a four-hour drive in the simulator. This collection is solely reporting, and there are no record-keeping costs to the respondents. NHTSA will use the information to produce a technical report that presents the results of the study. The technical report will provide aggregate (summary) statistics and tables as well as the results of statistical analysis of the information, but it will not include any personal information. The technical report will be shared with vehicle manufacturers and suppliers as well as other stakeholders interested in improving traffic safety by decreasing drowsy driving. The total estimated burden for qualifying 120 participants (30 hours), for screening 85 participants (85 hours) and for 75 participants to complete the study (713 hours) is 828 total hours.

Comments Are Invited on the Following

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) The accuracy of the Department's estimate of the burden of the proposed information collection;

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

(iv) Ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

A comment to OMB is most effective if OMB receives it within 30 days of publication of this notice.

Authority: 44 U.S.C. Section 3506(c)(2)(A).

Issued in Washington, DC, on August 3, 2018.

Jeff Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2018–16950 Filed 8–7–18; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Open Meeting: Community Development Advisory Board

ACTION: Notice of open meeting.

SUMMARY: This notice announces an open meeting of the Community Development Advisory Board (the Advisory Board), which provides advice to the Director of the Community Development Financial Institutions Fund (CDFI Fund). The meeting will be open to the public who may either attend the meeting in-person or view it as a live webcast. The meeting will be held at the U.S. Department of the Treasury in a room that will accommodate up to 50 members of the public on a first-come, first-served basis. The link to the live webcast can be found in the meeting announcement found at the top of *www.cdfifund.gov/cdab.*

DATES: The meeting will be held from 9:00 a.m. to 2:00 p.m. Eastern Time on Thursday, August 23, 2018.

ADDRESSES: The Advisory Board meeting will be held in Media Rooms A & B (Rooms 4121 and 4125) at the U.S. Department of the Treasury located at 1500 Pennsylvania Avenue NW, Washington, DC 20220.

Submission of Written Statements: Participation in the discussions at the meeting will be limited to Advisory Board members, Department of the Treasury staff, and certain invited guests. Anyone who would like to have the Advisory Board consider a written statement must submit it by 5:00 p.m. Eastern Time on Tuesday, August 14, 2018. Send paper statements to Bill Luecht, Senior Advisor, Office of Legislative and External Affairs, CDFI Fund, 1500 Pennsylvania Avenue NW, Washington, DC 20220. Send electronic statements to *AdvisoryBoard@cdfi.treas.gov*.

In general, the CDFI Fund will make all statements available in their original format, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers, for public inspection and photocopying at the CDFI Fund. The CDFI Fund is open on official business days between the hours of 9:00 a.m. and 5:00 p.m. Eastern Time. You can make an appointment to inspect statements by emailing *AdvisoryBoard@cdfi.treas.gov*. All statements received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should only submit information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Bill Luecht, Senior Advisor, Office of Legislative and External Affairs, CDFI Fund, 1500 Pennsylvania Avenue NW, Washington, DC 20220, (202) 653–0322 (this is not a toll free number) or *AdvisoryBoard@cdfi.treas.gov*. Other information regarding the CDFI Fund and its programs may be obtained through the CDFI Fund's website at *http://www.cdfifund.gov*.

SUPPLEMENTARY INFORMATION: Section 104(d) of the Riegle Community Development and Regulatory Improvement Act of 1994 (Pub. L. 103–325), which created the CDFI Fund, established the Advisory Board. The charter for the Advisory Board has been filed in accordance with the Federal

Advisory Committee Act, as amended (5 U.S.C. App.), and with the approval of the Secretary of the Treasury.

The function of the Advisory Board is to advise the Director of the CDFI Fund (who has been delegated the authority to administer the CDFI Fund) on the policies regarding the activities of the CDFI Fund. The Advisory Board does not advise the CDFI Fund on approving or declining any particular application for monetary or non-monetary awards.

In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2 and the regulations thereunder, Bill Luecht, Designated Federal Officer of the Advisory Board, has ordered publication of this notice that the Advisory Board will convene an open meeting, which will be held in Media Rooms A & B (Rooms 4121 and 4125) at the U.S. Department of the Treasury located at 1500 Pennsylvania Avenue NW, Washington, DC 20220, from 9:00 a.m. to 2:00 p.m. Eastern Time on Thursday, August 23, 2018. The room will accommodate up to 50 members of the public on a first-come, first-served basis.

Because the meeting will be held in a secure federal building, members of the public who wish to attend the meeting must register in advance. The link to the online registration system can be found in the meeting announcement found at the top of *www.cdfifund.gov/cdab*. The registration deadline is 11:59 p.m. Eastern Time on Thursday, August 16, 2018. For entry into the building on the date of the meeting, each attendee must present his or her government issued ID, such as a driver's license or passport, which includes a photo.

The Advisory Board meeting will include a report from the CDFI Fund Director on the activities of the CDFI Fund since the last Advisory Board meeting and on Fiscal Year 2019 priorities, including discussion on the reexamination of CDFI Certification policies and maximizing impact in Persistent Poverty Counties.

Authority: 12 U.S.C. 4703.

Dennis E. Nolan,

Deputy Director, Community Development Financial Institutions Fund.

[FR Doc. 2018–16891 Filed 8–7–18; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel (Foreign Assets Control), tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*http://www.treasury.gov/ofac*).

Notice of OFAC Actions

On July 25, 2018, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authorities listed below.

Individuals

1. AJAKA, Tony (a.k.a. AJAKA, Antoine); DOB 14 Mar 1968; nationality Lebanon (individual) [NPWMD] (Linked To: KATRANGI, Amir).

Designated pursuant to section 1(a)(iii) of Executive Order 13382 of June 28, 2005, ''Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters'' (E.O. 13382) for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, Amir KATRANGI, a person whose property and interests in property are blocked pursuant to E.O. 13382.

2. BEURKLIAN, Anni (a.k.a. AJAKA, Anni); DOB 17 May 1969; nationality Lebanon; citizen United States (individual) [NPWMD] (Linked To: KATRANGI, Amir).

Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, Amir KATRANGI, a person whose property and interests in property are blocked pursuant to E.O. 13382.

3. CHAHINE, Mireille; DOB 01 Mar 1983; POB Beirut, Lebanon; nationality Lebanon; Employee and Accountant at Electronic Katrangi Group (individual) [NPWMD] (Linked To: ELECTRONICS KATRANGI TRADING).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, ELECTRONICS KATRANGI TRADING, a person whose property and interests in property are blocked pursuant to E.O. 13382.

4. KATRANGI, Amir (a.k.a. ALKANTRANJI, Amir Hachem; a.k.a. KANTRAJI, Amir Hachem; a.k.a. KATRA, Amir; a.k.a. KATRANGI, Amir Hachem; a.k.a. KATRANJI, Amir; a.k.a. KATRANJI, Amir Hachem; a.k.a. KATRANJI, Amir Hashem); DOB 24 Jun 1966; POB Hama, Syria; nationality Syria; Managing Director and Co-founder of Electronic Katrangi Group (individual) [NPWMD] (Linked To: ELECTRONICS KATRANGI TRADING).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, ELECTRONICS KATRANGI TRADING, a person whose property and interests in property are blocked pursuant to E.O. 13382.

5. KATRANGI, Houssam Hachem (a.k.a. EL KATRANGI, Houssam Hachem; a.k.a. EL KATRANJI, Houssam Hachem; a.k.a. KATRANGI, Houssam Hachem; a.k.a. KATRANGI, Hussam; a.k.a. KATRANJI, Houssam Hachem; a.k.a. KATRANKI, Houssam Hashem; a.k.a. QATRANJI, Hussam), Khansa Jnah, Beirut, Lebanon; DOB 27 Nov 1973; POB Ramlet El Baida, Lebanon; nationality Lebanon; Co-founder and Associate of Electronic Katrangi Group (individual) [NPWMD] (Linked To: ELECTRONICS KATRANGI TRADING).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, ELECTRONICS KATRANGI TRADING, a person whose property and interests in property are blocked pursuant to E.O. 13382.

6. KATRANGI, Maher (a.k.a. EL KATRANGI, Maher Hachem; a.k.a. EL KATRANJI, Maher Hachem; a.k.a. KATRANGI, Maher Hachem; a.k.a. KATRANGI, Maher Mohamad; a.k.a. KATRANJI, Maher Hachem; a.k.a. KATRANJI, Maher Hashem), Khansa Jnah, Beirut, Lebanon; DOB 06 Jul 1967; POB Hama, Syria; nationality Syria; Co-

founder and Associate of Electronic Katrangi Group (individual) [NPWMD] (Linked To: ELECTRONICS KATRANGI TRADING).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, ELECTRONICS KATRANGI TRADING, a person whose property and interests in property are blocked pursuant to E.O. 13382.

7. KATRANGI, Mohamad (a.k.a. ALKTRANJI, Mohammed; a.k.a. KATRANJI, Mohammed); DOB 1928 (individual) [NPWMD] (Linked To: ELECTRONICS KATRANGI TRADING).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, ELECTRONICS KATRANGI TRADING, a person whose property and interests in property are blocked pursuant to E.O. 13382.

8. ZHOU, Yishan; DOB 08 Dec 1981; POB Guangdong, China; nationality China; Director, EKT Smart Technology (individual) [NPWMD] (Linked To: EKT SMART TECHNOLOGY).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, EKT SMART TECHNOLOGY, a person whose property and interests in property are blocked pursuant to E.O. 13382.

Entities

1. EKT SMART TECHNOLOGY, 38 Dongtang Jinguang South Road, Xiashan Street, Chaonan District, Guangdong to Shantou, China; Chase Business Centre, 39–41 Chase Side, London N14 5BP, United Kingdom; Company Number 08884792 (United Kingdom) [NPWMD] (Linked To: ELECTRONICS KATRANGI TRADING).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for acting or purporting to act for or on behalf of, directly or indirectly, ELECTRONICS KATRANGI TRADING, a person whose property and interests in property are blocked pursuant to E.O. 13382.

2. ELECTRONICS KATRANGI TRADING (a.k.a. AL AMIR ELECTRONICS; a.k.a. ALAMIR ELECTRONICS; a.k.a. AL–AMIR ELECTRONICS; a.k.a. AMIRCO ELECTRONICS; a.k.a. E.K.T. (KATRANGI BROS.); a.k.a. EKT (KATRANGI BROS); a.k.a. EKT ELECTRONICS; a.k.a. EKT KATRANGI BROTHERS; a.k.a. ELECTRONIC KATRANGI GROUP; a.k.a. KATRANGI ELECTRONICS; a.k.a. KATRANGI FOR ELECTRONICS INDUSTRIES; a.k.a. KATRANGI TRADING; a.k.a. KATRANJI LABS; a.k.a. LUMIERE ELYSEES (Latin: LUMIÈRE ELYSÉES); a.k.a. NKTRONICS; a.k.a. SMART GREEN POWER; a.k.a. SMART PEGASUS; a.k.a. ''E.K.T.''; a.k.a. ''EKT''; a.k.a. ''ELECTRONIC SYSTEM GROUP''; a.k.a. ''ESG''), 1st Floor, Hujij Building, Korniche Street, P.O. Box 817 No. 3, Beirut, Lebanon; P.O. Box 8173, Beirut, Lebanon; #1 fl., Grand Hills Bldg., Said Khansa St., Jnah (BHV), Beirut, Lebanon; 11/A, Abbasieh Building, Hijaz Street, Damascus, Syria; Lahlah Building, Industrial Zone, Hama, Syria; Awqaf Building, Naser Street, P.O. Box 34425, Damascus, Syria; #1 floor, 02/A, Fares Building, Rami Street, Margeh, Damascus, Syria; 46 El-Falaki Street, Facing Cook Door, BabLouk Area, Cairo, Egypt; website *www.ekt2.com;* alt. Website *www.katranji.com;* alt. Website *http://sgp-france.com;* alt. Website *http://lumiere-elysees.fr;* Identification Number 808 195 689 00019 (France); Chamber of Commerce Number 2014 B 24978 (France) [NPWMD] (Linked To: SCIENTIFIC STUDIES AND RESEARCH CENTER).

Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, the SCIENTIFIC STUDIES AND RESEARCH CENTER, a person whose property and interests in property are blocked pursuant to E.O. 13382.

3. GOLDEN STAR CO (a.k.a. GOLDEN STAR INTERNATIONAL FREIGHT LIMITED; a.k.a. GOLDEN STAR TRADING & INTERNATIONAL FREIGHT; a.k.a. GOLDEN STAR TRADING AND INTERNATIONAL FREIGHT; a.k.a. GOLDEN STAR TRADING INTERNATIONAL FREIGHT; a.k.a. KASSOUMA FZC; a.k.a. SHAREKAT GOLDEN STAR; a.k.a. SMART LOGISTICS F.S.S.A.L; a.k.a. SMART LOGISTICS OFFSHORE; a.k.a. SMART LOGISTICS TRADING & INTERNATIONAL FREIGHT; a.k.a. SMART LOGISTICS TRADING AND INTERNATIONAL FREIGHT), Al Awqaf building, 5th floor, Victoria Bridge, Damascus, Syria; 2 Floor, Inana Bldg, Damascus Free Zone, Damascus, Syria; Room 707, Fulijinxi Business Center, No. 05, Fuchang Road, Haizhu District, Guangzhou, China; Al Alshiah, Mar Mekheal Church, Amicho Building, 3rd Floor, Beirut, Lebanon; Office 112, First Floor, Al Manara Building, Port Street, Beirut, Lebanon; website *www.goldenstar-co.com* [NPWMD] (Linked To: ELECTRONICS KATRANGI TRADING).

Designated pursuant to section 1(a)(iii) of E.O. 13382 for having provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, ELECTRONICS KATRANGI TRADING, a person whose property and interests in property are blocked pursuant to E.O. 13382.

4. POLO TRADING, Fakhani Building, Korniche Mazraa Street, Beirut, Lebanon; Grand Hills/GF Al Khansa St., Beirut, Lebanon; website polo-trading.com [NPWMD] (Linked To: KATRANGI, Amir).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for being owned or controlled by Amir KATRANGI, a person whose property and interests in property are blocked pursuant to E.O. 13382.

5. TOP TECHNOLOGIES SARL, Ground Floor, Dedeyan center, Dora highway, Metn, Bauchrieh, Lebanon [NPWMD] (Linked To: AJAKA, Tony).

Designated pursuant to section 1(a)(iv) of E.O. 13382 for being owned or controlled by Antoine AJAKA, a person whose property and interests in property are blocked pursuant to E.O. 13382.

Dated: July 25, 2018.

Andrea M. Gacki,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2018–16906 Filed 8–7–18; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; or the Department of the Treasury's Office of the General Counsel: Office of the Chief Counsel

(Foreign Assets Control), tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On August 3, 2018, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked pursuant to the relevant sanctions authorities listed below.

Individual

1. RI, Jong Won (a.k.a. RI, Cho'ng-Wo'n; a.k.a. RI, Jung Won), Moscow, Russia; DOB 22 Apr 1971; Passport PS654320421 expires 11 Mar 2019 (individual) [DPRK2].

Designated pursuant to Section 1(a)(ii) of Executive Order 13687 of January 2, 2015, ''Imposing Additional Sanctions With Respect to North Korea'' for being an official of the Government of North Korea.

Entities

2. DANDONG ZHONGSHENG INDUSTRY & TRADE CO., LTD. (Chinese Simplified: 丹东中盛工贸有限公司) (a.k.a. DANDONG ZHONGSENG INDUSTRY & TRADE; a.k.a. DANDONG ZHONGSENG INDUSTRY AND TRADE; a.k.a. DANDONG ZHONGSHENG INDUSTRY AND TRADE CO., LTD.; a.k.a. DANDONG ZHONGSHONG INDUSTRY & TRADE; a.k.a. DANDONG ZHONGSHONG INDUSTRY & TRADE CORPORATION LTD.; a.k.a. DANDONG ZHONGSHONG INDUSTRY AND TRADE; a.k.a. DANDONG ZHONGSHONG INDUSTRY AND TRADE CORPORATION LTD.), Building 34, Chengjian Zone, Shiwei Road, Zhenxing District, Dandong, Liaoning, China; Zhenxing District, Building 34, Dandong, China; Business Registration Number 312106037714354404 (China) [NPWMD] (Linked To: FOREIGN TRADE BANK OF THE DEMOCRATIC PEOPLE'S REPUBLIC OF KOREA).

Designated pursuant to Section 1(a)(iv) of Executive Order 13382 of June 28, 2005, ''Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters'' (E.O. 13382) for being owned or controlled by, directly or indirectly, FOREIGN TRADE BANK, an entity whose property and interest in property are blocked pursuant to E.O. 13382.

3. KOREA UNGUM CORPORATION (a.k.a. KOREA UNGUM COMPANY), Pyongyang, Korea, North [DPRK3].

Designated pursuant to Section 2(a)(vii) of Executive Order 13722 of March 15, 2016, ''Blocking Property of the Government of North Korea and the Workers' Party of Korea, and Prohibiting Certain Transactions With Respect to North Korea'' (E.O. 13722) for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, FOREIGN TRADE BANK, an entity whose property and interest in property are blocked pursuant to E.O. 13722.

4. COMMERCIAL BANK AGROSOYUZ (Cyrillic: КОММЕРЧЕСКИЙ ВАНК АГРОСОЮЗ) (a.k.a. AGROSOYUZ (Cyrillic: АГРОСОЮЗ); a.k.a. AGROSOYUZ LLC (Cyrillic: АГРОСОЮЗ ООО); a.k.a. LLC COMMERCIAL BANK AGROSOYUZ (Cyrillic: ООО КОММЕРЧЕСКИЙ ВАНК АГРОСОЮЗ; Cyrillic: ООО КВ АГРОСОЮЗ)), Ulanskiy pereulok, number 13 building 1, Moscow 101000, Russia; SWIFT/BIC AGSZRU31; alt. SWIFT/BIC AGSZRU33 [DPRK4].

Blocked under Section 4(b)(ii) of Executive Order 13810 of September 20, 2017 ''Imposing Additional Sanctions With Respect to North Korea'' (E.O. 13810) pursuant to Section 4(a)(i) of E.O. 13810 for knowingly conducting or facilitating a significant transaction on behalf of HAN JANG SU, a person whose property and interests in property are blocked pursuant to E.O. 13382 in connection with North Korea-related activities.

Dated: August 3, 2018.

Andrea M. Gacki

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2018–16960 Filed 8–7–18; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions; Sanctions Actions Pursuant to Directive One of Executive Order 13662

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of persons who are no longer subject to the prohibitions imposed pursuant to Directive One under Executive Order 13662 of March 20, 2014, ''Blocking Property of Additional Persons Contributing to the Situation in Ukraine.''

DATES: OFAC's actions described in this notice were effective on July 25, 2018.

FOR FURTHER INFORMATION CONTACT: The Department of the Treasury's Office of Foreign Assets Control: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480, Assistant Director for Regulatory Affairs, tel.: 202–622–4855, or the Department of the Treasury's Office of the Chief Counsel (Foreign Assets Control), Office of the General Counsel, tel.: 202–622–2410.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Sectoral Sanctions Identification List (SSI List) and additional information concerning OFAC sanctions programs are available from OFAC's website at *http://www.treasury.gov/ofac.*

Notice of OFAC Actions

On July 25, 2018, OFAC removed from the SSI List the persons listed below, who were subject to prohibitions imposed pursuant to Directive One under Executive Order 13662.

Entity

EESTI KREDIIDIPANK AS (a.k.a. AS EESTI KREDIIDIPANK; a.k.a. ESTONIAN CREDIT BANK; a.k.a. JOINT-STOCK COMPANY EESTI KREDIDIPANK), Narve Road 4, Tallinn 15014, Estonia; SWIFT/BIC EKRD EE 22; website *http://www.krediidipank.ee;* Executive Order 13662 Directive Determination—Subject to Directive 1; All offices worldwide; for more information on directives, please visit the following link: *https://www.treasury.gov/resource-center/sanctions/Programs/Pages/ukraine.aspx#directives* [UKRAINE–EO13662] (Linked To: BANK OF MOSCOW).

Dated: July 25, 2018.

Andrea M. Gacki.

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2018–16907 Filed 8–7–18; 8:45 am]

BILLING CODE 4810–AL–P

FEDERAL REGISTER

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Part II

Department of Health and Human Service

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 413, and 424
Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNF) Final Rule for FY 2019, SNF Value-Based Purchasing Program, and SNF Quality Reporting Program; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 413, and 424

[CMS–1696–F]

RIN 0938–AT24

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNF) Final Rule for FY 2019, SNF Value-Based Purchasing Program, and SNF Quality Reporting Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2019. This final rule also replaces the existing case-mix classification methodology, the Resource Utilization Groups, Version IV (RUG–IV) model, with a revised case-mix methodology called the Patient-Driven Payment Model (PDPM) beginning on October 1, 2019. The rule finalizes revisions to the regulation text that describes a beneficiary's SNF ''resident'' status under the consolidated billing provision and the required content of the SNF level of care certification. The rule also finalizes updates to the SNF Quality Reporting Program (QRP) and the Skilled Nursing Facility Value-Based Purchasing (VBP) Program.

DATES:

Effective Date: This final rule is effective October 1, 2018.

Implementation Date: The implementation date for revised case-mix methodology, PDPM, and associated policies discussed in section V. is October 1, 2019.

FOR FURTHER INFORMATION CONTACT:

Penny Gershman, (410) 786–6643, for information related to SNF PPS clinical issues.

John Kane, (410) 786–0557, for information related to the development of the payment rates and case-mix indexes, and general information.

Kia Sidbury, (410) 786–7816, for information related to the wage index.

Bill Ullman, (410) 786–5667, for information related to level of care determinations, and consolidated billing.

Mary Pratt, (410) 786–6867, for information related to the skilled nursing facility quality reporting program.

Celeste Bostic, (410) 786–5603, for information related to the skilled nursing facility value-based purchasing program.

SUPPLEMENTARY INFORMATION:

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

As discussed in the FY 2014 SNF PPS final rule (78 FR 47936), tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are no longer published in the **Federal Register**. Instead, these tables are available exclusively through the internet on the CMS website. The wage index tables for this final rule can be accessed on the SNF PPS Wage Index home page, at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*.

Readers who experience any problems accessing any of these online SNF PPS wage index tables should contact Kia Sidbury at (410) 786–7816.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

Table of Contents

I. Executive Summary

A. Purpose

This final rule updates the SNF prospective payment rates for FY 2019 as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It will also respond to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register**, before the August 1 that precedes the start of each fiscal year (FY), certain specified information relating to the payment update (see section II.C. of this final rule). This final rule also replaces the existing case-mix classification methodology, the Resource Utilization Groups, Version IV (RUG–IV) model, with a revised case-mix methodology called the Patient-Driven Payment Model (PDPM) effective October 1, 2019. This rule also finalizes updates to the Skilled Nursing Facility Quality Reporting Program (SNF QRP) and Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP).

B. Summary of Major Provisions

In accordance with sections 1888(e)(4)(E)(ii)(IV) and 1888(e)(5) of the Act, the federal rates in this final rule will reflect an update to the rates that we published in the SNF PPS final

rule for FY 2018 (82 FR 36530), as corrected in the FY 2018 SNF PPS correction notice (82 FR 46163), which reflects the SNF market basket update for FY 2019, as required by section 1888(e)(5)(B)(iv) of the Act (as added by section 53111 of the Bipartisan Budget Act of 2018). This final rule also replaces the existing case-mix classification methodology, the Resource Utilization Groups, Version IV (RUG–IV) model, with a revised case-mix methodology called the Patient-Driven Payment Model (PDPM). It also finalizes revisions at 42 CFR 411.15(p)(3)(iv), which describes a beneficiary's SNF ''resident'' status under the consolidated billing provision, and 42 CFR 424.20(a)(1)(i), which describes the required content of the SNF level of care certification. Furthermore, in accordance with section 1888(h) of the Act, this final rule, beginning October 1, 2018, will reduce the adjusted federal per diem rate determined under section 1888(e)(4)(G) of the Act by 2 percent, and adjust the resulting rate by the value-based incentive payment amount earned by the SNF for that fiscal year under the SNF VBP Program. Additionally, this final rule updates policies for the SNF VBP, including requirements that apply beginning with the FY 2021 SNF VBP program year, changes to the SNF VBP scoring methodology, and the adoption of an Extraordinary Circumstances Exception policy. Finally, this rule updates requirements for the SNF QRP, including adopting a new quality measure removal factor and codifying in our regulations a number of requirements.

C. Summary of Cost and Benefits

TABLE 1—COST AND BENEFITS

Provision description	Total transfers
FY 2019 SNF PPS payment rate update\	The overall economic impact of this final rule is an estimated increase of $820 million in aggregate payments to SNFs during FY 2019.
FY 2019 SNF VBP changes	The overall economic impact of the SNF VBP Program is an estimated reduction of $211 million in aggregate payments to SNFs during FY 2019.

D. Improving Patient Outcomes and Reducing Burden Through Meaningful Measures

Regulatory reform and reducing regulatory burden are high priorities for us. To reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care, in October 2017, we launched the Meaningful Measures Initiative.[1] This initiative is one component of our agency-wide Patients Over Paperwork Initiative,[2] which is aimed at evaluating and streamlining regulations with a goal to reduce unnecessary cost and burden, increase efficiencies, and improve beneficiary experience. The Meaningful Measures Initiative is aimed at identifying the highest priority areas for quality measurement and quality improvement in order to assess the core quality of care issues that are most vital to advancing our work to improve patient outcomes. The Meaningful Measures Initiative represents a new approach to quality measures that fosters operational efficiencies, and will reduce costs including the collection and reporting burden while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures Framework has the following objectives:

- Address high-impact measure areas that safeguard public health;
- Patient-centered and meaningful to patients;
- Outcome-based where possible;
- Fulfill each program's statutory requirements;
- Minimize the level of burden for health care providers (for example, through a preference for EHR-based measures where possible, such as electronic clinical quality measures);
- Significant opportunity for improvement;
- Address measure needs for population based payment through alternative payment models; and
- Align across programs and/or with other payers.

In order to achieve these objectives, we have identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in Table 2.

TABLE 2—MEANINGFUL MEASURES FRAMEWORK DOMAINS AND MEASURE AREAS

Quality priority	Meaningful measure area
Making Care Safer by Reducing Harm Caused in the Delivery of Care	Healthcare-Associated Infections. Preventable Healthcare Harm.
Strengthen Person and Family Engagement as Partners in Their Care	Care is Personalized and Aligned with Patient's Goals. End of Life Care according to Preferences. Patient's Experience of Care Patient Reported Functional Outcomes.
Promote Effective Communication and Coordination of Care	Medication Management. Admissions and Readmissions to Hospitals. Transfer of Health Information and Interoperability.
Promote Effective Prevention and Treatment of Chronic Disease	Preventive Care. Management of Chronic Conditions. Prevention, Treatment, and Management of Mental Health. Prevention and Treatment of Opioid and Substance Use Disorders. Risk Adjusted Mortality.
Work with Communities to Promote Best Practices of Healthy Living	Equity of Care. Community Engagement.

[1] Meaningful Measures web page: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitativesGenIndo/MMF/General-info-Sub-Page.html.*

[2] See Remarks by Administrator Seema Verma at the Health Care Payment Learning and Action Network (LAN) Fall Summit, as prepared for delivery on October 30, 2017 *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html*

TABLE 2—MEANINGFUL MEASURES FRAMEWORK DOMAINS AND MEASURE AREAS—Continued

Quality priority	Meaningful measure area
Make Care Affordable	Appropriate Use of Healthcare. Patient-focused Episode of Care. Risk Adjusted Total Cost of Care.

By including Meaningful Measures in our programs, we believe that we can also address the following cross-cutting measure criteria:

- Eliminating disparities;
- Tracking measurable outcomes and impact;
- Safeguarding public health;
- Achieving cost savings;
- Improving access for rural communities; and
- Reducing burden.

We believe that the Meaningful Measures Initiative will improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers and promoting operational efficiencies.

Comment: We received numerous comments from stakeholders regarding the Meaningful Measures Initiative and the impact of its implementation in CMS' quality programs. Many of these comments pertained to specific program proposals, and are discussed in the appropriate program-specific sections of this final rule. However, commenters also provided insights and recommendations for the ongoing development of the Meaningful Measures Initiative generally, including: ensuring transparency in public reporting and usability of publicly reported data; evaluating the benefit of individual measures to patients via use in quality programs weighed against the burden to providers of collecting and reporting that measure data; and identifying additional opportunities for alignment across CMS quality programs.

Response: We will continue to work with stakeholders to refine and further implement the Meaningful Measures Initiative, and will take commenters' insights and recommendations into account moving forward.

E. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care. The Office of the National Coordinator for Health Information Technology (ONC) and CMS work collaboratively to advance interoperability across settings of care, including post-acute care.

The Improving Medicare Post-Acute Care Transformation Act of 2015 (IMPACT Act, Pub. L. 113–185) requires assessment data to be standardized and interoperable to allow for exchange of the data among post-acute providers and other providers. To further interoperability in post-acute care, CMS has developed a Data Element Library to serve as a publicly available centralized, authoritative resource for standardized data elements and their associated mappings to health IT standards. These interoperable data elements can reduce provider burden by allowing the use and reuse of healthcare data, support provider exchange of electronic health information for care coordination, person-centered care, and support real-time, data driven, clinical decision making. Standards in the Data Element Library (*https://del.cms.gov/*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2018 Interoperability Standards Advisory (ISA) is available at *https://www.healthit.gov/isa.*

Most recently, the 21st Century Cures Act (Pub. L. 114–255), enacted in late 2016, requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. Specifically, Congress directed ONC to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' This framework (*https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement*) outlines a common set of principles for trusted exchange and minimum terms and conditions for trusted exchange in order to enable interoperability across disparate health information networks. In another important provision, Congress defined ''information blocking'' as practices likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information, and established new authority for HHS to discourage these practices.

We invite providers to learn more about these important developments and how they are likely to affect SNFs.

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA 1997, Pub. L. 105–33, enacted on August 5, 1997), section 1888(e) of the Act provides for the implementation of a PPS for SNFs. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services defined in section 1888(e)(2)(A) of the Act. The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998, and covers all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Under section 1888(e)(2)(A)(i) of the Act, covered SNF services include post-hospital extended care services for which benefits are provided under Part A, as well as those items and services (other than a small number of excluded services, such as physicians' services) for which payment may otherwise be made under Part B and which are furnished to Medicare beneficiaries who are residents in a SNF during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998 interim final rule (63 FR 26252). In addition, a detailed discussion of the legislative history of the SNF PPS is available online at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_04152015.pdf.*

Section 215(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted on April 1, 2014) added section 1888(g) to the Act requiring the Secretary to specify an all-cause all-condition hospital readmission measure and an all-condition risk-adjusted potentially preventable hospital readmission measure for the SNF setting. Additionally, section 215(b) of PAMA added section 1888(h) to the Act requiring the Secretary to implement a VBP program for SNFs. Finally, section 2(c)(4) of the IMPACT Act added section 1888(e)(6) to the Act, which requires the Secretary to implement a quality reporting program for SNFs under which SNFs report data on measures and resident assessment data.

B. Initial Transition for the SNF PPS

Under sections 1888(e)(1)(A) and 1888(e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility's historical cost experience) with the federal case-mix adjusted rate. The transition extended through the facility's first 3 cost reporting periods under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments for SNFs entirely on the adjusted federal per diem rates, we no longer include adjustment factors under the transition related to facility-specific rates for the upcoming FY.

C. Required Annual Rate Updates

Section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. The most recent annual update occurred in a final rule that set forth updates to the SNF PPS payment rates for FY 2018 (82 FR 36530), as corrected in the FY 2018 SNF PPS correction notice (82 FR 46163).

Section 1888(e)(4)(H) of the Act specifies that we provide for publication annually in the **Federal Register** of the following:

- The unadjusted federal per diem rates to be applied to days of covered SNF services furnished during the upcoming FY.
- The case-mix classification system to be applied for these services during the upcoming FY.
- The factors to be applied in making the area wage adjustment for these services.

Along with other revisions discussed later in this preamble, this final rule will provide the required annual updates to the per diem payment rates for SNFs for FY 2019.

III. Analysis and Responses to Public Comments on the FY 2019 SNF PPS Proposed Rule

In response to the publication of the FY 2019 SNF PPS proposed rule, we received 290 public comments from individuals, providers, corporations, government agencies, private citizens, trade associations, and major organizations. The following are brief summaries of each proposed provision, a summary of the public comments that we received related to that proposal, and our responses to the comments.

A. General Comments on the FY 2019 SNF PPS Proposed Rule

In addition to the comments we received on specific proposals contained within the proposed rule (which we address later in this final rule), commenters also submitted the following, more general, observations on the SNF PPS and SNF care generally. A discussion of these comments, along with our responses, appears below.

Comment: A few commenters requested clarification of how a SNF may comply with the coverage requirement to provide skilled services on a daily basis and communicate intended compliance with such policy when skilled rehabilitative services are halted temporarily due to a holiday or patient illness, and the only skilled service required is rehabilitation services.

Response: As stated in the FY 2000 SNF PPS final rule (64 FR 41670), the requirement for daily skilled services should not be applied so strictly that it would not be met merely because there is a brief, isolated absence from the facility in a situation where discharge from the facility would not be practical. With regard to the ''daily basis'' requirement, the Medicare program does not specify in regulations or guidelines an official list of holidays of other specific occasions that a facility may observe as breaks in rehabilitation services, but recognizes that the resident's own condition dictates the amount of service that is appropriate. Accordingly, the facility itself must judge whether a brief, temporary pause in the delivery of therapy services would adversely affect the resident's condition.

This policy is also discussed at § 409.34(b), where the paragraph states that a break of 1 or 2 days in the furnishing of rehabilitation services will not preclude coverage if discharge would not be practical for the 1 or 2 days during which, for instance, the physician has suspended the therapy sessions because the patient exhibited extreme fatigue.

Comment: One commenter requested that CMS allow the addition of advanced registered nurse practitioners (ARNPs) to the rehabilitation team to meet regulatory requirements and deal with a shortage of rehabilitation physicians.

Response: We appreciate the comment. While ARNPs are eligible to enroll and participate in Medicare, it is unclear what federal regulatory requirements the commenter is concerned about that would prevent ARNPs from participating in rehabilitation team activities.

B. SNF PPS Rate Setting Methodology and FY 2019 Update

1. Federal Base Rates

Under section 1888(e)(4) of the Act, the SNF PPS uses per diem federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the federal rates also incorporated a Part B add-on, which is an estimate of the amounts that, prior to the SNF PPS, would be payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using a SNF market basket index, and then standardized for geographic variations in wages and for the costs of facility differences in case mix. In compiling the database used to compute the federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA 1997 prescribed, we set the federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas, and adjusted the portion of the federal rate attributable to wage-related costs by a wage index to reflect geographic variations in wages.

2. SNF Market Basket Update

a. SNF Market Basket Index

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we revised and rebased the market basket index, which

included updating the base year from FY 2010 to 2014.

The SNF market basket index is used to compute the market basket percentage change that is used to update the SNF federal rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV) of the Act. This market basket percentage update is adjusted by a forecast error correction, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act and described in section III.B.2.d of this final rule. For FY 2019, the growth rate of the 2014-based SNF market basket in the proposed rule was estimated to be 2.7 percent, based on the IHS Global Insight, Inc. (IGI) first quarter 2018 forecast with historical data through fourth quarter 2017, before the multifactor productivity adjustment is applied. Using IGIs most recent forecast, the second quarter 2018 forecast with historical data through first quarter 2018, we calculate a growth rate of the 2014-based SNF market basket of 2.8 percent.

However, we note that section 53111 of the Bipartisan Budget Act of 2018 (BBA 2018) (Pub. L. 115–123, enacted on February 9, 2018) amended section 1888(e) of the Act to add section 1888(e)(5)(B)(iv) of the Act. Section 1888(e)(5)(B)(iv) of the Act establishes a special rule for FY 2019 that requires the market basket percentage, after the application of the productivity adjustment, to be 2.4 percent. In accordance with section 1888(e)(5)(B)(iv) of the Act, we will use a market basket percentage of 2.4 percent to update the federal rates set forth in this final rule. We proposed to revise § 413.337(d) to reflect this statutorily required 2.4 percent market basket percentage for FY 2019. In addition, to conform with section 1888(e)(5)(B)(iii) of the Act, we proposed to update the regulations to reflect the 1 percent market basket percentage required for FY 2018 (as discussed in the FY 2018 SNF PPS final rule, 82 FR 36533). Accordingly, we proposed to revise paragraph (d)(1) of § 413.337, which sets forth the market basket update formula, by revising paragraph (d)(1)(v), and by adding paragraphs (d)(1)(vi) and (d)(1)(vii). The revision to add paragraph (d)(1)(vi) reflects section 1888(e)(5)(B)(iii) of the Act (as added by section 411(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10)), which, as discussed above, establishes a special rule for FY 2018 that requires the market basket percentage, after the application of the productivity adjustment, to be 1.0 percent. The revision to add paragraph (d)(1)(vii) reflects section 1888(e)(5)(B)(iv) of the Act (as added by section 53111 of BBA 2018), which establishes a special rule for FY 2019 that requires the market basket percentage, after the application of the productivity adjustment, to be 2.4 percent. These statutory provisions are self-implementing and do not require the exercise of discretion by the Secretary. In section III.B.2.e. of this final rule, we discuss the specific application of the BBA 2018-specified market basket adjustment to the forthcoming annual update of the SNF PPS payment rates. In addition, we also discuss in that section the 2 percent reduction applied to the market basket update for those SNFs that fail to submit measures data as required by section 1888(e)(6)(A) of the Act.

b. Use of the SNF Market Basket Percentage

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage as the percentage change in the SNF market basket index from the midpoint of the previous FY to the midpoint of the current FY. Absent the addition of section 1888(e)(5)(B)(iv) of the Act, added by section 53111 of BBA 2018, we would have used the percentage change in the SNF market basket index to compute the update factor for FY 2019. This factor is based on the FY 2019 percentage increase in the 2014-based SNF market basket index reflecting routine, ancillary, and capital-related expenses. In the proposed rule, the SNF market basket percentage was estimated to be 2.7 percent for FY 2019 based on IGI's first quarter 2018 forecast (with historical data through fourth quarter 2017). In this final rule, we are using IGI's more recent second quarter 2018 forecast (with historical data through first quarter 2018) and we calculate a SNF market basket percentage increase of 2.8 percent. As discussed in sections III.B.2.c and III.B.2.d of this final rule, this market basket percentage change would have been reduced by the applicable forecast error correction (as described in § 413.337(d)(2)) and by the MFP adjustment as required by section 1888(e)(5)(B)(ii) of the Act. As noted previously, section 1888(e)(5)(B)(iv) of the Act, added by section 53111 of the BBA 2018, requires us to update the SNF PPS rates for FY 2019 using a 2.4 percent SNF market basket percentage change, instead of the estimated 2.8 percent market basket percentage change adjusted by the multifactor productivity adjustment as described below. Additionally, as discussed in section II.B. of this final rule, we no longer compute update factors to adjust a facility-specific portion of the SNF PPS rates, because the initial three-phase transition period from facility-specific to full federal rates that started with cost reporting periods beginning in July 1998 has expired.

c. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003 final rule (68 FR 46057 through 46059), § 413.337(d)(2) provides for an adjustment to account for market basket forecast error. The initial adjustment for market basket forecast error applied to the update of the FY 2003 rate for FY 2004, and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent to the FY 2004 update. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there is final data, and apply the difference between the forecasted and actual change in the market basket when the difference exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425, August 3, 2007), we adopted a 0.5 percentage point threshold effective for FY 2008 and subsequent FYs. As we stated in the final rule for FY 2004 that first issued the market basket forecast error adjustment (68 FR 46058, August 4, 2003), the adjustment will reflect both upward and downward adjustments, as appropriate.

For FY 2017 (the most recently available FY for which there is final data), the estimated increase in the market basket index was 2.7 percentage points, while the actual increase for FY 2017 was 2.7 percentage points, resulting in the actual increase being the same as the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket index does not exceed the 0.5 percentage point threshold, the FY 2019 market basket percentage change of 2.7 percent would not have been adjusted to account for the forecast error correction. Table 3 shows the forecasted and actual market basket amounts for FY 2017.

TABLE 3—DIFFERENCE BETWEEN THE FORECASTED AND ACTUAL MARKET BASKET INCREASES FOR FY 2017

Index	Forecasted FY 2017 increase *	Actual FY 2017 increase **	FY 2017 difference
SNF	2.7	2.7	0.0

* Published in **Federal Register**; based on second quarter 2016 IGI forecast (2010-based index).
** Based on the second quarter 2018 IGI forecast, with historical data through the first quarter 2018 (2010-based index).

d. Multifactor Productivity Adjustment

Section 1888(e)(5)(B)(ii) of the Act, as added by section 3401(b) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148, enacted on March 23, 2010) requires that, in FY 2012 and in subsequent FYs, the market basket percentage under the SNF payment system (as described in section 1888(e)(5)(B)(i) of the Act) is to be reduced annually by the multifactor productivity (MFP) adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, in turn, defines the MFP adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost-reporting period, or other annual period). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS website at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. To generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS, using a series of proxy variables derived from IGI's U.S. macroeconomic models. For a discussion of the MFP projection methodology, we refer readers to the FY 2012 SNF PPS final rule (76 FR 48527 through 48529) and the FY 2016 SNF PPS final rule (80 FR 46395). A complete description of the MFP projection methodology is available on our website at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html*.

1. Incorporating the MFP Adjustment Into the Market Basket Update

Per section 1888(e)(5)(A) of the Act, the Secretary shall establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Section 1888(e)(5)(B)(ii) of the Act, added by section 3401(b) of the Affordable Care Act, requires that for FY 2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as the MFP adjustment). Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the MFP adjustment may result in the market basket percentage being less than zero for a FY, and may result in payment rates under section 1888(e) of the Act being less than such payment rates for the preceding fiscal year.

The MFP adjustment, calculated as the 10-year moving average of changes in MFP for the period ending September 30, 2019, is estimated to be 0.8 percent based on IGI's second quarter 2018 forecast. Also, consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2), the market basket percentage for FY 2019 for the SNF PPS is based on IGI's second quarter 2018 forecast of the SNF market basket percentage, which is estimated to be 2.8 percent. The proposed rule reflected a market basket percentage for FY 2019 of 2.7 percent and an MFP adjustment of 0.8 percent based on IGI's first quarter 2018 forecast.

If not for the enactment of section 53111 of the BBA 2018, the FY 2019 update would have been calculated in accordance with section 1888(e)(5)(B)(i) and (ii) of the Act, pursuant to which the market basket percentage determined under section 1888(e)(5)(B)(i) of the Act (that is, 2.8 percent) would have been reduced by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2019) of 0.8 percent, which would have been calculated as described above and based on IGI's second quarter 2018 forecast. Absent the enactment of section 53111 of the BBA 2018, the resulting MFP-adjusted SNF market basket update would have been equal to 2.0 percent, or 2.8 percent less 0.8 percentage point. However, as discussed above, section 1888(e)(5)(B)(iv) of the Act, added by section 53111 of the BBA 2018, requires us to apply a 2.4 percent market basket percentage increase in determining the FY 2019 SNF payment rates set forth in this final rule (without regard to the MFP adjustment described above).

e. Market Basket Update Factor for FY 2019

Sections 1888(e)(4)(E)(ii)(IV) and 1888(e)(5)(i) of the Act require that the update factor used to establish the FY 2019 unadjusted federal rates be at a level equal to the market basket index percentage change. Accordingly, we determined the total growth from the average market basket level for the period of October 1, 2017, through September 30, 2018 to the average market basket level for the period of October 1, 2018, through September 30, 2019. This process yields a percentage change in the 2014-based SNF market basket of 2.8 percent.

As further explained in section III.B.2.c. of this final rule, as applicable, we adjust the market basket percentage change by the forecast error from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage change in the market basket exceeds a 0.5 percentage point threshold. Since the difference between the forecasted FY 2017 SNF market basket percentage change and the actual FY 2017 SNF market basket percentage change (FY 2017 is the most recently available FY for which there is historical data) did not exceed the 0.5 percentage point threshold, the FY 2019 market basket percentage change of 2.8 percent would not be adjusted by the forecast error correction.

If not for the enactment of section 53111 of the BBA 2018, the SNF market basket for FY 2019 would have been determined in accordance with section

1888(e)(5)(B)(ii) of the Act, which requires us to reduce the market basket percentage change by the MFP adjustment (the 10-year moving average of changes in MFP for the period ending September 30, 2019) of 0.8 percent, as described in section III.B.2.d.1. of this final rule. Thus, absent the enactment of the BBA 2018, the resulting net SNF market basket update would have been equal to 2.0 percent, or 2.8 percent less the 0.8 percentage point MFP adjustment. We note that our policy has been that, if more recent data become available (for example, a more recent estimate of the SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the SNF PPS final rule.

Historically, we have used the SNF market basket, adjusted as described above, to adjust each per diem component of the federal rates forward to reflect the change in the average prices from one year to the next. However, section 1888(e)(5)(B)(iv) of the Act, as added by section 53111 of the BBA 2018, requires us to use a market basket percentage of 2.4 percent, after application of the MFP to adjust the federal rates for FY 2019. Under section 1888(e)(5)(B)(iv) of the Act, the market basket percentage increase used to determine the federal rates set forth in Table 4 and 5 in this final rule will be 2.4 percent for FY 2019.

In addition, we note that section 1888(e)(6)(A)(i) of the Act provides that, beginning with FY 2018, SNFs that fail to submit data, as applicable, in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for a fiscal year will receive a 2.0 percentage point reduction to their market basket update for the fiscal year involved, after application of section 1888(e)(5)(B)(ii) of the Act (the MFP adjustment) and section 1888(e)(5)(B)(iii) of the Act (the 1 percent market basket increase for FY 2018). In addition, section 1888(e)(6)(A)(ii) of the Act states that application of the 2.0 percentage point reduction (after application of section 1888(e)(5)(B)(ii) and (iii) of the Act) may result in the market basket index percentage change being less than 0.0 for a fiscal year, and may result in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Section 1888(e)(6)(A)(iii) of the Act further specifies that the 2.0 percentage point reduction is applied in a noncumulative manner, so that any reduction made under section 1888(e)(6)(A)(i) of the Act applies only with respect to the fiscal year involved, and that the reduction cannot be taken into account in computing the payment amount for a subsequent fiscal year.

Accordingly, we proposed that for SNFs that do not satisfy the reporting requirements for the FY 2019 SNF QRP, we would apply a 2.0 percentage point reduction to the SNF market basket percentage change for that fiscal year, after application of any applicable forecast error adjustment as specified in § 413.337(d)(2) and the MFP adjustment as specified in § 413.337(d)(3). In the FY 2019 SNF PPS proposed rule (83 FR 21024), we proposed that, for FY 2019, the application of this reduction to SNFs that have not met the requirements for the FY 2019 SNF QRP would result in a market basket index percentage change for FY 2019 that is less than zero (specifically, a net update of negative 0.1 percentage point, derived by subtracting 2 percent from the MFP-adjusted market basket update of 1.9 percent), and would also result in FY 2019 payment rates that are less than such payment rates for the preceding FY. However, we inadvertently applied the 2.0 percent reduction to the market basket adjustment factor that would have applied were it not for the application of the BBA 2018 stipulated market basket update factor rather than to the BBA 2018 stipulated market basket update factor of 2.4 percent. Therefore, when properly applied, the net update for providers that fail to meet the requirements for the FY 2019 SNF QRP will be 0.4 percent, rather than the negative 0.1 percent discussed in the proposed rule. We invited comments on these proposals.

Commenters submitted the following comments related to the proposed rule's discussion of the Market Basket Update Factor for FY 2019. A discussion of these comments, along with our responses, appears below.

Comment: We received a number of comments in relation to applying the FY 2019 market basket update factor in the determination of the FY 2019 unadjusted federal per diem rates, with some commenters supporting its application in determining the FY 2019 unadjusted per diem rates, while others opposed its application. In their March 2018 report (available at *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch8_sec.pdf*) and in their comment on the FY 2019 SNF PPS proposed rule, MedPAC recommended that we eliminate the market basket update for SNFs altogether for FY 2019 and FY 2020 and implement revisions to the SNF PPS.

Response: We appreciate all of the comments received on the proposed market basket update for FY 2019. In response to those comments opposing the application of the FY 2019 market basket update factor in determining the FY 2019 unadjusted federal per diem rates, specifically MedPAC's proposal to eliminate the market basket update for SNFs, we are required to update the unadjusted Federal per diem rates for FY 2019 by 2.4 percent under section 1888(e)(4)(E)(ii)(IV) and (e)(5)(B) of the Act. as amended by section 53111 of the BBA 2018.

Comment: A few commenters expressed concern with regard to CMS applying the 2.0 percentage point reduction to the market basket increase to the standard market basket adjustment of 1.9 percent, rather than to the market basket required as a result of the BBA 2018. These commenters requested that CMS reconsider this decision and to apply the QRP-related market basket reduction to the BBA 2018-stipulated market basket.

Response: We appreciate the comments on this issue. Further, we agree with commenters that the QRP-related reduction to the market basket should be applied to the BBA 2018-stipulated market basket. Therefore, the market basket update factor that would be applied in cases where a provider has not met the requirements of the FY 2019 SNF QRP would be a positive 0.4 percent, rather than the negative 0.1 percent discussed in the FY 2019 SNF PPS proposed rule.

Accordingly, for the reasons specified in this final rule and in the FY 2019 SNF PPS proposed rule (83 FR 21021 through 21024), we are applying the FY 2019 SNF market basket increase factor of 2.4 percent, as stipulated by the BBA 2018, in our determination of the FY 2019 SNF PPS unadjusted federal per diem rates. As described in this section, we are adjusting each per diem component of the federal rates forward to reflect the BBA 2018 stipulated update factor for FY 2019.

Tables 4 and 5 reflect the updated components of the unadjusted federal rates for FY 2019, prior to adjustment for case-mix.

TABLE 4—FY 2019 UNADJUSTED FEDERAL RATE PER DIEM—URBAN

Rate component	Nursing—case-mix	Therapy—case-mix	Therapy—non-case-mix	Non-case-mix
Per Diem Amount	$181.44	$136.67	$18.00	$92.60

TABLE 5—FY 2019 UNADJUSTED FEDERAL RATE PER DIEM—RURAL

Rate component	Nursing—case-mix	Therapy—case-mix	Therapy—Non-case-mix	Non-case-mix
Per Diem Amount	$173.34	$157.60	$19.23	$94.31

3. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the interim final rule with comment period that initially implemented the SNF PPS (63 FR 26252, May 12, 1998), we developed the RUG–III case-mix classification system, which tied the amount of payment to resident resource use in combination with resident characteristic information. Staff time measurement (STM) studies conducted in 1990, 1995, and 1997 provided information on resource use (time spent by staff members on residents) and resident characteristics that enabled us not only to establish RUG–III, but also to create case-mix indexes (CMIs). The original RUG–III grouper logic was based on clinical data collected in 1990, 1995, and 1997. As discussed in the SNF PPS proposed rule for FY 2010 (74 FR 22208), we subsequently conducted a multi-year data collection and analysis under the Staff Time and Resource Intensity Verification (STRIVE) project to update the case-mix classification system for FY 2011. The resulting Resource Utilization Groups, Version 4 (RUG–IV) case-mix classification system reflected the data collected in 2006 through 2007 during the STRIVE project, and was finalized in the FY 2010 SNF PPS final rule (74 FR 40288) to take effect in FY 2011 concurrently with an updated new resident assessment instrument, version 3.0 of the Minimum Data Set (MDS 3.0), which collects the clinical data used for case-mix classification under RUG–IV.

We note that case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy services. The case-mix classification system uses clinical data from the MDS to assign a case-mix group to each patient that is then used to calculate a per diem payment under the SNF PPS. As discussed in section IV.A. of this final rule, the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided extensive training on proper coding and the timeframes for MDS completion in our Resident Assessment Instrument (RAI) Manual. For an MDS to be considered valid for use in determining payment, the MDS assessment must be completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS website at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html*.

In addition, we note that section 511 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, Pub. L. 108–173, enacted December 8, 2003) amended section 1888(e)(12) of the Act to provide for a temporary increase of 128 percent in the PPS per diem payment for any SNF residents with Acquired Immune Deficiency Syndrome (AIDS), effective with services furnished on or after October 1, 2004. This special add-on for SNF residents with AIDS was to remain in effect only until the Secretary certifies that there is an appropriate adjustment in the case mix to compensate for the increased costs associated with such residents. The MMA add-on for SNF residents with AIDS is also discussed in Program Transmittal #160 (Change Request #3291), issued on April 30, 2004, which is available online at *www.cms.gov/transmittals/downloads/r160cp.pdf*. In the SNF PPS final rule for FY 2010 (74 FR 40288), we did not address this certification in that final rule's implementation of the case-mix refinements for RUG–IV, thus allowing the add-on payment required by section 511 of the MMA to remain in effect for the time being. (We discuss in section V.H. of this final rule the specific payment adjustments that we proposed under the proposed PDPM to provide for an appropriate adjustment in the case mix to compensate for the increased costs associated with such residents.)

For the limited number of SNF residents that qualify for the MMA add-on, there is a significant increase in payments. As explained in the FY 2016 SNF PPS final rule (80 FR 46397 through 46398), on October 1, 2015 (consistent with section 212 of PAMA), we converted from using ICD–9–CM code 042 to ICD–10–CM code B20 for identifying those residents for whom it is appropriate to apply the AIDS add-on established by section 511 of the MMA. For FY 2019, an urban facility with a resident with AIDS in RUG–IV group ''HC2'' would have a case-mix adjusted per diem payment of $453.52 (see Table 6) before the application of the MMA adjustment. After an increase of 128 percent, this urban facility would receive a case-mix adjusted per diem payment of approximately $1,034.03.

Under section 1888(e)(4)(H), each update of the payment rates must include the case-mix classification methodology applicable for the upcoming FY. The FY 2019 payment rates set forth in this final rule reflect the use of the RUG–IV case-mix classification system from October 1, 2018, through September 30, 2019. We list the final case-mix adjusted RUG–IV payment rates for FY 2019, provided separately for urban and rural SNFs, in

Tables 6 and 7 with corresponding case-mix values. We use the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634) to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility. Tables 6 and 7 do not reflect the add-on for SNF residents with AIDS enacted by section 511 of the MMA, which we apply only after making all other adjustments (such as wage index and case-mix). Additionally, Tables 6 and 7 do not reflect adjustments which may be made to the SNF PPS rates as a result of either the SNF QRP, discussed in section VI.B of this final rule, or the SNF VBP program, discussed in sections III.B.5 and VI.C of this final rule.

TABLE 6—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—URBAN

RUG–IV category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
RUX	2.67	1.87	$484.44	$255.57	.....	$92.60	$832.89
RUL	2.57	1.87	466.30	255.57	.....	92.60	814.74
RVX	2.61	1.28	473.56	174.94	.....	92.60	741.34
RVL	2.19	1.28	397.35	174.94	.....	92.60	665.11
RHX	2.55	0.85	462.67	116.17	.....	92.60	671.66
RHL	2.15	0.85	390.10	116.17	.....	92.60	599.06
RMX	2.47	0.55	448.16	75.17	.....	92.60	616.13
RML	2.19	0.55	397.35	75.17	.....	92.60	565.31
RLX	2.26	0.28	410.05	38.27	.....	92.60	541.10
RUC	1.56	1.87	283.05	255.57	.....	92.60	631.42
RUB	1.56	1.87	283.05	255.57	.....	92.60	631.42
RUA	0.99	1.87	179.63	255.57	.....	92.60	527.97
RVC	1.51	1.28	273.97	174.94	.....	92.60	541.69
RVB	1.11	1.28	201.40	174.94	.....	92.60	469.09
RVA	1.10	1.28	199.58	174.94	.....	92.60	467.27
RHC	1.45	0.85	263.09	116.17	.....	92.60	472.01
RHB	1.19	0.85	215.91	116.17	.....	92.60	424.82
RHA	0.91	0.85	165.11	116.17	.....	92.60	374.00
RMC	1.36	0.55	246.76	75.17	.....	92.60	414.66
RMB	1.22	0.55	221.36	75.17	.....	92.60	389.25
RMA	0.84	0.55	152.41	75.17	.....	92.60	320.28
RLB	1.50	0.28	272.16	38.27	.....	92.60	403.16
RLA	0.71	0.28	128.82	38.27	.....	92.60	259.78
ES3	3.58	.....	649.56	.....	18.00	92.60	760.41
ES2	2.67	.....	484.44	.....	18.00	92.60	595.25
ES1	2.32	.....	420.94	.....	18.00	92.60	531.72
HE2	2.22	.....	402.80	.....	18.00	92.60	513.57
HE1	1.74	.....	315.71	.....	18.00	92.60	426.45
HD2	2.04	.....	370.14	.....	18.00	92.60	480.90
HD1	1.60	.....	290.30	.....	18.00	92.60	401.04
HC2	1.89	.....	342.92	.....	18.00	92.60	453.68
HC1	1.48	.....	268.53	.....	18.00	92.60	379.26
HB2	1.86	.....	337.48	.....	18.00	92.60	448.23
HB1	1.46	.....	264.90	.....	18.00	92.60	375.63
LE2	1.96	.....	355.62	.....	18.00	92.60	466.38
LE1	1.54	.....	279.42	.....	18.00	92.60	390.15
LD2	1.86	.....	337.48	.....	18.00	92.60	448.23
LD1	1.46	.....	264.90	.....	18.00	92.60	375.63
LC2	1.56	.....	283.05	.....	18.00	92.60	393.78
LC1	1.22	.....	221.36	.....	18.00	92.60	332.07
LB2	1.45	.....	263.09	.....	18.00	92.60	373.82
LB1	1.14	.....	206.84	.....	18.00	92.60	317.55
CE2	1.68	.....	304.82	.....	18.00	92.60	415.56
CE1	1.50	.....	272.16	.....	18.00	92.60	382.89
CD2	1.56	.....	283.05	.....	18.00	92.60	393.78
CD1	1.38	.....	250.39	.....	18.00	92.60	361.11
CC2	1.29	.....	234.06	.....	18.00	92.60	344.78
CC1	1.15	.....	208.66	.....	18.00	92.60	319.37
CB2	1.15	.....	208.66	.....	18.00	92.60	319.37
CB1	1.02	.....	185.07	.....	18.00	92.60	295.77
CA2	0.88	.....	159.67	.....	18.00	92.60	270.36
CA1	0.78	.....	141.52	.....	18.00	92.60	252.21
BB2	0.97	.....	176.00	.....	18.00	92.60	286.70
BB1	0.90	.....	163.30	.....	18.00	92.60	273.99
BA2	0.70	.....	127.01	.....	18.00	92.60	237.69
BA1	0.64	.....	116.12	.....	18.00	92.60	226.80
PE2	1.50	.....	272.16	.....	18.00	92.60	382.89
PE1	1.40	.....	254.02	.....	18.00	92.60	364.74
PD2	1.38	.....	250.39	.....	18.00	92.60	361.11
PD1	1.28	.....	232.24	.....	18.00	92.60	342.96
PC2	1.10	.....	199.58	.....	18.00	92.60	310.29
PC1	1.02	.....	185.07	.....	18.00	92.60	295.77
PB2	0.84	.....	152.41	.....	18.00	92.60	263.10

TABLE 6—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—URBAN—Continued

RUG–IV category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
PB1	0.78		141.52		18.00	92.60	252.21
PA2	0.59		107.05		18.00	92.60	217.73
PA1	0.54		97.98		18.00	92.60	208.65

TABLE 7—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—RURAL

RUG–IV category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
RUX	2.67	1.87	$462.82	$294.71		$94.31	$852.10
RUL	2.57	1.87	445.48	294.71		94.31	834.76
RVX	2.61	1.28	452.42	201.73		94.31	748.68
RVL	2.19	1.28	379.61	201.73		94.31	675.85
RHX	2.55	0.85	442.02	133.96		94.31	670.48
RHL	2.15	0.85	372.68	133.96		94.31	601.13
RMX	2.47	0.55	428.15	86.68		94.31	609.32
RML	2.19	0.55	379.61	86.68		94.31	560.77
RLX	2.26	0.28	391.75	44.13		94.31	530.34
RUC	1.56	1.87	270.41	294.71		94.31	659.64
RUB	1.56	1.87	270.41	294.71		94.31	659.64
RUA	0.99	1.87	171.61	294.71		94.31	560.81
RVC	1.51	1.28	261.74	201.73		94.31	557.95
RVB	1.11	1.28	192.41	201.73		94.31	488.59
RVA	1.10	1.28	190.67	201.73		94.31	486.86
RHC	1.45	0.85	251.34	133.96		94.31	479.76
RHB	1.19	0.85	206.27	133.96		94.31	434.67
RHA	0.91	0.85	157.74	133.96		94.31	386.12
RMC	1.36	0.55	235.74	86.68		94.31	416.86
RMB	1.22	0.55	211.47	86.68		94.31	392.59
RMA	0.84	0.55	145.61	86.68		94.31	326.70
RLB	1.50	0.28	260.01	44.13		94.31	398.57
RLA	0.71	0.28	123.07	44.13		94.31	261.59
ES3	3.58		620.56		19.23	94.31	734.31
ES2	2.67		462.82		19.23	94.31	576.52
ES1	2.32		402.15		19.23	94.31	515.83
HE2	2.22		384.81		19.23	94.31	498.50
HE1	1.74		301.61		19.23	94.31	415.27
HD2	2.04		353.61		19.23	94.31	467.29
HD1	1.60		277.34		19.23	94.31	390.99
HC2	1.89		327.61		19.23	94.31	441.28
HC1	1.48		256.54		19.23	94.31	370.19
HB2	1.86		322.41		19.23	94.31	436.08
HB1	1.46		253.08		19.23	94.31	366.72
LE2	1.96		339.75		19.23	94.31	453.41
LE1	1.54		266.94		19.23	94.31	380.59
LD2	1.86		322.41		19.23	94.31	436.08
LD1	1.46		253.08		19.23	94.31	366.72
LC2	1.56		270.41		19.23	94.31	384.06
LC1	1.22		211.47		19.23	94.31	325.11
LB2	1.45		251.34		19.23	94.31	364.99
LB1	1.14		197.61		19.23	94.31	311.23
CE2	1.68		291.21		19.23	94.31	404.87
CE1	1.50		260.01		19.23	94.31	373.66
CD2	1.56		270.41		19.23	94.31	384.06
CD1	1.38		239.21		19.23	94.31	352.85
CC2	1.29		223.61		19.23	94.31	337.24
CC1	1.15		199.34		19.23	94.31	312.97
CB2	1.15		199.34		19.23	94.31	312.97
CB1	1.02		176.81		19.23	94.31	290.43
CA2	0.88		152.54		19.23	94.31	266.15
CA1	0.78		135.21		19.23	94.31	248.81
BB2	0.97		168.14		19.23	94.31	281.76
BB1	0.90		156.01		19.23	94.31	269.62
BA2	0.70		121.34		19.23	94.31	234.94
BA1	0.64		110.94		19.23	94.31	224.54
PE2	1.50		260.01		19.23	94.31	373.66
PE1	1.40		242.68		19.23	94.31	356.32
PD2	1.38		239.21		19.23	94.31	352.85
PD1	1.28		221.88		19.23	94.31	335.51
PC2	1.10		190.67		19.23	94.31	304.30

TABLE 7—RUG–IV CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—RURAL—Continued

RUG–IV category	Nursing index	Therapy index	Nursing component	Therapy component	Non-case mix therapy comp	Non-case mix component	Total rate
PC1	1.02		176.81		19.23	94.31	290.43
PB2	0.84		145.61		19.23	94.31	259.22
PB1	0.78		135.21		19.23	94.31	248.81
PA2	0.59		102.27		19.23	94.31	215.87
PA1	0.54		93.60		19.23	94.31	207.20

4. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We proposed to continue this practice for FY 2019, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. For FY 2019, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2014 and before October 1, 2015 (FY 2015 cost report data).

We note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554, enacted on December 21, 2000) authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF wage index that is based on wage data from nursing homes. However, to date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of that data. More specifically, auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the Inpatient Prospective Payment System (IPPS) wage index, would place a burden on providers in terms of recordkeeping and completion of the cost report worksheet. As discussed in greater detail later in this section, 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 nearly five times as many SNFs as there are inpatient hospitals. Therefore, while we continue to believe that the development of such an audit process could improve SNF cost reports in such a manner as to permit us to establish a SNF-specific wage index, we do not regard an undertaking of this magnitude as being feasible within the current level of programmatic resources.

In addition, we proposed to continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals, and thus, no hospital wage index data on which to base the calculation of the FY 2019 SNF PPS wage index. For rural geographic areas that do not have hospitals, and therefore, lack hospital wage data on which to base an area wage adjustment, we would use the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2019, there are no rural geographic areas that do not have hospitals, and thus, this methodology would not be applied. For rural Puerto Rico, we would 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 would continue to use the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we would use the average wage indexes of all of the urban areas within the state to serve as a reasonable proxy for the wage index of that urban CBSA. For FY 2019, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA. The final wage index applicable to FY 2019 is set forth in Tables A and B available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*.

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas. In adopting the CBSA geographic designations, we provided for a 1-year transition in FY 2006 with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), since the expiration of this 1-year transition on September 30, 2006, we have used the full CBSA-based wage index values.

In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY 2015, including a 1-year transition with a blended wage index for FY 2015. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010 in the **Federal Register** (75 FR 37246 through 37252). Subsequently, on July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides minor updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates

provided in OMB Bulletin No. 15–01 are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013. As we previously stated in the FY 2008 SNF PPS proposed and final rules (72 FR 25538 through 25539, and 72 FR 43423), we wish to note that this and all subsequent SNF PPS rules and notices are considered to incorporate any updates and revisions set forth in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index.

On August 15, 2017, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area (OMB Bulletin No. 17–01). The new urban CBSA is as follows:

- Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB bulletin is available on the OMB website at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*. As we stated in the proposed rule (83 FR 21028), we did not have sufficient time to include this change in the computation of the proposed FY 2019 wage index, rate setting, and tables. We also stated that this new CBSA may affect the budget neutrality factor and wage indexes, depending on the impact of the overall payments of the hospital located in this new CBSA. In the proposed rule, we provided an estimate of this new area's wage index based on the average hourly wage, unadjusted for occupational mix, for new CBSA 46300 and the national average hourly wages from the wage data for the proposed FY 2019 wage index. Currently, provider 130002 is the only hospital located in Twin Falls County, Idaho, and there are no hospitals located in Jerome County, Idaho. Thus, the wage index for CBSA 46300 is calculated using the average hourly wage data for one provider (provider 130002). In this final rule, we are providing below this new area's wage index based on the updated average hourly wage, unadjusted for occupational mix, for new CBSA 46300 and the updated national average hourly wages from the wage data for the FY 2019 wage index, and we are incorporating this change into the final FY 2019 wage index, rate setting and tables. Taking the unadjusted average hourly wage of $35.8336 of new CBSA 46300 and dividing by the national average hourly wage of $42.955567020 results in the FY 2019 wage index of 0.8334 for CBSA 46300.

In the proposed rule, we stated that in the final rule, we would incorporate this change into the final FY 2019 wage index, rate setting and tables. We did not receive any comments on this issue. Thus, in this final rule, we have incorporated this change into the final FY 2019 wage index, rate setting and tables. As we proposed, for FY 2019, we will use the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01. As noted above, the wage index applicable to FY 2019 (with the CBSA update from OMB Bulletin No. 17–01 specified above) is set forth in Tables A and B available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html*.

Once calculated, we stated in the proposed rule that we would apply the wage index adjustment to the labor-related portion of the federal rate. Each year, we calculate a revised labor-related share, based on the relative importance of labor-related cost categories (that is, those cost categories that are labor-intensive and vary with the local labor market) in the input price index. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we finalized a proposal to revise the labor-related share to reflect the relative importance of the 2014-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses.

We calculate the labor-related relative importance from the SNF market basket, and it approximates the labor-related portion of the total costs after taking into account historical and projected price changes between the base year and FY 2019. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2019 than the base year weights from the SNF market basket.

We calculate the labor-related relative importance for FY 2019 in four steps. First, we compute the FY 2019 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2019 price index level for that cost category by the total market basket price index level. Third, we determine the FY 2019 relative importance for each cost category by multiplying this ratio by the base year (2014) weight. Finally, we add the FY 2019 relative importance for each of the labor-related cost categories (Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, All Other: Labor-related services, and a portion of Capital-Related expenses) to produce the FY 2019 labor-related relative importance. Table 8 summarizes the updated labor-related share for FY 2019, based on IGI's second quarter 2018 forecast with historical data through first quarter 2018, compared to the labor-related share that was used for the FY 2018 SNF PPS final rule. In the FY 2019 proposed rule, we presented the FY 2019 labor-related share based on IGI's first quarter 2018 forecast and further stated that if more recent data became available (for example, a more recent estimate of the SNF market basket and/or MFP adjustment), we would use such data, if appropriate, to determine the SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, and MFP adjustment in the SNF PPS final rule.

TABLE 8—LABOR-RELATED RELATIVE IMPORTANCE, FY 2018 AND FY 2019

	Relative importance, labor-related, FY 2018 17:2 forecast [1]	Relative importance, labor-related, FY 2019 18:2 forecast [2]
Wages and salaries	50.3	50.2
Employee benefits	10.2	10.1
Professional Fees: Labor-Related	3.7	3.7
Administrative and facilities support services	0.5	0.5
Installation, Maintenance and Repair Services	0.6	0.6
All Other: Labor Related Services	2.5	2.5
Capital-related (.391)	3.0	2.9
Total	70.8	70.5

[1] Published in the **Federal Register**; based on second quarter 2017 IGI forecast.
[2] Based on second quarter 2018 IGI forecast, with historical data through first quarter 2018.

Tables 9 and 10 show the RUG–IV case-mix adjusted federal rates for FY 2019 by labor-related and non-labor-related components. Tables 9 and 10 do not reflect the add-on for SNF residents with AIDS enacted by section 511 of the MMA, which we apply only after making all other adjustments (such as wage index and case-mix). Additionally, Tables 9 and 10 do not reflect adjustments which may be made to the SNF PPS rates as a result of either the SNF QRP, discussed in section VI.B. of this final rule, or the SNF VBP program, discussed in sections III.B.5. and VI.C. of this final rule.

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TABLE 9: RUG-IV Case-Mix Adjusted Federal Rates for Urban SNFs By Labor and Non-Labor Component

RUG-IV Category	Total Rate	Labor Portion	Non-Labor Portion
RUX	$832.61	$586.99	$245.62
RUL	$814.47	$574.20	$240.27
RVX	$741.10	$522.48	$218.62
RVL	$664.89	$468.75	$196.14
RHX	$671.44	$473.37	$198.07
RHL	$598.87	$422.20	$176.67
RMX	$615.93	$434.23	$181.70
RML	$565.12	$398.41	$166.71
RLX	$540.92	$381.35	$159.57
RUC	$631.22	$445.01	$186.21
RUB	$631.22	$445.01	$186.21
RUA	$527.80	$372.10	$155.70
RVC	$541.51	$381.76	$159.75
RVB	$468.94	$330.60	$138.34
RVA	$467.12	$329.32	$137.80
RHC	$471.86	$332.66	$139.20
RHB	$424.68	$299.40	$125.28
RHA	$373.88	$263.59	$110.29
RMC	$414.53	$292.24	$122.29
RMB	$389.13	$274.34	$114.79
RMA	$320.18	$225.73	$94.45
RLB	$403.03	$284.14	$118.89
RLA	$259.69	$183.08	$76.61
ES3	$760.16	$535.91	$224.25
ES2	$595.04	$419.50	$175.54
ES1	$531.54	$374.74	$156.80
HE2	$513.40	$361.95	$151.45
HE1	$426.31	$300.55	$125.76
HD2	$480.74	$338.92	$141.82
HD1	$400.90	$282.63	$118.27
HC2	$453.52	$319.73	$133.79
HC1	$379.13	$267.29	$111.84
HB2	$448.08	$315.90	$132.18
HB1	$375.50	$264.73	$110.77
LE2	$466.22	$328.69	$137.53
LE1	$390.02	$274.96	$115.06
LD2	$448.08	$315.90	$132.18
LD1	$375.50	$264.73	$110.77
LC2	$393.65	$277.52	$116.13
LC1	$331.96	$234.03	$97.93
LB2	$373.69	$263.45	$110.24
LB1	$317.44	$223.80	$93.64
CE2	$415.42	$292.87	$122.55
CE1	$382.76	$269.85	$112.91
CD2	$393.65	$277.52	$116.13
CD1	$360.99	$254.50	$106.49
CC2	$344.66	$242.99	$101.67
CC1	$319.26	$225.08	$94.18
CB2	$319.26	$225.08	$94.18
CB1	$295.67	$208.45	$87.22
CA2	$270.27	$190.54	$79.73
CA1	$252.12	$177.74	$74.38
BB2	$286.60	$202.05	$84.55
BB1	$273.90	$193.10	$80.80
BA2	$237.61	$167.52	$70.09
BA1	$226.72	$159.84	$66.88
PE2	$382.76	$269.85	$112.91
PE1	$364.62	$257.06	$107.56
PD2	$360.99	$254.50	$106.49
PD1	$342.84	$241.70	$101.14
PC2	$310.18	$218.68	$91.50
PC1	$295.67	$208.45	$87.22
PB2	$263.01	$185.42	$77.59
PB1	$252.12	$177.74	$74.38
PA2	$217.65	$153.44	$64.21
PA1	$208.58	$147.05	$61.53

TABLE 10: RUG-IV Case-Mix Adjusted Federal Rates for Rural SNFs by Labor and Non-Labor Component

RUG-IV Category	Total Rate	Labor Portion	Non-Labor Portion
RUX	$851.84	$600.55	$251.29
RUL	$834.50	$588.32	$246.18
RVX	$748.46	$527.66	$220.80
RVL	$675.65	$476.33	$199.32
RHX	$670.29	$472.55	$197.74
RHL	$600.95	$423.67	$177.28
RMX	$609.14	$429.44	$179.70
RML	$560.60	$395.22	$165.38
RLX	$530.19	$373.78	$156.41
RUC	$659.43	$464.90	$194.53
RUB	$659.43	$464.90	$194.53
RUA	$560.63	$395.24	$165.39
RVC	$557.78	$393.23	$164.55
RVB	$488.45	$344.36	$144.09
RVA	$486.71	$343.13	$143.58
RHC	$479.61	$338.13	$141.48
RHB	$434.54	$306.35	$128.19
RHA	$386.01	$272.14	$113.87
RMC	$416.73	$293.79	$122.94
RMB	$392.46	$276.68	$115.78
RMA	$326.60	$230.25	$96.35
RLB	$398.45	$280.91	$117.54
RLA	$261.51	$184.36	$77.15
ES3	$734.10	$517.54	$216.56
ES2	$576.36	$406.33	$170.03
ES1	$515.69	$363.56	$152.13
HE2	$498.35	$351.34	$147.01
HE1	$415.15	$292.68	$122.47
HD2	$467.15	$329.34	$137.81
HD1	$390.88	$275.57	$115.31
HC2	$441.15	$311.01	$130.14
HC1	$370.08	$260.91	$109.17
HB2	$435.95	$307.34	$128.61
HB1	$366.62	$258.47	$108.15
LE2	$453.29	$319.57	$133.72
LE1	$380.48	$268.24	$112.24
LD2	$435.95	$307.34	$128.61
LD1	$366.62	$258.47	$108.15
LC2	$383.95	$270.68	$113.27
LC1	$325.01	$229.13	$95.88
LB2	$364.88	$257.24	$107.64
LB1	$311.15	$219.36	$91.79
CE2	$404.75	$285.35	$119.40
CE1	$373.55	$263.35	$110.20
CD2	$383.95	$270.68	$113.27
CD1	$352.75	$248.69	$104.06
CC2	$337.15	$237.69	$99.46
CC1	$312.88	$220.58	$92.30
CB2	$312.88	$220.58	$92.30
CB1	$290.35	$204.70	$85.65
CA2	$266.08	$187.59	$78.49
CA1	$248.75	$175.37	$73.38
BB2	$281.68	$198.58	$83.10
BB1	$269.55	$190.03	$79.52
BA2	$234.88	$165.59	$69.29
BA1	$224.48	$158.26	$66.22
PE2	$373.55	$263.35	$110.20
PE1	$356.22	$251.14	$105.08
PD2	$352.75	$248.69	$104.06
PD1	$335.42	$236.47	$98.95
PC2	$304.21	$214.47	$89.74
PC1	$290.35	$204.70	$85.65
PB2	$259.15	$182.70	$76.45
PB1	$248.75	$175.37	$73.38
PA2	$215.81	$152.15	$63.66
PA1	$207.14	$146.03	$61.11

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Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. For FY 2019 (federal rates effective October 1, 2018), we stated in the proposed rule that we would apply an adjustment to fulfill the budget neutrality requirement. We stated we would meet this requirement by multiplying each of the components of the unadjusted federal rates by a budget neutrality factor equal to the ratio of the weighted average wage adjustment factor for FY 2018 to the weighted average wage adjustment factor for FY 2019. For this calculation, we stated we would use the same FY 2017 claims utilization data for both the numerator and denominator of this ratio. We define the wage adjustment factor used in this calculation as the labor share of the rate component multiplied by the wage index plus the non-labor share of the rate component. We did not receive any comments regarding our proposed budget neutrality factor calculation. Thus, we are finalizing the budget neutrality methodology as proposed. The final budget neutrality factor for FY 2019 is 0.9999. We note that this is different from the budget neutrality factor (1.0002) provided in the FY 2018 SNF PPS proposed rule (83 FR 21031) due to an updated wage index file and updated

claims file used to calculate the budget neutrality factor.

As discussed above, we have historically used, and propose to continue using, pre-reclassified IPPS hospital wage data, unadjusted for occupational mix and the rural and imputed floors, as the basis for the SNF wage index. That being said, in the proposed rule, we noted that we have received recurring comments in prior rulemaking (most recently in the FY 2018 SNF PPS final rule (82 FR 36539 through 36541)) regarding the development of a SNF-specific wage index. It has been suggested that we develop a SNF-specific wage index utilizing SNF cost report wage data instead of hospital wage data. We have noted, in response 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 SNF 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, and it would be significantly more so in the case of approximately 15,000 SNFs. As discussed previously in this rule, we believe auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the IPPS wage index, would 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 nearly five times as many SNFs as there are hospitals. Therefore, while we continue to review all available data and contemplate the potential methodological approaches for a SNF-specific wage index in the future, we continue to believe that in the absence of the appropriate SNF-specific wage data, using the pre-reclassified, pre-rural and imputed floor hospital inpatient wage data (without the occupational mix adjustment) is appropriate and reasonable for the SNF PPS.

As an alternative to a SNF-specific wage index, it has also been suggested that we consider adopting certain wage index policies in use under the IPPS, such as geographic reclassification or rural floor. Although we have the authority under section 315 of BIPA to establish a geographic reclassification procedure specific to SNFs under certain conditions, as discussed previously, under BIPA, we cannot adopt a reclassification policy until we have collected the data necessary to establish a SNF-specific wage index. Thus, we cannot adopt a reclassification procedure at this time. With regard to adopting a rural floor policy, as we stated in the FY 2017 SNF PPS final rule (82 FR 36540), MedPAC has recommended eliminating the rural floor policy (which actually sets a floor for urban hospitals) from the calculation of the IPPS wage index (see, for example, Chapter 3 of MedPAC's March 2013 Report to Congress on Medicare Payment Policy, available at *http://medpac.gov/docs/default-source/reports/mar13_ch03.pdf,* which notes on page 65 that in 2007, MedPAC had ''. . . recommended eliminating these special wage index adjustments and adopting a new wage index system to avoid geographic inequities that can occur due to current wage index policies (Medicare Payment Advisory Commission 2007b.''). As we stated in the FY 2017 SNF PPS final rule, if we were to adopt the rural floor under the SNF PPS, we believe that the SNF PPS wage index could become vulnerable to problems similar to those that MedPAC identified in its March 2013 Report to Congress.

Given the perennial nature of these comments and responses on the SNF PPS wage index policy, in the proposed rule (89 FR 21032) we invited further comments on the issues discussed above. Specifically, we requested comment on how a SNF-specific wage index may be developed without creating significant administrative burdens for providers, CMS, or its contractors. Further, we requested comments on specific alternatives we may consider in future rulemaking which could be implemented in advance of, or in lieu of, a SNF-specific wage index. A discussion of the comments we received, along with our responses, appear below.

Comment: One commenter encouraged CMS to continue using hospital wage data when determining the SNF wage index, since it did not have a proposal for how to obtain a SNF-specific wage index in a manner that does not cause burden on providers.

Response: We appreciate the commenter's encouragement to continue using hospital wage data as a proxy for a SNF wage index.

Comment: Several commenters recommend that CMS pursue the establishment of a SNF-specific wage index. These commenters proposed phased-in recommendations to trim hospital wage data (as an interim step), to reflect positions staffed in nursing homes, allow for a reclassification system, account for occupational mix differences between hospitals and each post-acute care (PAC) setting using published BLS data, and apply a rural floor. Further, if determining a SNF wage index using SNF cost report data is too administratively complex, it was recommended that Payroll-based Journal (PBJ) data be used. Finally, the commenters recommended communicating with hospitals through Medicare Learning Network (MLN) transmittals for education and technical support.

Response: We appreciate the commenter's recommendation for collecting SNF cost report wage data to establish a SNF-specific wage index. We note that, consistent with the preceding discussion in this final rule as well as our previous responses to these recurring comments (most recently published in the FY 2018 SNF PPS final rule (82 FR 36540 through 36541)), 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 SNF cost report data in order for it to be used as part of this analysis.

Further, we appreciate these commenters' suggestion that we modify the current hospital wage data used to construct the SNF PPS wage index to reflect the SNF environment more accurately by trimming hospital wage data to reflect positions staffed in nursing homes, weighing it by occupational mix data published by the BLS, and using PBJ data. While we consider whether or not such an approach may constitute an interim step in the process of developing a SNF-specific wage index, we would note that other provider types also use the hospital wage index as the basis for their associated wage index. As such, we believe that such a recommendation should be part of a broader discussion on wage index reform across Medicare payment systems. With regard to the PBJ recommendation, we will pass this comment to our colleagues managing that initiative for further consideration.

With regard to reclassification and rural floor, as discussed above, section 315 of BIPA authorized us to establish a geographic reclassification procedure that is specific to SNFs, only after collecting the data necessary to establish a SNF-specific wage index that is based on data from nursing homes. However, to date this has been infeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of that data. Furthermore, we do not believe that using hospital reclassification data would be

appropriate as this data is specific to the requesting hospitals and it may or may not apply to a given SNF in a given instance. With regard to implementing a rural floor, we do not believe it would be prudent at this time to adopt such a policy, because MedPAC has recommended eliminating the rural floor policy from the calculation of the IPPS wage index (see, for example, Chapter 3 of MedPAC's March 2013 Report to Congress on Medicare Payment Policy, available at *http://medpac.gov/documents/reports/mar13_entirereport.pdf*, which notes on page 65 that in 2007, MedPAC had ''. . . recommended eliminating these special wage index adjustments and adopting a new wage index system to avoid geographic inequities that can occur due to current wage index policies (Medicare Payment Advisory Commission 2007b.'') If we adopted the rural floor at this time under the SNF PPS, we believe that, the SNF PPS wage index could become vulnerable to problems similar to those that MedPAC identified in its March 2013 Report to Congress.

While we continue to review all available data and contemplate the potential methodological approaches for a SNF-specific wage index in the future, we continue to believe that in the absence of the appropriate SNF-specific wage data, using the pre-reclassified, pre-rural and imputed floor hospital inpatient wage data (without the occupational mix adjustment) is appropriate and reasonable for the SNF PPS. We believe the commenters' recommendations should be part of a broader discussion of wage index reform across Medicare payment systems. In the event that a SNF-specific wage index is implemented in the future, CMS will provide education and support in a manner it deems appropriate, which may include MLN transmittals. We will continue to monitor closely research efforts surrounding the development of an alternative hospital wage index for the IPPS and the potential impact or influence of that research on the SNF PPS.

5. SNF Value-Based Purchasing Program

Beginning with payment for services furnished on October 1, 2018, section 1888(h) of the Act requires the Secretary to reduce the adjusted Federal per diem rate determined under section 1888(e)(4)(G) of the Act otherwise applicable to a SNF for services furnished during a fiscal year by 2 percent, and to adjust the resulting rate for a SNF by the value-based incentive payment amount earned by the SNF based on the SNF's performance score for that fiscal year under the SNF VBP Program. To implement these requirements, we proposed to add a new paragraph (f) to § 413.337. We did not receive any public comments regarding this proposal. Therefore, we are finalizing the addition of paragraph (f) to § 413.337 as proposed, without modification.

Please see section VI.C. of this final rule for further information regarding the SNF VBP Program, including a discussion of the methodology we will use to make the payment adjustments.

6. Adjusted Rate Computation Example

Using the hypothetical SNF XYZ, Table 11 shows the adjustments made to the federal per diem rates (prior to application of any adjustments under the SNF QRP and SNF VBP programs as discussed above) to compute the provider's actual per diem PPS payment for FY 2019. We derive the Labor and Non-labor columns from Table 9. The wage index used in this example is based on the FY 2019 SNF PPS wage index that appears in Table A available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.* As illustrated in Table 11, SNF XYZ's total PPS payment for FY 2019 would equal $48,779.14.

TABLE 11—ADJUSTED RATE COMPUTATION EXAMPLE SNF XYZ: LOCATED IN FREDERICK, MD (URBAN CBSA 43524), WAGE INDEX: 0.9880

[See wage index in Table A] [1]

RUG–IV group	Labor	Wage index	Adjusted labor	Non-labor	Adjusted rate	Percent adjustment	Medicare days	Payment
RVX	$522.48	0.9880	$516.21	$218.62	$734.83	$734.83	14	$10,287.62
ES2	419.50	0.9880	414.47	175.54	590.01	590.01	30	17,700.30
RHA	263.59	0.9880	260.43	110.29	370.72	370.72	16	5,931.52
CC2 [2]	242.99	0.9880	240.07	101.67	341.74	779.17	10	7,791.70
BA2	167.52	0.9880	165.51	70.09	235.60	235.60	30	7,068.00
	.....	.....	.....	.....	.....	.....	100	48,779.14

[1] Available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*
[2] Reflects a 128 percent adjustment from section 511 of the MMA.

IV. Additional Aspects of the SNF PPS

A. SNF Level of Care—Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section III.B.3. of this final rule. This approach includes an administrative presumption that utilizes a beneficiary's initial classification in one of the upper 52 RUGs of the current 66-group RUG–IV case-mix classification system to assist in making certain SNF level of care determinations.

In accordance with the regulations at § 413.345, we include in each update of the federal payment rates in the **Federal Register** a discussion of the resident classification system that provides the basis for case-mix adjustment. Under that discussion, we designate those specific classifiers under the case-mix classification system that represent the required SNF level of care, as provided in § 409.30. As set forth in the FY 2011 SNF PPS update notice (75 FR 42910), this designation reflects an administrative presumption under the 66-group RUG–IV system that beneficiaries who are correctly assigned to one of the upper 52 RUG–IV groups on the initial 5-day, Medicare-required assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date (ARD) on the 5-day Medicare-required assessment.

A beneficiary assigned to any of the lower 14 RUG–IV groups is not automatically classified as either meeting or not meeting the definition, but instead receives an individual level of care determination using the existing administrative criteria. This presumption recognizes the strong likelihood that beneficiaries assigned to one of the upper 52 RUG–IV groups during the immediate post-hospital period require a covered level of care, which would be less likely for those beneficiaries assigned to one of the lower 14 RUG–IV groups.

In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure. The FY 2018 final rule (82 FR 36544) further specified that we would henceforth disseminate the standard description of the administrative presumption's designated groups via the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html* (where such designations appear in the paragraph entitled ''Case Mix Adjustment''), and would publish such designations in rulemaking only to the extent that we actually intend to make changes in them. (We discuss in section V.G. of this final rule the modifications to the administrative level of care presumption that we are finalizing in order to accommodate the PDPM case-mix classification system.)

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that the services prompting the assignment of one of the designated case-mix classifiers (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667), the administrative presumption is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of the Act). Accordingly, the presumption would not apply, for example, in those situations in which a resident's assignment to one of the upper groups is itself based on the receipt of services that are subsequently determined to be not reasonable and necessary. Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the ARD of the 5-day assessment.

B. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA 1997) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor (MAC) for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, section 1862(a)(18) of the Act places the responsibility with the SNF for billing Medicare for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. (Please refer to section VI.A. of this final rule for a discussion of a revision to the regulation text that describes a beneficiary's status as a SNF ''resident'' for consolidated billing purposes.) Section 1888(e)(2)(A) of the Act excludes a small list of services from the consolidated billing provision (primarily those services furnished by physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF's Part A resident. These excluded service categories are discussed in greater detail in section V.B.2. of the May 12, 1998 interim final rule (63 FR 26295 through 26297).

A detailed discussion of the legislative history of the consolidated billing provision is available on the SNF PPS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_04152015.pdf*. In particular, section 103 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113, enacted on November 29, 1999) amended section 1888(e)(2)(A) of the Act by further excluding a number of individual high-cost, low probability services, identified by Healthcare Common Procedure Coding System (HCPCS) codes, within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discuss this BBRA amendment in greater detail in the SNF PPS proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB–00–18 (Change Request #1070), issued March 2000, which is available online at *www.cms.gov/transmittals/downloads/ab001860.pdf*.

As explained in the FY 2001 proposed rule (65 FR 19232), the amendments enacted in section 103 of the BBRA not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices), but also gave the Secretary the authority to designate additional, individual services for exclusion within each of the specified service categories. In the proposed rule for FY 2001, we also noted that the BBRA Conference report (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)) characterizes the individual services that this legislation targets for exclusion as high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment SNFs receive under the PPS. According to the conferees, section 103(a) of the BBRA is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs. By contrast, the amendments enacted in section 103 of the BBRA do not designate for exclusion any of the remaining services within those four categories (thus, leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the final rule for FY 2001 (65 FR 46790), and as is consistent with our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA: they must fall within one of the four service categories specified in the BBRA; and they also must meet the same standards of high cost and low probability in the SNF setting, as discussed in the BBRA Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice) (65 FR 46791). In the proposed rule (83 FR 21033), we specifically invited public comments identifying HCPCS codes in any of these four service categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic

devices) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. We stated that we may consider excluding a particular service if it met our criteria for exclusion as specified above. We further stated that commenters should identify in their comments the specific HCPCS code that is associated with the service in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded.

We note that the original BBRA amendment (as well as the implementing regulations) identified a set of excluded services by means of specifying HCPCS codes that were in effect as of a particular date (in that case, as of July 1, 1999). Identifying the excluded services in this manner made it possible for us to utilize program issuances as the vehicle for accomplishing routine updates of the excluded codes, to reflect any minor revisions that might subsequently occur in the coding system itself (for example, the assignment of a different code number to the same service). Accordingly, we stated in the proposed rule that, in the event that we identify through the current rulemaking cycle any new services that would actually represent a substantive change in the scope of the exclusions from SNF consolidated billing, we would identify these additional excluded services by means of the HCPCS codes that are in effect as of a specific date (in this case, as of October 1, 2018). By making any new exclusions in this manner, we could similarly accomplish routine future updates of these additional codes through the issuance of program instructions.

Commenters submitted the following comments related to the proposed rule's discussion of the consolidated billing aspects of the SNF PPS. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters reiterated previous recommendations regarding the exclusion of certain drugs from consolidated billing that had been submitted and addressed repeatedly in a number of prior rulemaking cycles. One such recommendation involved excluding the commonly used prostate cancer drug Lupron® (leuprolide acetate). Other commenters once again raised the issue of nursing home residents bringing their own medications, as a means of minimizing the nursing home's cost of caring for the resident. Still another reiterated previous recommendations to exclude a broader range of expensive drugs beyond the category of chemotherapy alone, citing anecdotal evidence that leaving such drugs within the SNF PPS bundle may, among other things, create a disincentive for admitting those patients who require them.

Response: For the reasons discussed previously in prior rulemaking, the particular drugs cited in these comments remain subject to consolidated billing. In the case of leuprolide acetate, the most recent discussion appears in the SNF PPS final rule for FY 2015 (79 FR 45642, August 5, 2014), which explained that this drug is unlikely to meet the criterion of ''low probability'' specified in the BBRA. Regarding the issue of nursing homes having residents supply their own medications, the SNF PPS final rule for FY 2018 (82 FR 36548, August 4, 2017) explained that the applicable terms of the SNF's provider agreement would preclude this practice, in that they require the SNF to accept Medicare's payment for covered services as payment in full. Finally, the issue of establishing a broader exclusion that would encompass expensive non-chemotherapy drugs was addressed in the SNF PPS final rule for FY 2017 (81 FR 51985, August 5, 2016), which explained that existing law does not provide for such an expansion. In addition, it is worth noting in this context that in accounting more accurately for the costs of NTA services such as drugs, the PDPM model has the potential to ameliorate some of the concerns cited in these comments.

Comment: One commenter urged us to expand the scope of the chemotherapy exclusion, advancing an interpretation of the Secretary's authority under section 1888(e)(2)(A)(iii)(II) of the Act to designate ''additional'' chemotherapy items for exclusion as not actually being restricted to the types of ''high-cost, low probability'' chemotherapy items and services described elsewhere in that provision, and further suggesting that identifying a given item or service as either ''high-cost'' or ''low probability'' alone should be sufficient grounds for its exclusion. The commenter also submitted well over 100 codes that it suggested should be added to the chemotherapy portion of the exclusion list. The commenter reiterated previous recommendations to expand the existing chemotherapy exclusion to encompass related drugs such as anti-emetics (anti-nausea drugs)—which, while they do not in themselves fight cancer, are commonly administered along with the chemotherapy drug to ameliorate its side effects. While we have, in fact, already addressed such recommendations repeatedly in previous rulemaking (most recently, in the FY 2015 SNF PPS final rule (79 FR 45642, August 5, 2014)), the commenter cited in further support of its position the similarity between the recommended approach and the existing policy under the dialysis exclusion from consolidated billing, in which the exclusion encompasses related services along with the dialysis itself. In addition, the commenter reiterated previous concerns about the complexity of the existing set of consolidated billing exclusions, suggesting that it should be streamlined and simplified.

Response: Approximately two-thirds of the codes that the commenter submitted *already appear* on the chemotherapy exclusion list. Of the remaining codes, several were already in existence in 1999 when the BBRA enacted the statutory ranges of excluded codes, but were skipped over by those ranges; as discussed repeatedly in previous rulemaking—most recently, in the FY 2018 SNF PPS final rule (82 FR 36547, August 4, 2017)—this action indicates that such drugs were intended to remain within the SNF PPS bundle, subject to the BBRA Conference Report's provision for a GAO review of the code set that was conducted the following year. Still others were codes such as those for anti-emetic (anti-nausea) drugs, which serve to address the chemotherapy drug's side effects rather than actually fighting the cancer itself; as we have noted repeatedly in prior rulemaking (most recently, in the FY 2015 SNF PPS final rule, 79 FR 45642, August 5, 2014), such drugs do not, in fact, represent ''chemotherapy'' (that is, cancer-fighting) drugs within the meaning of this exclusion. Further, the commenter's proposed interpretation suggesting that the exclusion is not restricted to ''high-cost, low probability'' chemotherapy services, or that a given chemotherapy service need only be *either* ''high-cost'' *or* ''low probability'' alone in order to qualify for exclusion would not be consistent with Congress' stated intent with respect to this provision. In fact, in the above-cited BBRA Conference Report (H.R. Rep. 106–479 at 854 (1999) (Conf. Rep.)), the Congress clearly specified the overall purpose of this provision: ''This provision is an attempt to exclude from the PPS certain services and *costly items that are provided infrequently in SNFs*'' (emphasis added); thus, any ''additional'' chemotherapy services that the Secretary might designate for exclusion under this authority, like those already excluded, would remain subject to *both* the ''high-cost'' *and* ''low

probability'' thresholds. Regarding the commenter's further suggestion that the dialysis exclusion might serve as a possible precedent for broadening the chemotherapy exclusion to include related services, we note that as one of the BBA 1997's original set of consolidated billing exclusions enacted in clause (ii) of section 1888(e)(2)(A) of the Act, the dialysis exclusion fundamentally differs from the BBRA's subsequent, more targeted set of exclusions in clause (iii) of that section (such as the one for chemotherapy) in that the BBA 1997 excluded *entire service categories* from consolidated billing, whereas the BBRA focused more narrowly on excluding certain designated ''high-cost, low probability'' services, identified by HCPCS code, within several broader categories that otherwise *remained subject* to the provision. In the FY 2015 SNF PPS final rule (79 FR 45644, August 5, 2014), we specifically contrasted the relatively broad exclusions enacted in the BBA 1997 with the more narrowly targeted BBRA exclusions, in the context of another one of the latter exclusions that involves radioisotope services. In that context, we noted that the statutory exclusion for ''radioisotope services'' at section 1888(e)(2)(A)(iii)(IV) of the Act stands in marked contrast, for example, to the ones for dialysis and erythropoietin (EPO) at section 1888(e)(2)(A)(ii) of the Act, which consist of—*and, in fact, are defined by*—explicit cross-references to the corresponding Part B benefit categories appearing in sections 1861(s)(2)(F) and 1861(s)(2)(O) of the Act, respectively. Under this framework, the scope of the consolidated billing provision's dialysis exclusion is effectively defined by the scope of coverage under the separate Part B dialysis benefit at section 1861(s)(2)(F) of the Act, which would encompass dialysis-related services along with the dialysis itself. By contrast, the more targeted BBRA exclusions in areas such as chemotherapy and radioisotope services focus specifically on those particular services that are directly designated as in themselves meeting the applicable criteria for exclusion.

Finally, regarding the comment about the complexity of this provision, in the FY 2010 SNF PPS final rule (74 FR 40355, August 11, 2009), we noted in response to a previous, similar comment that while the commenter's interest in promoting improved ease of administration is understandable, current law contains no authority to effect a comprehensive overhaul of the existing requirements administratively. However, we would also note in this context that we continue to conduct an active educational and training initiative on the consolidated billing provision that includes the following:

- A recently updated and expanded set of consolidated billing instructions in Chapter 6 of the Medicare Claims Processing Manual (available online at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c06.pdf*), at §§ 10–20.6;
- Addressing questions that arise on this topic during CMS's recurring nationwide SNF/Long-Term Care Open Door Forums (*https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/ODF_SNFLTC.html*);
- Development of sample model agreements between SNFs and their suppliers, which are posted online for review at our ''Best Practices'' website (at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/BestPractices.html*); and
- Creation of a web-based training (WBT) module accessible from the Medicare Learning Network (MLN) website at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/WebBasedTraining.html*, which offers interactive online training on consolidated billing.

Comment: One commenter recommended for exclusion a pair of oral chemotherapy drugs, ZYTIGA® (abiraterone acetate) and ERLEADA® (apalutamide), which are used in treating certain uncommon and otherwise resistant forms of prostate cancer. The commenter acknowledged our previous discussion of oral drugs in this context in the FY 2017 SNF PPS final rule (81 FR 51985, August 5, 2016), which described them as not reasonably characterized as meeting the BBRA's chemotherapy exclusion criterion of ''requiring special staff expertise to administer.'' However, the commenter then went on to point out that the accompanying Conference Report language (H. Conf. Rep. No. 106–479 at 854), in discussing the statutory exclusion of ''high-cost, low probability'' chemotherapy items, lists as examples those drugs that ''. . . are not typically administered in a SNF, *or* are exceptionally expensive, *or* are given as infusions, thus requiring special staff expertise to administer'' (emphasis added). Thus, the commenter suggested that while the Conference Report language itself specifies ''high-cost, low probability'' as the applicable standard for the chemotherapy exclusion, its use of the word ''or'' in the specific context of ''requiring special staff expertise to administer'' identifies this particular criterion as merely an illustrative example that is not an absolute prerequisite for meeting the standard in all cases. The commenter also acknowledged our explanation in the FY 2015 SNF PPS final rule (79 FR 45642, August 5, 2014) in connection with a previous comment regarding ZYTIGA® and another oral chemotherapy drug, REVLIMID® (lenalidomide), that it would not be operationally feasible to utilize a miscellaneous ''not otherwise specified'' (NOS) code such as J8999 to effect such an exclusion, and then urged us to consider other options, such as establishing a separate code or modifier for the particular drugs in question, or utilizing the already-existing National Drug Codes (NDCs) that are specific to those drugs. Other commenters similarly recommended the oral chemotherapy drugs REVLIMID® and GLEEVEC® (imatinib mesylate) for exclusion.

Response: We believe that the commenter's point that an oral chemotherapy drug which does not require ''special staff expertise to administer'' can nonetheless qualify for exclusion as long as it can otherwise meet the ''high-cost, low probability'' standard merits further consideration. However, we note that the four oral chemotherapy drugs at issue here differ from previously-excluded, non-oral chemotherapy drugs in that they are not covered under Part B. We note that while Part B would authorize coverage for drugs (including those chemotherapy drugs that are excluded from consolidated billing under section 1888(e)(2)(A)(iii)(II) of the Act) as either an incident to a physician's professional services (under section 1861(s)(2)(A) of the Act) or as an outpatient hospital service (under section 1861(s)(2)(B) of the Act), this authority is specifically limited in both cases to those drugs ''that are not usually self-administered by the patient,'' thus effectively excluding oral drugs as a class. Further, while Part B does, in fact, include a specific benefit category for oral chemotherapy drugs (at section 1861(s)(2)(Q) of the Act), that benefit is restricted to those with the same indication and active ingredient(s) as a covered non-oral anti-cancer drug, which is not the case for the specific four drugs in question.

Because the drugs at issue here would not be covered under Part B, we believe that the applicable provisions at section 1888(e)(2)(A) may not provide a basis for excluding them from consolidated billing. Accordingly, because of the need for further consideration of this

issue, we are unable to adopt the commenters' recommendations at this time.

Comment: A few commenters reiterated previous recommendations to expand the existing exclusion for certain high-intensity outpatient hospital services to encompass non-hospital settings as well.

Response: Similar concerns have been raised and addressed repeatedly in prior rulemaking (most recently, in the FY 2018 SNF PPS final rule (82 FR 36547, August 4, 2017)), as follows:

• As noted in numerous previous rules, as well as in Medicare Learning Network (MLN) Matters article SE0432 (available online at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE0432.pdf*), the rationale for establishing this exclusion was to address those types of services that are so far beyond the normal scope of SNF care that they *require the intensity of the hospital setting* in order to be furnished safely and effectively. Moreover, when the Congress enacted the consolidated billing exclusion for certain RHC and FQHC services in section 410 of the MMA, the accompanying legislative history's description of present law directly acknowledged the hospital-specific nature of this exclusion.

• Ever since its inception, this exclusion was intended to be hospital-specific; as explained in the original SNF PPS interim final rule (63 FR 26298, May 12, 1998), this exclusion was created within the context of the concurrent development of a new PPS specifically for outpatient hospital services, reflecting the need to delineate the respective areas of responsibility for the SNF under the consolidated billing provision, and for the hospital under the outpatient bundling provision, with regard to these services. This point was further reinforced in the subsequent final rule for FY 2000 (64 FR 41676, July 30, 1999), in which we explained that a key concern underlying the development of the consolidated billing exclusion of certain outpatient hospital services specifically involved the need to distinguish those services that comprise the SNF bundle from those that will become part of the outpatient hospital bundle that is currently being developed in connection with the outpatient hospital PPS. Accordingly, we noted at that time that we would not be extending the outpatient hospital exclusion from consolidated billing to encompass any other, freestanding settings.

• Finally, the FY 2010 final rule (74 FR 40355, August 11, 2009), while acknowledging that advances in medical technology over time may make it feasible to perform such high-intensity outpatient services more widely in nonhospital settings, then went on to cite the FY 2006 final rule (70 FR 45049, August 4, 2005) in noting that such a development would not argue in favor of excluding the nonhospital performance of the service from consolidated billing, but rather, would call into question whether the service should continue to be excluded from consolidated billing at all, even when performed in the hospital setting.

Comment: Several commenters reiterated comments submitted previously during the FY 2016 rulemaking cycle in the context of the SNF VBP provision, in which they had sought to portray a portable x-ray service's transportation and setup as a separately billable ''physician'' service by suggesting that such activities should appropriately be regarded as part of the diagnostic test's professional component (PC) for interpreting the test results rather than the technical component (TC) for performing the test itself. They now reiterated those same comments in the context of the PDPM, and additionally indicated that allowing these services to be paid separately outside of the Part A bundle would be consistent with the proration policy that applies under Part B when a single portable x-ray visit serves multiple patients, under which the trip itself is allocated among all of the patients served (regardless of payment source) in order to calculate the prorated payment amount that applies specifically to each of the Part B patients. Some of the commenters also cited certain HCPCS codes, such as R0076 (''transportation of portable EKG to facility or location, per patient''), and suggested that all of the ''medical and other health services'' enumerated in section 1861(s) of the Act—including the diagnostic test benefit at section 1861(s)(3) of the Act—should be regarded as excluded ''physician'' services.

Response: As we explained previously in the FY 2016 SNF PPS final rule (80 FR 46408, August 4, 2015), we do not share the view of those commenters who would categorize a portable x-ray service's transportation and setup as part of the separately billable PC. In that discussion, we cited § 90.5 of the Medicare Claims Processing Manual, Chapter 13 (available online at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c13.pdf*), which states that the bundled TC (to which consolidated billing applies) specifically includes ''any associated transportation and setup costs.'' As indicated in the FY 2016 SNF PPS final rule (80 FR 46408, August 4, 2015), to be considered a separately billable ''physician'' service in this context, a given service must not only be *furnished personally by* a physician, but must actually be a type of service that *ordinarily requires* such performance; we further noted that a portable x-ray service's transportation and setup would never meet these criteria, as the service's excluded PC relates solely to *reading* the x-ray rather than *taking* it, and the physician's personal performance clearly would not be required for activities such as driving the supplier's vehicle to the SNF, or setting up the equipment once it arrives there.

Further, we believe the comments that cited the proration policy in this context (which involves a single portable x-ray trip that serves multiple patients) may reflect a certain amount of misunderstanding about the proration policy's actual nature and purpose. As explained in the Medicare Physician Fee Schedule (MPFS) final rule for calendar year (CY) 2016 (80 FR 70886, November 16, 2015), the reason for allocating such a trip among *all* of the patients served is to ensure that *Medicare Part B* should not pay for more than its share of the transportation costs for portable x-ray services (80 FR 71068 through 71069). However, while all of the patients served (both the Part B and non-Part B patients) would be included in calculating the proration itself, the resulting prorated *amount* would be payable only for the *Part B* patients. By contrast, for any *Part A* SNF residents served by the same trip, the transportation cost associated with the portable x-ray service would be subsumed in the SNF's payment to the supplier for the bundled TC, as discussed above. In terms of Part A payment, that bundled TC, in turn, would be included (along with all other bundled services) within the global PPS per diem that the SNF receives for the covered Part A stay itself. Moreover, the SNF's actual payment amount to its supplier in this scenario would not be tied to the prorated payment amount made for the Part B patients served on the same trip; as explained in § 70.4 of the Medicare Benefit Policy Manual, Chapter 8 (available online at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c08.pdf*), for a bundled service, the specific details of the ensuing payment arrangement between the SNF and the outside supplier (such as the actual payment

amount and timeframe) represent a private, ''marketplace'' transaction that is negotiated between the parties themselves.

Regarding the suggestion that *all* of the Part B ''medical and other health services'' specified in section 1861(s) of the Act (including diagnostic tests such as portable x-ray services) should be considered physician services, we note that the physician services benefit at section 1861(s)(1) of the Act actually represents only a small subset of the overall ''medical and other health services'' enumerated throughout section 1861(s) of the Act, and that the diagnostic test benefit at section 1861(s)(3) of the Act (which would encompass the TC for a portable x-ray service) is, in fact, a separate and distinct benefit category from the one at section 1861(s)(1) of the Act for physician services. Finally, regarding the comments on certain HCPCS codes, we acknowledge that among the various consolidated billing exclusions listed in section 1888(e)(2)(A)(ii) of the Act are ''transportation costs of electrocardiogram equipment for electrocardiogram test services (HCPCS code R0076).'' However, that portion of the law additionally specifies that this particular exclusion is in effect ''only with respect to services furnished during 1998;'' accordingly, the statutory exclusion for these particular services has long since expired.

C. Payment for SNF-Level Swing-Bed Services

Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute- or SNF-level care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF-level services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, SNF-level services furnished by non-CAH rural hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. As explained in the FY 2002 final rule (66 FR 39562), this effective date is consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have now come under the SNF PPS. Therefore, all rates and wage indexes outlined in earlier sections of this final rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. A complete discussion of assessment schedules, the MDS, and the transmission software (RAVEN–SB for Swing Beds) appears in the FY 2002 final rule (66 FR 39562) and in the FY 2010 final rule (74 FR 40288). As finalized in the FY 2010 SNF PPS final rule (74 FR 40356 through 40357), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html*. We refer readers to section V.D.2. of this final rule for a discussion of the revisions we are finalizing to the MDS 3.0 swing-bed assessment effective October 1, 2019.

V. Revisions to SNF PPS Case-Mix Classification Methodology

A. Background and General Comments

In the FY 2019 SNF PPS proposed rule, we discussed our proposed changes to the SNF PPS, specifically the proposed comprehensive revisions to the SNF PPS case-mix classification system whereby we proposed to replace the current RUG–IV system with the Patient Driven Payment Model (PDPM) effective October 1, 2019. In section V.A of the FY 2019 SNF PPS proposed rule (83 FR 21034–21036), we discuss the basis for the proposed PDPM and our reasons for proposing to replace the existing case-mix classification system with the PDPM, effective October 1, 2019.

Section 1888(e)(4)(G)(i) of the Act requires the Secretary to make an adjustment to the per diem rates to account for case-mix. The statute specifies that the adjustment is to be based on both a resident classification system that the Secretary establishes that accounts for the relative resource use of different resident types, as well as resident assessment and other data that the Secretary considers appropriate.

In general, the case-mix classification system currently used under the SNF PPS classifies residents into payment classification groups, called RUGs, based on various resident characteristics and the type and intensity of therapy services provided to the resident. Under the existing SNF PPS methodology, there are two case-mix-adjusted components of payment: Nursing and therapy. Each RUG is assigned a CMI for each payment component to reflect relative differences in cost and resource intensity. The higher the CMI, the higher the expected resource utilization and cost associated with residents assigned to that RUG. The case-mix-adjusted nursing component of payment reflects relative differences in a resident's associated nursing and non-therapy ancillary (NTA) costs, based on various resident characteristics, such as resident comorbidities, and treatments. The case-mix-adjusted therapy component of payment reflects relative differences in a resident's associated therapy costs, which is based on a combination of PT, OT, and SLP services. Resident classification under the existing therapy component is based primarily on the amount of therapy the SNF chooses to provide to a SNF resident. Under the RUG–IV model, residents are classified into rehabilitation groups, where payment is determined primarily based on the intensity of therapy services received by the resident, and into nursing groups, based on the intensity of nursing services received by the resident and other aspects of the resident's care and condition. However, only the higher paying of these groups is used for payment purposes. For example, if a resident is classified into a both the RUA (Rehabilitation) and PA1 (Nursing) RUG–IV groups, where RUA has a higher per-diem payment rate than PA1, the RUA group is used for payment purposes. It should be noted that the vast majority of Part A covered SNF days (over 90 percent) are paid using a rehabilitation RUG. A variety of concerns have been raised with the current SNF PPS, specifically the RUG–IV model, which we discuss below.

When the SNF PPS was first implemented in 1998 (63 FR 26252), we developed the RUG–III case-mix classification model, which tied the amount of payment to resident resource use in combination with resident characteristic information. Staff time measurement (STM) studies conducted in 1990, 1995, and 1997 provided information on resource use (time spent by staff members on residents) and resident characteristics that enabled us not only to establish RUG–III but also to create CMIs. This initial RUG–III model was refined by changes finalized in the FY 2006 SNF PPS final rule (70 FR 45032), which included adding nine case-mix groups to the top of the original 44-group RUG–III hierarchy, which created the RUG–53 case-mix model.

In the FY 2010 SNF PPS proposed rule (74 FR 22208), we proposed the RUG–IV model based on, among other reasons, concerns that incentives in the SNF PPS had changed the relative amount of nursing resources required to treat SNF residents (74 FR 22220). These concerns led us to conduct a new

Staff Time Measurement (STM) study, the Staff Time and Resource Intensity Verification (STRIVE) project, which served as the basis for developing the current SNF PPS case-mix classification model, RUG–IV, which became effective in FY 2011. At that time, we considered alternative case mix models, including predictive models of therapy payment based on resident characteristics; however, we had a great deal of concern that by separating payment from the actual provision of services, the system, and more importantly, the beneficiaries would be vulnerable to underutilization (74 FR 22220). Other options considered at the time included a non-therapy ancillary (NTA) payment model based on resident characteristics (74 FR 22238) and a DRG-based payment model that relied on information from the prior inpatient stay (74 FR 22220); these and other options are discussed in detail in a CMS Report to Congress issued in December 2006 (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/RC_2006_PC-PPSSNF.pdf*).

As we explained in the proposed rule (83 FR 21034), in the years since we implemented the SNF PPS, finalized RUG–IV, and made statements regarding our concerns about underutilization of services in previously considered models, we have witnessed a significant trend that has caused us to reconsider these concerns. More specifically, as discussed in section V.E. of the FY 2015 SNF PPS proposed rule (79 FR 25767), we documented and discussed trends observed in therapy utilization in a memo entitled ''Observations on Therapy Utilization Trends'' (which may be accessed at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Therapy_Trends_Memo_04212014.pdf*). The two most notable trends discussed in that memo were that the percentage of residents classifying into the Ultra-High therapy category has increased steadily and, of greater concern, that the percentage of residents receiving just enough therapy to surpass the Ultra-High and Very-High therapy thresholds has also increased. In that memo, we state ''the percentage of claims-matched MDS assessments in the range of 720 minutes to 739 minutes, which is just enough to surpass the 720 minute threshold for RU groups, has increased from 5 percent in FY 2005 to 33 percent in FY 2013'' and this trend has continued since that time. We stated in the proposed rule (83 FR 21035) that while it might be possible to attribute the increasing share of residents in the Ultra-High therapy category to increasing acuity within the SNF population, we believe the increase in ''thresholding'' (that is, of providing just enough therapy for residents to surpass the relevant therapy thresholds) is a strong indication of service provision predicated on financial considerations rather than resident need. We discussed this issue in response to comments in the FY 2015 SNF PPS final rule. In that rule, in response to comments regarding the lack of ''current medical evidence related to how much therapy a given resident should receive,'' we stated that with regard to the comments which highlight the lack of existing medical evidence for how much therapy a given resident should receive, we would note that the number of therapy minutes provided to SNF residents within certain therapy RUG categories is, in fact, clustered around the minimum thresholds for a given therapy RUG category. We further stated that given the comments highlighting the lack of medical evidence related to the appropriate amount of therapy in a given situation, it is all the more concerning that practice patterns would appear to be as homogenized as the data would suggest. (79 FR 45651).

In response to comments which highlighted potential explanatory factors for the observed trends, such as internal pressure within SNFs that would override clinical judgment, we stated that we found these potential explanatory factors troubling and entirely inconsistent with the intended use of the SNF benefit. Specifically, the minimum therapy minute thresholds for each therapy RUG category are certainly not intended as ceilings or targets for therapy provision. As discussed in Chapter 8, Section 30 of the Medicare Benefit Policy Manual (Pub. 100–02), to be covered, the services provided to a SNF resident must be ''reasonable and necessary for the treatment of a patient's illness or injury, that is, are consistent with the nature and severity of the individual's illness or injury, the individual's particular medical needs, and accepted standards of medical practice.'' Therefore, we stated that services which are not specifically tailored to meet the individualized needs and goals of the resident, based on the resident's condition and the evaluation and judgment of the resident's clinicians, may not meet this aspect of the definition for covered SNF care, and we stated we believe that internal provider rules should not seek to circumvent the Medicare statute, regulations and policies, or the professional judgment of clinicians. (79 FR 45651 through 45652).

In addition to this discussion of observed trends, we noted in the proposed rule (83 FR 21035) that others have also identified potential areas of concern within the current SNF PPS. The two most notable sources are the Office of the Inspector General (OIG) and the Medicare Payment Advisory Commission (MedPAC).

For the OIG, three recent OIG reports describe the OIG's concerns with the current SNF PPS. In December 2010, the OIG released a report entitled ''Questionable Billing by Skilled Nursing Facilities'' (which may be accessed at *https://oig.hhs.gov/oei/reports/oei-02-09-00202.pdf*). In this report, among its findings, the OIG found that ''from 2006 to 2008, SNFs increasingly billed for higher paying RUGs, even though beneficiary characteristics remained largely unchanged'' (OEI–02–09–00202, ii), and among other things, recommended that we should ''consider several options to ensure that the amount of therapy paid for by Medicare accurately reflects beneficiaries' needs'' (OEI–02–09–00202, iii). Further, in November 2012, the OIG released a report entitled ''Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than a Billion Dollars in 2009'' (which may be accessed at *https://oig.hhs.gov/oei/reports/oei-02-09-00200.pdf*). In this report, the OIG found that ''SNFs billed one-quarter of all claims in error in 2009'' and that the ''majority of the claims in error were upcoded; many of these claims were for ultrahigh therapy.'' (OEI–02–09–00200, Executive Summary). Among its recommendations, the OIG stated that ''the findings of this report provide further evidence that CMS needs to change how it pays for therapy'' (OEI–02–09–00200, 15). Finally, in September 2015, the OIG released a report entitled ''The Medicare Payment System for Skilled Nursing Facilities Needs to be Reevaluated'' (which may be accessed at *https://oig.hhs.gov/oei/reports/oei-02-13-00610.pdf*). Among its findings, the OIG found that ''Medicare payments for therapy greatly exceed SNFs' costs for therapy,'' further noting that ''the difference between Medicare payments and SNFs' costs for therapy, combined with the current payment method, creates an incentive for SNFs to bill for higher levels of therapy than necessary'' (OEI–02–13–00610, 7). Among its recommendations, the OIG stated that CMS should ''change the method of paying for therapy'', further stating that ''CMS should accelerate its efforts to develop and implement a new method of paying for therapy that relies on

beneficiary characteristics or care needs.'' (OEI–02–13–00610, 12).

For MedPAC's recommendations in this area, Chapter 8 of MedPAC's March 2017 Report to Congress (available at *http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch8.pdf*) includes the following recommendation: ''The Congress should . . . direct the Secretary to revise the prospective payment system (PPS) for skilled nursing facilities'' and ''. . . make any additional adjustments to payments needed to more closely align payment with costs.'' (March 2017 MedPAC Report to Congress, 220). This recommendation is seemingly predicated on MedPAC's own analysis of the current SNF PPS, where they state that ''almost since its inception the SNF PPS has been criticized for encouraging the provision of excessive rehabilitation therapy services and not accurately targeting payments for nontherapy ancillaries'' (March 2017 MedPAC Report to Congress, 202). Finally, with regard to the possibility of changing the existing SNF payment system, MedPAC stated that ''since 2015, [CMS] has gathered four expert panels to receive input on aspects of possible design features before it proposes a revised PPS'' and further that ''the designs under consideration are consistent with those recommended by the Commission'' (March 2017 MedPAC Report to Congress, 203).

As we discussed in the proposed rule (83 FR 21035), the combination of the observed trends in the current SNF PPS discussed above (which strongly suggest that providers may be basing service provision on financial reasons rather than resident need), the issues raised in the OIG reports discussed above, and the issues raised by MedPAC, has caused us to consider significant revisions to the existing SNF PPS, in keeping with our overall responsibility to ensure that payments under the SNF PPS accurately reflect both resident needs and resource utilization.

We explained in the proposed rule (83 FR 20135 through 21036) that under the RUG–IV system, therapy service provision determines not only therapy payments but also nursing payments. This is because, as noted above, payment is based on the highest RUG category that the resident could be assigned to, so only one of a resident's assigned RUG groups, rehabilitation or nursing, is used for payment purposes. Each rehabilitation group is assigned a nursing CMI to reflect relative differences in nursing costs for residents in those rehabilitation groups, which is less specifically tailored to the individual nursing costs for a given resident than the nursing CMIs assigned for the nursing RUGs. We explained that, as mentioned above, because most resident days are paid using a rehabilitation RUG, and since assignment into a rehabilitation RUG is based on therapy service provision, this means that therapy service provision effectively determines nursing payments for those residents who are assigned to a rehabilitation RUG. Thus, we stated that we believe any attempts to revise the SNF PPS payment methodology to better account for therapy service provision under the SNF PPS would need to be comprehensive and affect both the therapy and nursing case-mix components. Moreover, we noted that in the FY 2015 SNF PPS final rule, in response to comments regarding access for certain ''specialty'' populations (such as those with complex nursing needs), that we agreed with the commenter that access must be preserved for all categories of SNF residents, particularly those with complex medical and nursing needs. We stated that, as appropriate, we would examine our current monitoring efforts to identify any revisions which may be necessary to account appropriately for these populations. (79 FR 45651).

In addition, MedPAC, in its March 2017 Report to Congress, stated that it has previously recommended that we revise the current SNF PPS to ''base therapy payments on patient characteristics (not service provision), remove payments for NTA services from the nursing component, [and] establish a separate component within the PPS that adjusts payments for NTA services'' (March 2017 MedPAC Report to Congress, 202). Accordingly, included among the proposed revisions we discussed in the proposed rule were revisions to the SNF PPS to address longstanding concerns regarding the ability of the RUG–IV system to account for variation in nursing and NTA services.

In May 2017, CMS released an Advance Notice of Proposed Rulemaking with comment (82 FR 20980) (the ANPRM), in which we discussed the history of and analyses conducted during the SNF Payment Models Research (PMR) project, which sought to address these concerns with the RUG–IV model, and sought comments on a possible replacement to the current RUG–IV model, which we called the Resident Classification System, Version I (RCS–I). As we stated in the proposed rule (83 FR 21036), this model was intended as an improvement over the RUG–IV model because it would better account for resident characteristics and care needs, thus better aligning SNF PPS payments with resource use and eliminating therapy provision-related financial incentives inherent in the current payment model used in the SNF PPS. We received many comments from stakeholders on a wide variety of aspects of the RCS–I model. After considering these comments, we made significant revisions to the RCS–I model to account for the concerns or questions raised by stakeholders, resulting in a revised case-mix classification model which we proposed in the FY 2019 SNF PPS proposed rule (83 FR 21018). To make clear the purpose and intent of replacing the existing RUG–IV system, the model we proposed is called the Patient-Driven Payment Model (PDPM). We refer readers to the FY 2019 SNF PPS proposed rule (83 FR 21036) for a discussion of the SNF PMR project, and the resulting SNF PMR technical report which contains supporting language and documentation related to the RCS–I model (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/SNF_Payment_Models_Research_Technical_Report201704.pdf*), and the SNF PDPM technical report which presents analyses and results that were used to develop the proposed PDPM (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/PDPM_Technical_Report_508.pdf*). We invited comments on any and all aspects of the proposed PDPM, including the research analyses described in the proposed rule, the SNF PDPM technical report and the SNF PMR technical report.

As further detailed below, and as we stated in the proposed rule (83 FR 21036), we believe that the PDPM represents an improvement over the RUG–IV model and the RCS–I model because it would better account for resident characteristics and care needs while reducing both systemic and administrative complexity. To better ensure that resident care decisions appropriately reflect each resident's actual care needs, we believe it is important to remove, to the extent possible, service-based metrics from the SNF PPS and derive payment from verifiable resident characteristics. In the sections that follow, we describe the comprehensive revisions we are implementing to the SNF PPS through the PDPM. Additionally, we discuss the comments we received on each of the proposed policies, our responses to these comments and the PDPM-related policies we are finalizing in this rule.

Before moving into the specific policy areas, we first discuss general comments

we received on the PDPM, along with our responses.

Comment: Many commenters expressed support for the goals of the proposed PDPM, acknowledging that changes must be made to the current payment system. Many commenters also expressed concerns regarding the potential impacts on patient care which could result from implementing PDPM, specifically that PDPM will introduce new incentives into SNF payment that will have a negative impact on patient care. Some commenters believe that SNF providers could stint on care, most notably therapy services, and that such providers will be overcompensated for care that is not being delivered. Some commenters urged CMS to monitor the impacts on patient care of implementing PDPM and take action upon evidence of adverse trends. One commenter noted that PDPM does not correct the problems in the existing reimbursement model, assigning too few resources to nursing and NTAs.

Response: We appreciate the support we have received for PDPM and its goals. With respect to the concerns raised by commenters with regard to the potential impact of PDPM on patient care, specifically the possibility that some providers may stint on care or provide fewer services to patients, we plan to monitor closely service utilization, payment, and quality trends which may change as a result of implementing PDPM. If changes in practice and/or coding patterns arise, then we may take further action, which may include administrative action against providers as appropriate and/or proposing changes in policy (for example, system recalibration, rebasing case-mix weights, case mix creep adjustment) to address any concerns. We will also continue to work with the HHS Office of Inspector General, should any specific provider behavior be identified which may justify a referral for additional action.

With regard to the comment that PDPM does not correct the issues with the current reimbursement model and assigns too few resources to nursing and NTAs, we would refer the commenter to the impact analysis presented in Table 37, which indicates that the broadest shifts in payment are to those patients with high nursing and NTA needs.

Comment: Several commenters raised concerns regarding the use of historical data as the basis for developing PDPM. One commenter stated that PDPM is overly complex and that the majority of patient days are captured in a small number of case-mix groups. One commenter stated that because PDPM is based on historical utilization, it does not sufficiently reflect current best practices or high quality care.

Response: Historical data are the only form of data that can be used for any data analysis, so it is not clear what other data, that are not historical, CMS could have used to develop PDPM. Further, as these data are reported by SNFs, we believe that these data should be best reflective of SNF costs and patient needs. With regard to the comment that the majority of patient days are captured in a small number of case-mix groups, we agree with this comment and believe that this is precisely part of the motivation for implementing a new case-mix classification model. The current case-mix model has caused a homogenization in patient classification such that the current payment model does not adequately reflect differences among SNF patients. We believe that PDPM is a significant improvement in this regard, better reflecting the myriad differences between SNF patients in terms of their characteristics, care needs, and goals.

With regard to the comment that the historical data do not sufficiently reflect current best practices or high quality care, while we are concerned about this assertion from a patient care perspective, we do not believe that this would affect the accuracy of the reported data in terms of reflecting relative differences in costs, which is all that is necessary for developing accurate case-mix groups.

Comment: Several commenters requested clarification on the effect of implementing PDPM on the development of a unified Post-Acute Care (PAC) PPS and how PDPM would interact with a PAC PPS. One commenter requested that CMS establish a panel to advise on payment system changes across the PAC continuum.

Response: As a PAC PPS has not been established, we cannot provide guidance as to how the PDPM would interact with such a system, once developed. However, given that PDPM shifts away from the current case-mix model that utilizes service-based metrics as the primary determinant of payment for most days paid under the SNF Part A benefit to a model that utilizes patient characteristics as the basis for payment, and that most other PAC payment systems already rely more heavily on patient characteristics within their payment model, we believe that PDPM will better align the SNF PPS for this eventual transition to a PAC PPS as it brings the SNF PPS closer to those other PAC payment systems. We will consider the commenter's recommendation to establish a panel on payment system changes across the PAC continuum, particularly as we work to develop a PAC PPS.

Comment: Some commenters suggested that CMS consider including quality measures of effective rehabilitation services when evaluating the impact of PDPM.

Response: We appreciate these commenters' suggestion. In monitoring the impact of the PDPM, we will consider including measures for a variety of service areas as a component of our planned monitoring efforts.

Comment: Several commenters suggested that CMS should establish a plan to recalibrate the system to address any unanticipated impacts. More specifically, these commenters requested that CMS provide more details on plans to recalibrate the system in case of unanticipated service and performance changes, as well as plans to recalibrate the payment weights associated with the revised payment model.

Response: We appreciate the suggestions made by these commenters with regard to CMS providing plans for recalibrating the payment system after implementing PDPM. However, such recalibrations will depend largely on the results of our monitoring efforts and could take various forms. For example, in the FY 2012 SNF PPS final rule (76 FR 48486), we recalibrated the parity adjustment that was intended to ensure that SNF payments under RUG–IV matched those that would have been made under RUG–III, similar to how the parity adjustment discussed below for PDPM is intended to ensure that SNF payments under PDPM mirror those that would have been made under RUG–IV. As discussed in that rule, our assumptions regarding case-mix distribution that were used to calculate the RUG–IV parity adjustment subsequently proved to be inaccurate, which caused us to recalculate the RUG–IV parity adjustment in the following year. We anticipate similarly monitoring PDPM implementation closely and may propose adjustments as appropriate if we discover evidence that payments are either higher or lower than anticipated, or if provider costs change in such a manner that the current relationship between provider costs and provider payments changes from that currently observed.

Comment: One commenter raised the concern that the PDPM model has low explanatory power and lacks an objective threshold for inclusion of various components in the model. This commenter suggested that if CMS intends to update this model with new

data over time to reflect changes in clinical practice and resource utilization, there is a need for a systematic determination of the minimum acceptable R-squared values for the model features. Model components currently excluded may increase in predictive power over time and merit inclusion in future versions of PDPM. In addition, current model components may decrease in predictive power such that they should be removed from the model.

Response: Setting an absolute minimum threshold would not only be arbitrary but also deviates from the practical use of the R-squared metric, which is to evaluate the proportion of variance explained and compare models with the same dependent variable vector. Additionally, R-squared is not the only measure we use to evaluate PDPM. In fact, because the current system is heavily based on service provision and most residents are classified into the Ultra-High therapy category, we are dealing with a dataset with little explainable variance. Each of the PDPM case-mix groups meets clinical expectations, which is a convincing validation of the model given the data available. We note that with the change to a patient driven model, we expect more variation will appear in therapy costs. This will allow for future development of models with higher explanatory power.

Comment: Several commenters requested clarification on how PDPM would interact with other CMS initiatives, such as the SNF Quality Reporting Program (QRP), Value-Based Purchasing (VBP) program, revised conditions of participation and other such initiatives. A few commenters also requested clarification on how PDPM accounts for or would interact with the *Jimmo* v *Sebelius* settlement surrounding the provision of maintenance therapy. These commenters requested clarification on how CMS would track maintenance therapy services, as compared to other forms of therapy. Several commenters requested clarification on how Comprehensive Person-Centered Plan maintenance services, new Requirements of Participation and other CMS initiatives will be factored into CMS burden estimates and that CMS should revise existing burden estimates to incorporate these changes.

Response: We anticipate that PDPM will only serve to strengthen the various quality and payment reform initiatives throughout CMS, by shifting payment away from the current service-driven model that has produced nearly homogenized care for SNF beneficiaries, to a more resident-centered model that focuses more on the individual patient's needs and characteristics. We also believe that through the use of standardized assessment items (as discussed in section V.D. of this final rule) and changes to the assessment schedule to mirror that of other PAC settings that use a similar admission/discharge assessment model (as discussed in section V.E. of this final rule), the PDPM would better align with the current direction of PAC reform and standardization efforts supported by the IMPACT Act.

With regard to the comment about tracking maintenance services, we do not believe it is necessary at this time to track maintenance services separately. Such tracking would be burdensome and it would be difficult to do so accurately, as it is possible that many patients have both maintenance and restorative goals, and allocating therapy minutes among these varied goals would be particularly complicated for providers.

With regard to the burden of the Comprehensive Person-Centered Plan, new requirements of participation, and other CMS initiatives, the burdens estimated in relation to PDPM are only those in relation to implementation of the PDPM and its related policies. As the Comprehensive Person-Centered Plan and other issues mentioned are outside of these PDPM related policies, we do not address the potential burden of such issues in this section.

Comment: Several commenters expressed concerns regarding the potential impact of implementing PDPM on Medicaid programs. A few commenters raised concerns regarding the impact of PDPM on calculating the Upper Payment Limit (UPL), which is utilized as part of calculating Medicaid payment rates. One commenter questioned if states would be permitted to still use RUG–IV as the basis for estimating the UPL. One commenter requested clarification on if any changes would be necessary for Medicaid claims systems. One commenter stated that Medicaid providers will have less incentive to provide therapy and Medicaid beneficiaries will have lower nursing case-mix scores under PDPM, thereby incentivizing states to transition to PDPM in order to reduce Medicaid spending. Commenters suggested that CMS work closely with states, who may wish to transition to PDPM, to ensure a smooth transition. Some commenters also stated that, should certain states not transition to PDPM, this would mean operating two different payment systems. A few commenters requested clarification on if CMS would continue to support previous payment systems for states that do not make the transition to PDPM or have access to MDS data for Medicaid rate-setting purposes. These commenters also requested if CMS could provide a further breakdown of certain cost categories, such as NTA costs, in a manner that would be more helpful to states in conducting UPL calculations.

Response: We appreciate the commenters' concerns with the potential impact of PDPM on Medicaid programs. We agree with the commenters that this is an area that deserves significant attention in terms of education and training, and we plan to work with states to ensure a smooth transition between the current RUG–IV model and PDPM. With regard to questions on how PDPM may relate to UPL calculations, these calculations are based on how Medicare pays for services under Part A and not based on a prior payment system. Therefore, UPL calculations, after PDPM has been implemented, would need to be based on the payments made under PDPM. That being said, we expect that, because PDPM bases payment on patient characteristics and not service utilization, payments made under PDPM will more accurately reflect patient needs and goals, which should also improve the basis for Medicaid payments which may be related to Medicare payments. With regard to having the data necessary for such UPL calculations, whether in regard to specific rate components (for example, NTA costs) or more generally, we will work with states to help ensure that they have the necessary information so PDPM implementation does not negatively impact on their ability to manage their Medicaid programs.

With regard to the comment that states may have more of an incentive to transition to PDPM in order to reduce Medicaid spending, we believe that the primary reason that Medicaid programs may adopt PDPM is due to its focus on patient characteristics and goals, rather than on service utilization. Given the improvements in Medicare payment that this transition represents, we would expect a similar improvement in Medicaid payments in states that make this transition.

With regard to the comment that Medicaid providers will be incentivized to provide less therapy or that Medicaid beneficiaries will have lower nursing case-mix scores, we would encourage states that decide to transition to PDPM to ensure they are monitoring the impacts of such a change on their beneficiaries and the care they receive.

In terms of those states that opt not to transition to PDPM and instead use some form of legacy payment system, we would note that a number of states use systems quite distinct from the existing RUG–IV model and we are not aware of any difficulties or complexities for providers or states in managing these systems concurrently. These states still have access to MDS data for ratesetting purposes and nothing associated with PDPM implementation, in and of itself, would affect state access to MDS data. That being said, we would likely need to evaluate the costs and benefits of continued support for certain legacy payment systems, most notably any RUG–III based payment models.

Comment: One commenter requested that CMS consider the possibility that some Medicare Advantage plans could reform their payment models to mirror PDPM, while others may maintain their existing payment models, which could include models that resemble RUG–IV. The commenter requested that CMS consider working with those plans that opt to modify their payment models to resemble PDPM and consider the impact of having multiple payment models that providers must operate under simultaneously.

Response: We acknowledge that some Medicare Advantage plans could change their payment models to mirror PDPM, while others may not change their payment models in relation to the changes finalized in this rule. We would note, however, that, as private plans, Medicare Advantage plans currently take a wide variety of forms, with some already approximating the structure of PDPM, using patient characteristics rather than service utilization as the basis for payment. We will work generally with stakeholders, including these private plans, to help ensure that adequate education and resources are available for all parties.

Comment: One commenter requested clarification on how CMS will track and reconcile patient diagnosis and classification information reported at admission with such information at discharge, expressing concern regarding what might occur in the case that the information from these two points is different, as well as diagnosis or procedural information from the preceding hospital stay, noting that some information for SNF payment comes from the hospital, and how these issues could affect provider risk of alleged improper billing and recovery efforts.

Response: We plan to develop a robust monitoring program that utilizes data from many sources, such as assessments, claims, cost reports and other data that would prove valuable in assessing both the impact of implementing PDPM, as well as identify any provider level issues related to PDPM payments. While the vast majority of information related to PDPM classification and payment is derived from the SNF, there is one area (surgical procedural information) which may come from the preceding hospital stay. However, nothing in PDPM should change the relationship or need for information between the hospital and SNF, given that the information that PDPM requires is no more information than the SNF would need simply for basic care planning purposes. As such, there should be no impact on improper billing or recovery efforts that derive from the implementation of PDPM.

Comment: One commenter requested clarification on how PDPM will address the number of face-to-face hours the registered therapist spends treating the patients. This commenter states they have observed nursing staff instructed to complete certain activities with patients who are receiving therapy.

Response: PDPM does not address the specific number of face-to-face hours that therapists spend with their patients. The expectations for what is considered skilled therapy and reasonable and necessary care found in Chapter 8 of the Medicare Benefit Policy Manual (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c08.pdf*) and the MDS 3.0 RAI manual (*https://downloads.cms.gov/files/MDS-30-RAI-Manual-v115-October-2017.pdf*) will not change under PDPM. We continue to expect that patients will receive high quality skilled rehabilitation services based on their individual needs and we do not believe that patients should have any nursing care that they require reduced because they happen to be receiving therapy. If a patient requires nursing care (including restorative nursing), the SNF should provide that nursing care as medically necessary. Similarly, if a patient requires therapy, the SNF should provide the therapy as medically necessary. One should not impact the other and PDPM does not affect this either.

Comment: Several commenters requested clarification about how SNFs are expected to comply with Medicare and Medicaid Conditions of Participation and whether SNFs will continue to be required to complete the discharge assessments required by the Omnibus Budget Reconciliation Act (OBRA), as well as the end of therapy-related assessments.

Response: PDPM is not intended to affect any of the Medicare and Medicaid Conditions of Participation for SNFs. Facilities should continue to follow these regulations as they always have. Additionally, even though under PDPM, the majority of PPS assessments will now be removed (as discussed later in this final rule), all OBRA assessments will still be required. PDPM will not affect the OBRA requirements. With regard to existing therapy-related assessments (the Start of Therapy, End of Therapy, and Change of Therapy assessments), these assessments would no longer exist under PDPM.

Comment: Several commenters expressed concern that PDPM may not fully account for mild cognitive impairment and encouraged CMS to collect more sensitive data, in line with the IMPACT Act, to ensure necessary attention to cognition.

Response: We appreciate these commenters' concerns and also believe that attention should be paid to cognition as an area for potential future system refinements. However, as the only change in the proposed use of cognition as a factor in payment classification is under the SLP component, and because for this component, we proposed to use even mild cognitive impairment as the basis for a payment classification, we believe that PDPM does adequately account for mild cognitive impairment. We will consider the commenter's concerns as we continue to evaluate potential refinements to our assessment tools.

Comment: One commenter expressed concern that PDPM does not incorporate incentives for quality improvement.

Response: PDPM, as a case-mix classification system, is intended to classify SNF patients for purposes of reimbursement based on the resource utilization associated with treating those patients. However, there do exist programs, such as the SNF VBP program, that is a part of the SNF PPS which does incentivize quality improvement. Therefore, while we agree that PDPM, in and of itself, does not include incentives for quality improvement, other aspects of the SNF PPS do include such incentives.

Comment: Some commenters requested clarification about the appeals process that will be available to help patients in case of shortcomings in their care and coverage, including any inaccurate assignments to payment classifications.

Response: We appreciate this comment, but would note that nothing associated with PDPM implementation would affect existing patient appeal rights or processes.

Comment: One commenter requested clarification on how items Z0100A and

Z0150A on the MDS would be populated and how the classifications would translate to a billable claim code.

Response: We will provide detail on how these MDS items, which relate to patient billing codes, will be populated as part of our updates to the MDS manual.

Comment: One commenter requested clarification on how a patient's voice would be heard in a care design driven by medical information.

Response: While patient case-mix classification, for purposes of payment, would be driven by medical information, as occurs under the current payment system, care design should be driven by patient goals and needs, as well as discussions with the patient and his or her family. Further, while under the current payment model over 90 percent of patient days are paid for using a therapy RUG, which utilizes only therapy minutes and ADLs as the basis for payment, PDPM provides a more holistic approach to payment classifications. More specifically, by separately adjusting for the nursing component, which utilizes patient interviews as a major component of patient classification, we believe that this achieves the commenter's goal of elevating the patient's voice.

Comment: Some commenters requested that CMS consider adopting an outlier policy as part of the SNF PPS to account for patients whose costs far exceed the cost of typical patients. These commenters stated that a SNF outlier policy would ensure access to clinically complex patients and align with other PAC systems.

Response: Under the current statutory provisions governing the SNF PPS, there is no specific statutory authority for an outlier payment as part of the SNF PPS.

B. Revisions to SNF PPS Federal Base Payment Rate Components

1. Background on SNF PPS Federal Base Payment Rates and Components

Section 1888(e)(4) of the Act requires that the SNF PPS per diem federal payment rates be based on FY 1995 costs, updated for inflation to the first effective period of the PPS. These base rates are then required to be adjusted to reflect differences among facilities in patient case-mix and in average wage levels by area. In keeping with this statutory requirement, the base per diem payment rates were set in 1998 and reflect average SNF costs in a base year (FY 1995), updated for inflation to the first period of the SNF PPS, which was the 15-month period beginning on July 1, 1998. The federal base payment rates were calculated separately for urban and rural facilities and based on allowable costs from the FY 1995 cost reports of hospital-based and freestanding SNFs, where allowable costs included all routine, ancillary, and capital-related costs (excluding those related to approved educational activities) associated with SNF services provided under Part A, and all services and items for which payment could be made under Part B prior to July 1, 1998.

In general, routine costs are those included by SNFs in a daily service charge and include regular room, dietary, and nursing services, medical social services and psychiatric social services, as well as the use of certain facilities and equipment for which a separate charge is not made. Ancillary costs are directly identifiable to residents and cover specialized services, including therapy, drugs, and laboratory services. Lastly, capital-related costs include the costs of land, building, and equipment and the interest incurred in financing the acquisition of such items (63 FR 26253).

There are four federal base payment rate components which may factor into SNF PPS payment. Two of these components, ''nursing case-mix'' and ''therapy case-mix,'' are case-mix adjusted components, while the remaining two components, ''therapy non-case-mix'' and ''non-case-mix,'' are not case-mix adjusted. While we discussed the details of the proposed PDPM and justifications for certain associated policies we proposed throughout section V of the FY 2019 SNF PPS proposed rule, we note that, as part of the PDPM case-mix model, we proposed to bifurcate the ''nursing case-mix'' component of the federal base payment rate into two case-mix adjusted components and separate the ''therapy case-mix'' component of the federal base payment rate into three case-mix adjusted components, thereby creating five case-mix adjusted components of the federal base per diem rate. More specifically, we proposed to separate the ''therapy case-mix'' rate component into a ''Physical Therapy'' (PT) component, an ''Occupational Therapy'' (OT) component, and a ''Speech-Language Pathology'' (SLP) component. Our rationale for separating the therapy case-mix component in this manner is presented in section V.D.3.b. of the proposed rule. Based on the results of the SNF PMR, we also proposed to separate the ''nursing case-mix'' rate component into a ''Nursing'' component and a ''Non-Therapy Ancillary'' (NTA) component. Our rationale for proposing to bifurcate the nursing case-mix component in this manner is presented in section V.D.3.d. of the proposed rule. Given that all SNF residents under PDPM would be assigned to a classification group for each of the three proposed therapy-related case-mix adjusted components as further discussed below, we proposed eliminating the ''therapy non-case-mix'' rate component under PDPM and stated that we would distribute the dollars associated with this current rate component amongst the proposed PDPM therapy components. We also stated in the proposed rule (83 FR 21038) that the existing non-case-mix component would be maintained as it is currently constituted under the existing SNF PPS. We explained that although the case-mix components of the proposed PDPM case-mix classification system would address costs associated with individual resident care based on an individual's specific needs and characteristics, the non-case-mix component addresses consistent costs that are incurred for all residents, such as room and board and various capital-related expenses. As these costs are not likely to change, regardless of what changes we might make to the SNF PPS, we proposed to maintain the non-case-mix component as it is currently used.

In the next section, we discuss the methodology used to create the proposed PDPM case-mix adjusted components, as well as the data sources used in this calculation. As we stated in the proposed rule (83 FR 21038), the proposed methodology does not calculate new federal base payment rates but simply proposes to modify the existing base rate case-mix components for therapy and nursing. The methodology and data used in this calculation are based on the data and methodology used in the calculation of the original federal payment rates in 1998, as further discussed below.

2. Data Sources Utilized for Revision of Federal Base Payment Rate Components

Section II.A.2. of the interim final rule with comment period that initially implemented the SNF PPS (63 FR 26256 through 26260) provides a detailed discussion of the data sources used to calculate the original federal base payment rates in 1998. Except as discussed below, we proposed to use the same data sources (that is, cost information from FY 1995 cost reports) to determine the portion of the therapy case-mix component base rate that would be assigned to each of the proposed therapy component base rates (PT, OT, and SLP). As we stated in the proposed rule (83 FR 21038), we believe that using the same data sources, to the extent possible, that were used to calculate the original federal base

payment rates in 1998 results in base rates for the components that resemble as closely as possible what they would have been had these components initially been established in 1998. The portion of the nursing component base rate that corresponds to NTA costs was already calculated using the same data source used to calculate the federal base payment rates in 1998. As explained below and in the proposed rule (83 FR 21038), we used the previously calculated percentage of the nursing component base rate corresponding to NTA costs to set the NTA base rate and verified this calculation with the analysis described in section V.C.3. of the FY 2019 SNF PPS proposed rule. Therefore, the steps described below address the calculations performed to separate out the therapy base rates alone.

As discussed in the proposed rule (83 FR 21038), the percentage of the current therapy case-mix component of the federal base payment rates that would be assigned to the three proposed therapy components (PT, OT, and SLP) of the federal base payment rates was determined using cost information from FY 1995 cost reports, after making the following exclusions and adjustments: First, only settled and as-submitted cost reports for hospital-based and freestanding SNFs for periods beginning in FY 1995 and spanning 10 to 13 months were included. This set of restrictions replicates the restrictions used to derive the original federal base payment rates as set forth in the 1998 interim final rule with comment period (63 FR 26256). Following the methodology used to derive the SNF PPS base rates, routine and ancillary costs from as-submitted cost reports were adjusted down by 1.31 and 3.26 percent, respectively. As discussed in the 1998 interim final rule with comment period, the specific adjustment factors were chosen to reflect average adjustments resulting from cost report settlement and were based on a comparison of as-submitted and settled reports from FY 1992 to FY 1994 (63 FR 26256); these adjustments are in accordance with section 1888(e)(4)(A)(i) of the Act. We used similar data, exclusions, and adjustments as in the original base rates calculation so the resulting base rates for the components would resemble as closely as possible what they would have been had they been established in 1998. However, as we discussed in the proposed rule, there were two ways in which the PT, OT, and SLP percentage calculations deviate from the 1998 base rates calculation. First, the 1998 calculation of the base rates excluded reports for facilities exempted from cost limits in the base year. The available data do not identify which facilities were exempted from cost limits in the base year, so this restriction was not implemented. As we stated in the proposed rule, we do not believe this had a notable impact on our estimate of the PT, OT, and SLP percentages, because only a small fraction of facilities were exempted from cost limits. Consistent with the 1998 base rates calculation, we excluded facilities with per diem costs more than three standard deviations higher than the geometric mean across facilities. Therefore, facilities with unusually high costs did not influence our estimate. Second, the 1998 calculation of the base rates excluded costs related to exceptions payments and costs related to approved educational activities. The available cost report data did not identify costs related to exceptions payments nor indicate what percentage of overall therapy costs or costs by therapy discipline were related to approved educational activities, so these costs are not excluded from the PT, OT, and SLP percentage calculations. We stated in the proposed rule that because exceptions were only granted for routine costs, we believe the inability to exclude these costs should not affect our estimate of the PT, OT, and SLP percentages as exceptions would not apply to therapy costs. Additionally, the data indicate that educational costs made up less than one-hundredth of 1 percent of overall SNF costs. Therefore, we stated that we believe the inability to exclude educational costs should have a negligible impact on our estimates.

In addition to Part A costs from the cost report data, the 1998 federal base rates calculation incorporated estimates of amounts payable under Part B for covered SNF services provided to Part A SNF residents, as required by section 1888(e)(4)(A)(ii) of the Act. We stated in the proposed rule (83 FR 21038) that in calculating the PT, OT, and SLP percentages, we also estimated the amounts payable under Part B for covered SNF services provided to Part A residents. All Part B claims associated with Part A SNF claims overlapping with FY 1995 cost reports were matched to the corresponding facility's cost report. For each cost center (PT, OT, and SLP) in each cost report, a ratio was calculated to determine the amount by which Part A costs needed to be increased to account for the portion of costs payable under Part B. This ratio for each cost center was determined by dividing the total charges from the matched Part B claims by the total charges from the Part A SNF claims overlapping with the cost report. The 1998 interim final rule (63 FR 26256) states that to estimate the amounts payable under Part B for covered SNF services provided to Part A SNF residents, CMS (then known as HCFA) matched 100 percent of Part B claims associated with Part A covered SNF stays to the corresponding facility's cost report. Part B allowable charges were then incorporated at the facility level by the appropriate cost report center. Although the interim final rule does not provide further detail on how Part B allowable charges were incorporated at the facility level, we stated in the proposed rule that we believe our methodology reasonably approximates the methodology described in the interim final rule, and provides a reasonable estimate of the amounts payable under Part B for covered SNF services provided to Part A residents for purposes of calculating the PT, OT, and SLP percentages. Therefore, we stated that we believe it is reasonable to use this methodology to calculate the PT, OT, and SLP percentages of the therapy case-mix component.

Finally, the 1998 federal base rates calculation standardized the cost data for each facility to control for the effects of case-mix and geographic-related wage differences, as required by section 1888(e)(4)(C) of the Act. As we stated in the proposed rule, when calculating the PT, OT and SLP shares of the current therapy base rate, we replicated the method used in 1998 to standardize for wage differences, as described in the 1998 interim final rule with comment period (63 FR 26259 through 26260). We applied a hospital wage index to the labor-related share of costs, estimated at 75.888 percent, and used an index composed of hospital wages from FY 1994. We noted in the proposed rule that the PT, OT, and SLP percentage calculations did not include the case-mix adjustment used in the 1998 calculation because the 1998 adjustment relied on the obsolete RUG–III classification system. In the 1998 federal base rates calculation, information from SNF and inpatient claims was mapped to RUG–III clinical categories at the resident level to case-mix adjust facility per diem costs. However, the 1998 interim final rule did not document this mapping, and the data used as the basis for this adjustment are no longer available, and therefore, this step could not be replicated. We stated in the proposed rule that we believe the inability to apply the case-mix

adjustment likely has a small impact on our estimate of the PT, OT, and SLP percentages. The 1998 interim final rule indicates that the case-mix adjustment was applied by dividing facility per diem costs for a given component by average facility case mix for that component; in other words, multiplying by the inverse of average facility case mix. As we discussed in the proposed rule, as long as average facility case-mix values are within a relatively narrow range, adjustment for facility case mix should not have a large impact on the estimated PT, OT, and SLP percentages. Because the RUG–III case-mix indexes shown in the 1998 interim final rule are within a relatively narrow range (for example, therapy indexes range from 0.43 to 2.25), we stated that we do not expect the inability to apply the case-mix adjustment to facility per diem costs to have a large influence on the estimated PT, OT, and SLP percentages. These data sources are described in more detail in section 3.10. of the SNF PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*.

We invited comments on the data sources used to determine the PT, OT, and SLP rate components, as discussed above.

Commenters submitted the following comments related to the proposed rule's discussion of the Data Sources Utilized for Proposed Revision of Federal Base Payment Rate Components. A discussion of these comments, along with our responses, appears below.

Comment: One commenter requested additional information on the data sources used to develop PDPM. Specifically, the commenter requested that CMS clarify which year of claims and cost report data was used to develop PDPM.

Response: As detailed in section 3.1 of the SNF PDPM technical report and FY 2019 SNF PPS proposed rule (83 FR 21041), we used data, including claims and assessments, corresponding to Medicare Part A SNF stays with admissions in FY 2017. This was the most complete year of data available when PDPM was developed and continues to be the most complete year of data available as of the FY 2019 final rule. Foundational analyses—for example, those discussed throughout the SNF PMR technical report that accompanied the 2017 ANPRM—used FY 2014 data, as that was the most recent complete year of data available when those analyses were completed. Finally, based on suggestions from commenters responding to the 2017 ANPRM, the analysis that established the list of comorbidities used for payment in the PDPM NTA component and the points associated with each comorbid condition used multiple years of data to generate more robust results. Specifically, resource utilization and assessment data from FYs 2014–2017 were used to determine the comorbid conditions associated with high NTA utilization and estimate the specific resource utilization associated with each condition for the purpose of assigning points and payment to these conditions under PDPM. This methodology is discussed in further detail in section 3.7 of the SNF PDPM technical report and in the FY 2019 SNF PPS proposed rule (83 FR 21056). In terms of cost reports, since providers have their own fiscal year and reporting schedule, we used the cost report closest to the stay window among the cost reports of that provider recorded in the database as of November 2017.

Comment: Some commenters questioned whether it is appropriate to use the same data sources and methodology from 1998 (that is, 1995 cost reports) to set base rates given updated technology and changes in SNF care practices since then. Particularly, a few commenters stated that the estimated share of the nursing base rate attributed to NTA services (43 percent) is outdated and not representative of the proportion of the nursing base rate that corresponds to NTA services. These commenters requested that we consider recalculating SNF base rates using more recent data on SNF costs.

Response: We appreciate the commenters' suggestion to use more recent data in calculating the SNF base rates. However, in accordance with section 1888(e)(4)(A) of the Act, the federal per diem rates used for SNF payment are based on the FY 1995 cost reports. Therefore, we cannot consider recalculating the SNF base rates using more recent data. Additionally, given this statutory requirement, we believed that it was appropriate to use these cost reports to set the base rates for the proposed new components to reflect as closely as possible what the base rates would have been for these components if they had been separately established in 1998. Finally, while it may be the case that, as the commenter stated, changes in SNF care practices may have occurred, such changes would more likely be reflected in differences in the relative costs of treating different types of patients and these types of changes in relative costs are reflected in the revised case-mix weights under PDPM, which does use more recent data than FY 1995. Specifically, as discussed in section 3.1 of the SNF PDPM technical report and FY 2019 SNP PPS proposed rule (83 FR 21041), we developed PDPM using data, including claims and assessments, corresponding to Medicare Part A SNF stays with admissions in FY 2017.

Comment: One commenter recommends that CMS treat respiratory therapy as ''therapy'' and not ''nursing'' for purpose of payment, and recommends CMS consider incorporating an add-on payment for respiratory therapy to ensure it is reimbursed appropriately to safeguard the continuation of these therapy services.

Response: Under Chapter 8 of the Medicare Benefit Policy manual, section 30.4, ''skilled therapy services'' includes physical therapy, occupational therapy, and speech-language pathology therapy (reflecting the regulations at 42 CFR 409.23). Respiratory therapy, on the other hand, is treated as a separate service category in section 50.8.2 of the same chapter (reflecting the regulations at § 409.27(b)). As such, respiratory therapy is distinct from other forms of therapy and is not included among the other therapy components. Additionally, therapy services, as defined in § 409.33 make specific reference to skilled therapy services provided by physical and occupational therapists and speech-language pathologists. Finally, while respiratory therapists have specialized training in addressing respiratory issues, much of the work conducted by respiratory therapists falls within the scope of practice for nurses, which further supports the closer relationship between respiratory therapy and nursing, rather than with the three therapy disciplines. With regard to developing an add-on payment for respiratory therapy, given that such services are currently captured through the global per diem payment, we do not believe that an add-on payment would be warranted.

3. Methodology Used for the Calculation of Federal Base Payment Rate Components

As discussed previously in this section, we proposed to separate the current therapy components into a PT component, an OT component, and an SLP component. To do this, we calculated the percentage of the current therapy component of the federal base rate that corresponds to each of the three proposed PDPM therapy components (PT, OT, and SLP) in accordance with the methodology set forth below and in the FY 2019 SNF PPS proposed rule (83 FR 21039).

The data described in section V.C.2. of the proposed rule (primarily, cost information from FY 1995 cost reports)

provides cost estimates for the Medicare Part A SNF population for each cost report that met the inclusion criteria. Cost reports stratify costs by a number of cost centers that indicate different types of services. For instance, costs are reported separately for each of the three therapy disciplines (PT, OT, and SLP). Cost reports also include the number of Medicare Part A utilization days during the cost reporting period. As we stated in the proposed rule, this allows us to calculate both average total therapy costs per day and average therapy costs by discipline in the facility during the cost reporting period. Therapy costs are defined as the sum of costs for the three therapy disciplines.

As explained in the proposed rule (83 FR 21039), the goal of this methodology is to estimate the proportion of therapy costs that corresponds to each of the three therapy disciplines. We use the facility-level per-diem costs developed from 1995 cost reports to derive average per diem amounts for both total therapy costs and for PT, OT, and SLP costs separately. To do this, we followed the methodology outlined in section II.A.3. of the 1998 interim final rule with comment period (63 FR 26260), which was used by CMS (then known as HCFA) to create the federal base payment rates:

(1) For each of the four measures of cost (PT, OT, SLP, and total therapy costs per day), we computed the mean based on data from freestanding SNFs only. This mean was weighted by the total number of Medicare days of the facility.

(2) For each of the four measures of cost (PT, OT, SLP, and total therapy costs per day), we computed the mean based on data from both hospital-based and freestanding SNFs. This mean was weighted by the total number of Medicare days of the facility.

(3) For each of the four measures of cost (PT, OT, SLP, and total therapy costs per day), we calculated the arithmetic mean of the amounts determined under steps (1) and (2) above.

In section 3.10.3. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*), we show the results of these calculations.

The three steps outlined above produce a measure of costs per day by therapy discipline and a measure of total therapy costs per day. We divided the discipline-specific (PT, OT, SLP) cost measure by the total therapy cost measure to obtain the percentage of the therapy component that corresponds to each therapy discipline. As we discussed in the proposed rule (83 FR 21039), we believe that following a methodology to derive the discipline-specific therapy percentages that is consistent with the methodology used to determine the base rates in the 1998 interim final rule with comment period is appropriate because a consistent methodology helps to ensure that the resulting base rates for the components resemble what they would be had they been established in 1998. We found that PT, OT, and SLP costs correspond to 43.4 percent, 40.4 percent, and 16.2 percent of the therapy component of the federal per diem rate for urban SNFs, and 42.9 percent, 39.4 percent, and 17.7 percent of the therapy component of the federal per diem rate for rural SNFs. Under the proposed PDPM, we stated that the current therapy case-mix component would be separated into a Physical Therapy component, an Occupational Therapy component, and a Speech-Language Pathology component using the percentages derived above. We stated that this process would be done separately for urban and for rural facilities. In the appendix of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*) we provided the specific cost centers used to identify PT, OT, and SLP costs.

In addition, we proposed to separate the current nursing case-mix component into a nursing case-mix component and an NTA component. Similar to the therapy component, we calculated the percentage of the current nursing component of the federal base rates that corresponds to each of the two proposed PDPM components (NTA and nursing). The 1998 reopening of the comment period for the interim final rule (63 FR 65561, November 27, 1998) states that NTA costs comprise 43.4 percent of the current nursing component of the urban federal base rate, and the remaining 56.6 percent accounts for nursing and social services salary costs. These percentages for the nursing component of the federal base rate for rural facilities are 42.7 percent and 57.3 percent, respectively (63 FR 65561). Therefore, we proposed to assign 43 percent of the current nursing component of the federal base rates to the new NTA component of the federal base rates and assign the remaining 57 percent to the new nursing component of the federal base rates to reflect what the base rates would have been for these components if they had been separately established in 1998.

As discussed in the proposed rule (83 FR 21040), we verified the 1998 calculation of the percentages of the nursing component federal base rates that correspond to NTA costs by developing a measure of NTA costs per day for urban and rural facilities. We used the same data (that is, cost information from 1995 cost reports) and followed the same methodology described above to develop measures of PT, OT, and SLP costs per day and total therapy costs per day. The measure of NTA costs per day produced by this analysis was $47.70 for urban facilities and $47.30 for rural facilities. The original 1998 federal base rates for the nursing component, which relied on a similar methodology, were $109.48 for urban facilities and $104.88 for rural facilities. Therefore, our measure of NTA costs in urban facilities was equivalent to 43.6 percent of the urban 1998 federal nursing base rate, and our measure of NTA costs in rural facilities was equivalent to 45.1 percent of the rural 1998 federal nursing base rate. These results are similar to the estimates published in the 1998 reopening of the comment period for the interim final rule (63 FR 65561, November 27, 1998), which we stated we believe supports the validity of the 43 percent figure stated above.

For illustration purposes, Tables 12 and 13 set forth what we stated the unadjusted federal per diem rates would be for each of the case-mix adjusted components if we were to apply the proposed PDPM to the FY 2019 base rates given in Tables 4 and 5. These were derived by dividing the FY 2019 SNF PPS base rates according to the percentages described above. Tables 12 and 13 also show what the unadjusted federal per diem rates for the non-case-mix component would be, which are not affected by the change in case-mix methodology from RUG–IV to PDPM. We used these unadjusted federal per diem rates in calculating the impact analysis discussed in section V.J. of the proposed rule.

TABLE 12—FY 2019 PDPM UNADJUSTED FEDERAL RATE PER DIEM—URBAN [1]

Rate component	Nursing	NTA	PT	OT	SLP	Non-case-mix
Per Diem Amount	$103.46	$78.05	$59.33	$55.23	$22.15	$92.63

[1] The rates shown in Tables 12 and 13 illustrate what the adjusted federal per diem rates would be for each of the case-mix adjusted components if we were to apply the proposed PDPM to the proposed FY 2019 base rates given in Tables 4 and 5.

TABLE 13—FY 2019 PDPM UNADJUSTED FEDERAL RATE PER DIEM—RURAL

Rate component	Nursing	NTA	PT	OT	SLP	Non-case-mix
Per Diem Amount	$98.83	$74.56	$67.63	$62.11	$27.90	$94.34

We invited comments on the proposed data sources and proposed methodology for calculating the unadjusted federal per diem rates that would be used in conjunction with the proposed PDPM effective October 1, 2019.

Commenters submitted the following comments related to the proposed rule's discussion of the Methodology Used for the Calculation of Federal Base Payment Rate Components. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters supported the proposed changes to the SNF PPS base rates. One commenter specifically highlighted their support for including an NTA component. Some commenters sought clarification regarding how CMS intends to distribute system resources currently associated with the ''therapy non-case-mix'' base rate. Specifically, they stated that the FY 2019 SNF proposed rule and the SNF PDPM technical report that accompanied the proposed rule appear to be inconsistent in describing how resources associated with this payment component will be distributed under the new payment model. Commenters note that the proposed rule stated that resources associated with the ''therapy non-case-mix'' base rate will be redistributed among the three PDPM case-mix therapy components, while the SNF PDPM technical report states that the ''therapy non-case-mix'' payment component is dropped from the payment model under PDPM.

Response: We appreciate the support for our proposed changes. As stated in the proposed rule, we believe it is appropriate to eliminate the non-case-mix therapy base rate because facilities will be compensated for residents who receive nominal amounts of therapy (for example, therapy evaluations) through the three PDPM base rates corresponding to the three disciplines of therapy provided in the SNF setting (PT, OT, and SLP) under the new payment model. In other words, whereas under the existing RUG–IV reimbursement model, facilities receive a non-case-mix therapy payment for residents who receive nominal amounts of therapy, under PDPM facilities would receive payment for these residents through the PT, OT, and SLP payment components.

Additionally, in setting component base rates under PDPM, we sought to replicate the methodology used to estimate the SNF PPS original base rates in 1998 as closely as possible. This is consistent with the requirements of section 1888(e)(4) of the Act, which requires that SNF PPS per diem federal payment rates be based on FY 1995 costs reports. Therefore, to ensure that the PDPM base rates resembled as closely as possible what they would have been had these components been established in 1998, we used FY 1995 cost reports to determine the share of therapy costs accounted for by PT, OT, and SLP. As described in the proposed rule (83 FR 21038 through 21039) and in section 3.10 of the SNF PDPM technical report, we then used the percentage of costs associated with each of these disciplines to calculate the corresponding base rates for the PT, OT, and SLP components under PDPM.

Finally, as further discussed in section 3.11 of the SNF PDPM technical report, we adjusted CMIs for each of the five case-mix-adjusted components of PDPM to ensure budget neutrality between RUG–IV and PDPM. In doing so, we applied a multiplier to CMIs for all five case-mix-adjusted PDPM payment components so that total estimated payments under PDPM are budget neutral relative to RUG–IV. This procedure effectively distributes resources that are currently associated with the ''therapy non-case-mix'' component of RUG–IV across all five case-mix components of PDPM. We acknowledge that the proposed rule inadvertently stated that the resources associated with the therapy non-case mix component were distributed across only the three PDPM case-mix therapy components. Thus, we are clarifying that, while we did eliminate the therapy non-case mix component from the model, we redistributed resources associated with this component across the five PDPM case-mix components as described in section 3.11 of the PDPM technical report.

Comment: Many commenters expressed concern regarding the base rate for the SLP component, specifically that it is much lower than that of the other therapy base rates. Commenters suggested that this may be taken to devalue SLP services and that low reimbursement will lead to a decrease in the utilization of SLP services. Some commenters further suggested that such low reimbursement rates could lead to layoffs among SLPs and believe that PDPM should pay equally for all three therapy disciplines.

Response: We appreciate the concerns raised by these commenters regarding the potential impact on SLP services resulting from the payment policies in relation to SLP services discussed in the proposed rule. With regard to the comment about the SLP component base rate, as described above, we utilized the proportion of the current therapy base rate corresponding to each therapy discipline as the basis for allocating the therapy base rate as the basis for allocating the therapy base rate among each of the individual components. As SLP services represented approximately 17 percent, on average, of overall therapy costs, we believed it was appropriate to allocate this percentage as the base rate for the SLP component. If we were to make all three components equal, as one commenter had suggested, then this would overinflate SLP payment in relation to SLP costs. We would note, however, that while the base rate for the SLP component is lower than the other therapy component base rates, the case-mix weights for this component, as described in section V.B.3.c. of this final rule, are far greater for the SLP component than for either of the PT or OT components. This reflects that when SLP services are

predicted to be necessary, there is adequate reimbursement for these services. Therefore, we expect that utilization of and access to SLP services should not be adversely affected merely because the base rate is lower for this component.

Accordingly, after considering the comments received, for the reasons specified in the FY 2019 SNF PPS proposed rule and in this final rule, we are finalizing, effective October 1, 2019, our proposals related to the calculation of the federal base payment rate components, as described in this section, with the following clarification. As discussed above, we are clarifying that, while we did eliminate the therapy non-case mix component from the model, we redistributed resources associated with this component across the five PDPM case-mix components as described in the PDPM technical report.

4. Updates and Wage Adjustments of Revised Federal Base Payment Rate Components

In section III.B. of the proposed rule, we described the process used to update the federal per diem rates each year. Additionally, as discussed in section III.B.4 of the proposed rule, SNF PPS rates are adjusted for geographic differences in wages using the most recent hospital wage index data. Under PDPM, we proposed to continue to update the federal base payment rates and adjust for geographic differences in wages following the current methodology used for such updates and wage index adjustments under the SNF PPS (83 FR 21040). Specifically, we proposed to continue the practice of using the SNF market basket, adjusted as described in section III.B. of the proposed rule to update the federal base payment rates and to adjust for geographic differences in wages as described in section III.B.4. of the proposed rule.

We received comments on the proposed methodology for updating the federal base payment rates and adjusting the per diem rates for geographic differences in wages under the PDPM. Those comments, and our responses, appear below.

Comment: Most commenters agreed with using the standard rate update policy and the existing wage index policy as the basis for updating the payment rates and adjusting the rates for geographic variation. One commenter stated that the lack of separate labor-share adjustment for each component may lead to provision of fewer services as each component would not be appropriately wage adjusted. This commenter stated that because CMS has already calculated payment amounts for each component and because cost reports contain all the information necessary to determine the labor share for each component, it would be appropriate for CMS to make separate wage adjustment calculations for each PDPM component.

Response: We appreciate the support for this proposal. With regard to the comment that CMS should separately wage adjust each PDPM component, the labor-related share reflects the facility Medicare-allowable costs (including all of the PDPM components) that are labor-intensive and vary with the local labor market. Specifically, it is equal to the following cost categories from the 2014-based SNF market basket: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses. The majority of these labor-related costs are derived using the MCR data; however, a notable portion is based on other government data sources. A complete description of the methodology used to derive the 2014-based SNF market basket is available in the FY 2018 final rule (82 FR 36548 through 36566). Given that these categories cut across PDPM components, to wage adjust for each component separately would require a substantial increase in the specificity of reporting these MCR data items, as well as developing a methodology for accurately assigning these costs to each component. We believe that the additional reporting burden associated with implementing this suggestion would not justify the increased specificity of applying the wage index adjustment to each component under PDPM.

Accordingly, after considering the comments received, for the reasons specified in the FY 2019 SNF PPS proposed rule (83 FR 21040) and discussed in this section, we are finalizing our proposal, without modification, for updating the federal base payment rates and for adjusting the per diem rates for geographic differences in wages under the PDPM, effective October 1, 2019.

C. Design and Methodology for Case-Mix Adjustment of Federal Rates

1. Background on PDPM

Section 1888(e)(4)(G)(i) of the Act requires that the Secretary provide an appropriate adjustment to account for case mix and that such an adjustment shall be based on a resident classification system that accounts for the relative resource utilization of different patient types. The current case-mix classification system uses a combination of resident characteristics and service intensity metrics (for example, therapy minutes) to assign residents to one of 66 RUGs, each of which corresponds to a therapy CMI and a nursing CMI, which are indicative of the relative cost to a SNF of treating residents within that classification category. However, as noted in section V.A. of the proposed rule, incorporating service-based metrics into the payment system can incentivize the provision of services based on a facility's financial considerations rather than resident needs. To better ensure that resident care decisions appropriately reflect each resident's actual care needs, we stated in the proposed rule (83 FR 21040) that we believe it is important to remove, to the extent possible, service-based metrics from the SNF PPS and derive payment from verifiable resident characteristics that are patient, and not facility, centered. To that end, as we stated in the proposed rule, the proposed PDPM was developed to be a payment model which derives payment classifications almost exclusively from verifiable resident characteristics.

Additionally, the current RUG–IV case-mix classification system reduces the varied needs and characteristics of a resident into a single RUG–IV group that is used for payment. As of FY 2017, of the 66 possible RUG classifications, over 90 percent of covered SNF PPS days are billed using one of the 23 Rehabilitation RUGs, with over 60 percent of covered SNF PPS days billed using one of the three Ultra-High Rehabilitation RUGs. As we stated in the proposed rule (83 FR 21040), the implication of this pattern is that more than half of the days billed under the SNF PPS effectively utilize only a resident's therapy minutes and Activities of Daily Living (ADL) score to determine the appropriate payment for all aspects of a resident's care. Both of these metrics, more notably a resident's therapy minutes, may not derive so much from the resident's own characteristics, but rather, from the type and amount of care the SNF decides to provide to the resident. We stated that even assuming that the facility takes the resident's needs and unique characteristics into account in making these service decisions, the focus of payment remains centered, to a potentially great extent, on the facility's own decision making and not on the resident's needs.

We explained in the proposed rule (83 FR 21041) that while the RUG–IV model

utilizes a host of service-based metrics (type and amount of care the SNF decides to provide) to classify the resident into a single RUG–IV group, the proposed PDPM would separately identify and adjust for the varied needs and characteristics of a resident's care and combine this information together to determine payment. We stated we believe the proposed PDPM would improve the SNF PPS by basing payments predominantly on clinical characteristics rather than service provision, thereby enhancing payment accuracy and strengthening incentives for appropriate care. For these reasons, we proposed that, effective October 1, 2019, SNF residents would be classified using the PDPM, as further discussed below. As discussed in the proposed rule and in section V.I. of this final rule, we proposed to implement the PDPM on October 1, 2019 to allow all stakeholders adequate time for systems updates and staff training needed to assure smooth implementation.

2. Data Sources Utilized for Developing PDPM

To understand, research, and analyze the costs of providing Part A services to SNF residents, we utilized a variety of data sources in the course of research. In the proposed rule (83 FR 21041) and in this section, we discuss these sources and how they were used in the SNF PMR in developing the proposed PDPM. A more thorough discussion of the data sources used during the SNF PMR is available in section 3.1. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*).

a. Medicare Enrollment Data

Beneficiary enrollment and demographic information was extracted from the CMS enrollment database (EDB) and Common Medicare Environment (CME). Beneficiaries' Medicare enrollment was used to apply restrictions to create a study population for analysis. For example, beneficiaries were required to have continuous Medicare Part A enrollment during a SNF stay. Demographic characteristics (for example, age) were incorporated as being predictive of resource use. Furthermore, enrollment and demographic information from these data sources were used to assess the impact of the proposed PDPM on subpopulations of interest. In particular, the EDB and CME include indicators for potentially vulnerable subpopulations, such as those dually-enrolled in Medicaid and Medicare.

b. Medicare Claims Data

Medicare Parts A and B claims from the CMS Common Working File (CWF) were used to conduct claims analyses as part of the SNF PMR. SNF claims (CMS–1450 form, OMB control number 0938–0997), including type of bill (TOB) 21x (SNF Inpatient Part A) and 18x (hospital swing bed), were used to identify Medicare Part A stays paid under the SNF PPS. Part A stays were constructed by linking claims that share the same beneficiary, facility CMS Certification Number (CCN), and admission date. Stays created from SNF claims were linked to other claims data and assessment data via beneficiary identifiers.

Acute care hospital stays that qualified the beneficiary for the SNF benefit were identified using Medicare inpatient hospital claims. The dates of the qualifying hospital stay listed in the span codes of the SNF claim were used to connect inpatient claims with those dates listed as the admission and discharge dates. Although there are exceptions, the claims from the preceding inpatient hospitalization commonly contain clinical and service information relevant to the care administered during a SNF stay. Components of this information were used in the regression models predicting therapy and NTA costs and to better understand patterns of post-acute care (PAC) referrals for patients requiring SNF services. Additionally, the most recent hospital stay was matched to the SNF stay, which often (though not always) was the same as the preceding inpatient hospitalization, and used in the regression models.

Other Medicare claims, including outpatient hospital, physician, home health, hospice, durable medical equipment, and drug prescriptions, were incorporated, as necessary, into the analysis in one of three ways: (1) To verify information found on assessments or on SNF or inpatient claims; (2) to provide additional resident characteristics to test outside of those found in assessment and SNF and inpatient claims data; and (3) to stratify modeling results to identify effects of the system on beneficiary subpopulations. These claims were linked to SNF claims using beneficiary identifiers.

c. Assessment Data

Minimum Data Set (MDS) assessments were the primary source of resident characteristic information used to explain resource utilization in the SNF setting. The data repositories include MDS assessments submitted by SNFs and swing-bed hospitals. MDS version 2.0 assessments were submitted until October 2010, at which point MDS version 3.0 assessments began. MDS data were extracted from the Quality Improvement Evaluation System (QIES). MDS assessments were then matched to SNF claims data using the beneficiary identifier, assessment indicator, assessment date, and Resource Utilization Group (RUG).

d. Facility Data

Facility characteristics, while not considered as explanatory variables when modeling service use, were used for impact analyses. By incorporating this facility-level information, we could identify any disproportionate effects of the proposed case-mix classification system on different types of facilities.

Facility-level characteristics were taken from the Certification and Survey Provider Enhanced Reports (CASPER). From CASPER, we draw facility-level characteristics such as ownership, location, facility size, and facility type. CASPER data were supplemented with information from publicly available data sources. The principal data sources that are publicly available include the Medicare Cost Reports (Form 2540–10, 2540–96, and 2540–92) extracted from the Healthcare Cost Report Information System (HCRIS) files, Provider-Specific Files (PSF), Provider of Service files (POS), and Nursing Home Compare (NHC). These data sources have information on facility costs, payment, and characteristics that directly affect PPS calculations.

We received comments from stakeholders regarding the data used to develop PDPM, though we address these comments later in this section in relation to the specific PDPM component to which the comments were addressed.

3. Resident Classification Under PDPM

a. Background

As noted above, section 1888(e)(4)(G)(i) of the Act requires that the Secretary provide for an appropriate adjustment to account for case mix and that such an adjustment shall be based on a resident classification system that accounts for the relative resource utilization of different patient types. As we stated in the proposed rule (83 FR 21040), the proposed PDPM was developed to be a payment model which derives almost exclusively from resident characteristics. We stated that the proposed PDPM would separately identify and adjust five different case-mix components for the varied needs and characteristics of a resident's care

and then combine these together with the non-case-mix component to form the full SNF PPS per diem rate for that resident.

We stated in the proposed rule (83 FR 21041 through 21042) that, as with any case-mix classification system based on resident characteristics, the proposed predictors that would be part of case-mix classification under PDPM are those which our analysis identified as associated with variation in costs for the given case-mix component. We explained that the proposed federal per diem rates discussed above serve as ''base rates'' specifically because they set the basic average cost of treating a typical SNF resident. Based on the presence of certain needs or characteristics, caring for certain residents may cost more or less than that average cost. We explained that a case-mix system identifies certain aspects of a resident or of a resident's care which, when present, lead to average costs for that group being higher or lower than the average cost of treating a typical SNF resident. For example, if we found that therapy costs were the same for two residents regardless of having a particular condition, then that condition will not be relevant in predicting increases in therapy costs. If, however, we found that, holding all else constant, the presence of a given condition was correlated with an increase in therapy costs for residents with that condition over those without that condition, then this could mean that this condition is indicative, or predictive, of increased costs relative to the average cost of treating SNF residents generally.

In the subsections that follow, we describe each of the five case-mix adjusted components under the proposed PDPM and the basis for each of the predictors that we stated would be used within the PDPM to classify residents for payment purposes.

b. Physical and Occupational Therapy Case-Mix Classification

As we stated in the proposed rule (83 FR 21042), a fundamental aspect of the proposed PDPM is to use resident characteristics to predict the costs of furnishing similarly situated residents with SNF care. Costs derived from the charges on claims and cost-to-charge ratios (CCRs) on facility cost reports were used as the measure of resource use to develop the proposed PDPM. We explained that costs better reflect differences in the relative resource use of residents as opposed to charges, which partly reflect decisions made by providers about how much to charge payers for certain services. We further explained that costs derived from charges are reflective of therapy utilization as they are correlated to the therapy minutes recorded for each therapy discipline. Under the current RUG–IV case-mix model, therapy minutes for all three therapy disciplines (PT, OT, SLP) are added together to determine the appropriate case-mix classification for the resident. However, as shown in section 3.3.1. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*), and as explained in the proposed rule, when we began to investigate resident characteristics predictive of therapy costs for each therapy discipline, we found that PT and OT costs per day are only weakly correlated with SLP costs per day (correlation coefficient of 0.04). The set of resident characteristics from the MDS that predicted PT and OT utilization was different than the set of characteristics predicting SLP utilization. Additionally, many predictors of high PT and OT costs per day predicted lower SLP costs per day, and vice versa. For example, we found that residents with cognitive impairments receive less physical and occupational therapy but receive more speech-language pathology. As a result of this analysis, as we explained in the proposed rule, we found that basing case-mix classification on total therapy costs per day obscured differences in the determinants of PT, OT, and SLP utilization.

In contrast, we stated in the proposed rule (83 FR 21042) that the correlation coefficient between PT and OT costs per day was high (0.62). Additionally, regression analyses found that predictors of high PT costs per day were also predictive of high OT costs per day. For example, the analyses found that late-loss ADLs are strong predictors of both PT and OT costs per day. We then used a range of resident characteristics to predict PT and OT costs per day separately and we found that the coefficients in both models followed similar patterns. Finally, we noted that resident characteristics were found to be better predictors of the sum of PT and OT costs per day than for either PT or OT costs separately. These analyses used a variety of items from the MDS as independent variables and used PT, OT, and SLP costs per day as dependent variables. In the proposed rule, we referred readers to section 3.3.1. of the SNF PMR technical report that accompanied the ANPRM available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html for more information on these analyses.*

Given the results of this analytic work, as well as feedback from multiple stakeholders, we proposed three separate case-mix adjusted components, one corresponding to each therapy discipline: PT, OT, and SLP. In the original RCS–I model presented in the ANPRM, we stated that we were considering addressing PT and OT services through a single component, given the strong correlation between PT and OT costs and our finding that very similar predictors explained variation in the utilization of both therapy disciplines. However, as we explained in the proposed rule (83 FR 21042), commenters on the ANPRM stated that having a single combined PT and OT component could encourage providers to inappropriately substitute PT for OT and vice versa. We stated that this belief comports with feedback received from professional organizations and other stakeholders during technical expert panels (TEPs). The TEP commenters stated that PT and OT services should be addressed via separate components given the different aims of the two therapy disciplines and differences in the clinical characteristics of the resident subpopulations for which PT or OT services are warranted. For example, clinicians consulted during development of PDPM advised that personal hygiene, dressing, and upper extremity motion may bear a closer clinical relationship to OT utilization, while lower extremity motion may be more closely related to PT utilization. We stated in the proposed rule that while we do not believe that RCS–I, which included two separate components for PT/OT and SLP, contained stronger incentives for substitution across therapy disciplines compared to RUG–IV, which reimburses all three therapy disciplines through a single therapy component, we concur with the TEP commenters that PT and OT have different aims and that there are clinically relevant differences between residents who could benefit from PT, residents who could benefit from OT, and residents who could benefit from both disciplines. For the foregoing reasons, we decided to separate the combined PT/OT component presented in the ANPRM into two separate case-mix adjusted components in the proposed PDPM. As we stated in the proposed rule, because of the strong correlation between the dependent variables used for both components and the similarity in predictors, we decided to maintain the same case-mix classification model for

both components. We stated that in practice, this means that the same resident characteristics will determine a resident's classification for PT and OT payment. However, we stated that each resident would be assigned separate case-mix groups for PT and OT payment, which correspond to separate case-mix indexes and payment rates. We explained that we believe providing separate case-mix-adjusted payments for PT and OT may allay concerns about inappropriate substitution across disciplines and encourage provision of these services according to clinical need. We further noted that as clinical practices evolve independently of incentives created by the current RUG–IV payment model, we would re-evaluate the different sets of resident characteristics that are predictive of PT and OT utilization after the PDPM is implemented. We stated that if based on this re-evaluation we determine that different sets of characteristics are predictive of PT and OT resource utilization, we could consider revising the payment model to better reflect clinical differences between residents who receive PT services and those who receive OT services.

After delineating the three separate case-mix adjusted therapy components, we continued our analysis, as described in the proposed rule (83 FR 21043), by identifying resident characteristics that were best predictive of PT and OT costs per day. To accomplish this, we conducted cost regressions with a host of variables from the MDS assessment, the prior inpatient claims, and the SNF claims that were believed to be potentially predictive of relative increases in PT and OT costs. As we stated in the proposed rule, the variables were selected with the goal of being as inclusive as possible with respect to characteristics related to the SNF stay and the prior inpatient stay. The selection also incorporated clinical input. We explained that these initial costs regressions were exploratory and meant to identify a broad set of resident characteristics that are predictive of PT and OT resource utilization. The results were used to inform which variables should be investigated further and ultimately included in the payment system. A table of all of the variables considered as part of this analysis appears in the appendix of the SNF PMR technical report that accompanied the ANPRM available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html.* As explained in the proposed rule, based on our regression analyses, we found that the three most relevant categories of predictors of PT and OT costs per day were the clinical reasons for the SNF stay, the resident's functional status, and the presence of a cognitive impairment. More information on this analysis can be found in section 3.4.1. of the SNF PDPM technical report available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html.*

Under the RUG–IV case-mix model, residents are first categorized based on being a rehabilitation resident or a non-rehabilitation resident, then categorized further based on additional aspects of the resident's care. As explained in the proposed rule (83 FR 21043), under the proposed PDPM, for the purposes of determining the resident's PT and OT groups and, as will be discussed below, the resident's SLP group, the resident would first be categorized based on the clinical reasons for the resident's SNF stay. We stated that empirical analyses demonstrated that the clinical basis for the resident's stay (that is, the primary reason the resident is in the SNF) is a strong predictor of therapy costs. For example, we explained that all of the clinical categories (described below) developed to characterize the primary reason for a SNF stay (except the clinical category used as the reference group) were found to be statistically significant predictors of therapy costs per day. More detail on these analyses can be found in section 3.4.1. of the SNF PMR technical report that accompanied the ANPRM (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html).* In consultation with stakeholders (industry representatives, beneficiary representatives, clinicians, and payment policy experts) at multiple technical expert panels (TEPs), we created a set of ten inpatient clinical categories that we believe capture the range of general resident types which may be found in a SNF. These proposed clinical categories were provided in Table 14 of the proposed rule (83 FR 21043) and are reflected in Table 14.

TABLE 14—PDPM CLINICAL CATEGORIES

Major Joint Replacement or Spinal Surgery.
Non-Surgical Orthopedic/Musculoskeletal.
Orthopedic Surgery (Except Major Joint Replacement or Spinal Surgery).
Acute Infections.
Medical Management.
Cancer.
Pulmonary.
Cardiovascular and Coagulations.
Acute Neurologic.
Non-Orthopedic Surgery.

We proposed to categorize a resident into a PDPM clinical category using item I8000 on the MDS 3.0. We stated in the proposed rule (83 FR 21043) that providers would use the first line in item I8000 to report the ICD–10–CM code that represents the primary reason for the resident's Part A SNF stay. We further stated that this code would be mapped to one of the ten clinical categories provided in Table 14 of the proposed rule (set forth at Table 14 of this final rule). The mapping between ICD–10–CM codes and the ten clinical categories is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html.* As explained in the proposed rule, the mapping indicates that in some cases, a single ICD–10–CM code maps to more than one clinical category because the care plan for a resident with this diagnosis may differ depending on the inpatient procedure history. In these cases, we explained that a resident may be categorized into a surgical clinical category if the resident received a surgical procedure during the immediately preceding inpatient stay that relates to the primary reason for the Part A SNF stay and typically requires extensive post-surgical rehabilitation or nursing care. If the resident did not receive a related surgical procedure during the prior inpatient stay that typically requires extensive post-surgical rehabilitation or nursing care, the resident may be categorized into a non-surgical clinical category. For example, we explained that certain wedge compression fractures that were treated with an invasive surgical procedure such as a fusion during the prior inpatient stay would be categorized as Major Joint Replacement or Spinal Surgery, but if these cases were not treated with a surgical procedure they would be categorized as Non-Surgical Orthopedic/Musculoskeletal. For residents who received a related surgical procedure during the prior inpatient stay, we stated that a provider would need to indicate the type of surgical procedure performed for the resident to be appropriately classified under PDPM. Thus, in these cases we proposed to require providers to record the type of inpatient surgical procedure performed during the prior inpatient stay so that residents can be appropriately classified into a PDPM clinical category for purposes of PT, OT, and SLP classification. We proposed that providers record the type of surgical procedure performed during the prior inpatient stay by coding an ICD–10–PCS code that corresponds to the inpatient

surgical procedure in the second line of item I8000 in cases where inpatient surgical information is required to appropriately categorize a resident under PDPM. We noted that if we were to use the second line of item I8000 to record inpatient surgical information, we would provide a list of ICD–10–PCS codes that map to the surgical clinical categories. We stated that we believe this approach would allow for patients to be appropriately classified under the PDPM because it would provide sufficient information on the primary reason for SNF care and inpatient surgical procedures to assign a resident to the appropriate surgical or non-surgical clinical category. We invited comments on this proposal. In addition, we solicited comments on alternative methods for recording the type of inpatient surgical procedure to appropriately classify a patient into a clinical category. We explained that the clinical category into which the resident is classified would be used to classify the resident into a PT and OT category as discussed below, as well as an SLP category, as explained in section V.D.3.c. of the proposed rule.

As discussed above, we proposed to categorize a resident into a PDPM clinical category for purposes of PT, OT, and SLP classification using the ICD–10–CM code in the first line of item I8000, and if applicable, the ICD–10 PCS code in the second line of item I8000. As an alternative to using item I8000 to classify a resident into a clinical category, we stated in the proposed rule (83 FR 21044) that we were considering using a resident's primary diagnosis as reflected in MDS item I0020 as the basis for assigning the resident to a clinical category, and were evaluating the categories provided in item I0020 to determine if there is sufficient overlap between the categories used in item I0020 and the proposed PDPM clinical categories provided in Table 14 that this item could serve as the basis for a resident's initial classification into a clinical category under PDPM. We stated that the MDS item I0020 would require facilities to select a primary diagnosis from a pre-populated list of primary diagnoses representing the most common types of beneficiaries treated in a SNF, while item I8000, if used to assign residents to clinical categories, would require facilities to code a specific ICD–10–CM code that corresponds to the primary reason for the resident's Part A SNF stay. As indicated above, we also proposed that providers would code a specific ICD–10–PCS code in the second line of item I8000 when surgical information from the prior inpatient stay is necessary to assign a resident to a clinical category. We explained that if we were to use item I0020 to categorize residents under PDPM, we would not require providers to record additional information on inpatient surgical procedures as we expect the primary diagnosis information provided through item I0020 to be adequate to appropriately assign a resident to a clinical category.

We invited comments on our proposal to categorize a resident into a PDPM clinical category using the ICD–10–CM code recorded in the first line of item I8000 on the MDS 3.0, and the ICD–10–PCS code recorded on the second line of item I8000 on the MDS 3.0. In addition, we solicited comments on the alternative of using item I0020 on the MDS 3.0, as discussed above, as the basis for resident classification into one of the ten clinical categories in Table 14.

Commenters submitted the following comments related to the proposed rule's discussion of the clinical category assignments under PDPM. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters expressed concern about ICD–10 coding requirements under PDPM. Some commenters are concerned that these requirements, especially ICD–10–PCS coding requirements, would create compliance risks because of SNFs' limited expertise in using ICD codes. A few commenters request that CMS offer ICD–10 coding training for clinicians, billers, coders, and other SNF personnel, prior and subsequent to PDPM implementation. Another commenter requested that CMS provide case studies and other resources as part of its educational strategy with respect to ICD–10 coding in the SNF setting. This commenter also recommended that CMS develop explicit instructions for how providers should record diagnosis and procedure information in MDS item I8000 for resident classification purposes under PDPM. One commenter recommends requiring the employment of credentialed medical record staff to ensure accurate coding. One commenter seeks clarification about potential consequences of ICD–10 coding errors during RAC audits. Another commenter questioned if the proposed ICD–10 coding is considered a transaction under the HIPPA transaction coding requirement.

Response: We appreciate the commenters' concerns regarding ICD–10 coding, but do not concur with stakeholder claims that SNF providers are unfamiliar with ICD–10 coding practices. While ICD–10 codes are not, in most instances, a factor in determining payment under the current SNF Part A benefit, ICD–10 has been an aspect of Medicare since FY 2016. Moreover, ICD–10 provides the most accurate coding and diagnosis information on patients, which can only serve to improve provider understanding of their patient's condition and resultant care plan. Finally, we believe that given the type of homogeneity of care currently provided by SNF providers (as evidenced by the existing case-mix distribution that has over 90 percent of patient billed days in one of 23 RUGs that utilize therapy service utilization as the primary determinant), moving to a system that utilizes the primary patient diagnosis as the key determinant of payment will help to ensure that the patient's unique condition and goals is the primary driver of care planning and care delivery and case mix classification, rather than the patient's ability to tolerate a high volume of therapy services.

With regard to the comment that CMS offer ICD–10 coding training for clinicians and other personnel, we do not believe it is the role of CMS to offer this type of professional training, as it is the responsibility of the provider to ensure that their staff is properly trained to perform these types of more general tasks that are not specific to a given payer or requirement. With regard to the comment that CMS provide case studies and other resources as part of an educational strategy, we appreciate this comment and will take it into consideration as we develop the educational materials for PDPM. In terms of the explicit instructions for how providers record diagnosis and procedure information, we do intend to provide such information in the MDS RAI manual.

With regard to the comment that we should require that providers employ credentialed medical record staff to ensure accurate coding, we agree that the emphasis on ICD–10 could cause changes in staffing at some providers. However, we do not believe it would be appropriate for CMS, in this instance, to specifically identify the type of staff that providers must employ to ensure accurate coding, as this is a decision best left to the provider. With regard to the potential consequences of ICD–10 coding errors on RAC audits, as under the current payment system, the information reported to CMS must be accurate. Inaccuracies in the data reported to CMS, or a failure to document the basis for such data, will necessitate the same types of administrative actions as occur today.

Finally, with regard to the question of whether the reporting of ICD–10 coding information constitutes a HIPAA transaction, we note that while some HIPAA Administrative Simplification requirements at 45 CFR part 162 require the use of ICD–10 codes, reporting ICD–10 codes does not in and of itself constitute a HIPAA transaction.

Comment: One commenter stated that CMS's proposal to use the first line of I8000 to capture the primary reason for SNF stay, the second line to capture procedure code, and the remaining spaces to capture comorbidities is overly complex. The commenter expressed concern that coding a procedure code in the second line of I8000 would not follow current RAI coding instructions. Some commenters support using MDS item I0020 to record the primary diagnosis, stating this will reduce provider burden. Other commenters opposed using item I0020 for this purpose because this item is designed for the Quality Reporting Program and does not align well with the PDPM clinical categories. One commenter stated that coding primary reason for SNF care in both item I8000 and item I0020 for different purposes will be confusing and will lead to errors. Another commenter sought clarity on whether providers would still be required to code ICD–10 diagnosis or procedure codes in item I8000 if item I0020 is used for resident classification. This commenter also questioned what providers should do if a resident does not fall into one of the I0020 categories. A few commenters suggest instead adding checkboxes in section I of the MDS to indicate the ten PDPM clinical categories. One commenter recommended the use of MDS item J2000 for procedure information, because SNFs have minimal experience with ICD–10–PCS codes and it can be difficult to obtain precise information on procedures performed during the preceding inpatient stay.

Response: We appreciate these comments regarding the complexity of the proposed methodology for collecting diagnosis and procedure information and appreciate the suggestions for ways to improve coding without compromising the overall integrity of the information reported. We agree with commenters who stated that the I0020 categories are not currently aligned with the clinical categories used under PDPM, specifically that the categories used under I0020 do not match the clinical categories that we use under PDPM, which means that using I0020 at this time would not be appropriate. We will continue to work to determine if refinements may be made in that item in the future which could allow for a transition to this item. With regard to comments concerning the potential for confusion associated with coding the patient's primary diagnosis in both I8000 and I0020 for different purposes, we believe this both affords the potential to confirm the primary diagnosis coding on the MDS (to the extent that we can identify areas of alignment between the two items) and helps us to refine the categories for a potential future transition to item I0020 under PDPM. With regard to the question of what providers should do if a patient does not fall into one of the I0020 categories, we would recommend that the provider refer to the I0020 coding instructions in the MDS manual for guidance on this issue.

With regard to suggestions of using a checkbox for recording diagnosis information, we believe that the use of such checkboxes for recording diagnosis information may not provide sufficient granularity for CMS to monitor properly the effects of PDPM implementation or to accurately classify patients for payment purposes, nor provide enough information for the SNF in terms of care planning. Given the use of ICD–10 diagnosis coding in other Medicare payment systems and given efforts to align payment across multiple post-acute care payment systems, we believe that using the actual diagnosis code, rather than a checkbox for a category, will provide greater consistency between payment systems and would provide a smoother transition to the extent such payment systems are aligned further in the future.

With regard to the comment that CMS consider using item J2000 to report procedural information, we believe that while the actual ICD–10 code is important in the case of diagnosis coding, we agree with the commenter that the procedural information may be coded at a more aggregated level, as this information is only being used to augment the patient's classification rather than as the primary basis for the classification. However, we believe that item J2000 (which requires providers to report if the patient experienced a surgical procedure in the preceding 100 days) would not adequately link to the care being delivered in the SNF, potentially close to 100 days after the surgical event. To address this, consistent with this commenter's suggestion, and in response to other concerns about the complexity of the proposed methodology, we believe that it would be appropriate and sufficient to develop subitems for item J2000 that would allow providers to report, through a checkbox-style mechanism, if a surgical procedure occurred during the preceding hospital stay (as opposed to the previous 100 days, as is used for J2000), and then provide a series of procedural categories, related to the PDPM clinical categories, that providers could select using a checkbox style mechanism, that would allow the provider to report on the relevant procedural information (rather than recording the specific ICD–10–PCS code). We believe this is a substantial improvement to the procedure we proposed for recording surgical procedure information, as it reduces the burden and complexity of provider reporting on procedural information while maintaining payment accuracy and integrity. Moreover, similar to how PDPM utilizes the procedural information to augment the patient's clinical category classification, we believe that using a checkbox mechanism also augments care-planning by helping ensure that the procedural history information from the hospital is properly taken into account in determining the resident's care needs and care plan. Therefore, we are developing sub-items for item J2000, which will allow providers to report the patient's procedural information in a way that uses a checkbox mechanism, and this procedural information will be used in concert with the patient's diagnosis information, as was discussed above and in the FY 2019 SNF PPS proposed rule, to classify the patient into a clinical category. We will provide both the subitems under item J2000, and the instructions regarding their use, for this purpose in the RAI manual.

Comment: One commenter was opposed to PDPM's focus on one primary diagnosis, as SNF residents can be admitted with complex medical conditions and multiple diagnoses. The commenter recommends that SNFs should select all resident conditions and allow the software to select the highest case-mix index achieved. In a similar vein, another commenter requested that CMS clarify which inpatient procedure SNFs should select for purposes of resident classification and payment under PDPM when the patient record includes multiple procedure codes.

Response: While we agree with the commenter that a SNF patient may suffer from multiple conditions, we believe that one of these reasons prompted transfer to the SNF. This reason would function as the patient's primary diagnosis, as it represents the primary reason for the patient being in the SNF. We would also note that primary diagnosis, as a concept, is used throughout the Medicare program as the basis for payment and, in each area in

which it is used, patients have the potential to present with multiple conditions and multiple diagnoses. Therefore, we do not believe it would be appropriate for providers simply to report all conditions and be paid for the highest case-mix index, but rather that providers should determine the primary reason for the patient's stay, as this should also be the primary motivation behind the patient's SNF care.

With regard to the comment related to multiple inpatient surgical procedures, we expect that the checkbox mechanism discussed above, which would include more aggregated procedural groupings, should address much of this possibility, as often times multiple procedures may be done of the same type. In the case of different types of procedures, providers should code or check-off all information supportable by the patient's medical record.

Comment: One commenter stated that ICD–10 codes do not contain adequate specificity to indicate whether a condition is active/stable or active/non-stable. This information, according to the commenter, is needed to identify relevant comorbidities. As a result, the commenter states that SNFs may inappropriately use active/stable conditions to achieve higher reimbursement although these conditions may not indicate higher resource utilization.

Response: We do not agree with the commenter that the ICD–10 codes do not contain this degree of specificity. Further, to the extent that providers would code conditions solely for purposes of achieving higher reimbursement, this type of behavior can be identified through medical record reviews, which could prompt additional administrative action.

Comment: One commenter stated that chronic conditions may not be coded consistently year over year. Specifically, a chronic condition may be coded one year but not the following year for a long term care resident moving in and out of post-acute stays or a post-acute-care patient with more than one spell of illness. For example, the commenter noted that care may have been provided to the patient but the provider did not accurately capture it in reporting. The commenter further stated that such coding inconsistencies may lead to unexpected payment changes. The commenter recommended that CMS should clarify how chronic conditions should be reported and handled by medical reviewers as PDPM is implemented.

Response: We do not believe that any of the PDPM-related policies should affect the reporting of chronic conditions. Care should be properly documented, regardless of whether it is for a chronic or acute condition. Failure to document and code such information accurately could lead not only to payment errors, but also to patient care errors. We encourage providers to ensure the accuracy and completeness of their documentation.

Comment: Several commenters expressed concern about potential logistical issues arising from the time lag in SNFs receiving clinical information on admitted patients from the prior inpatient stay. Specifically, they state that it is difficult for SNF providers to obtain diagnosis and procedure information, as well as other clinical information such as discharge summaries, from the facility where a resident was treated during their prior inpatient stay. A commenter recommended that CMS require hospitals to provide diagnostic and procedural information within 48 hours of discharge to the receiving facility. This commenter requested that CMS clarify which medical records SNFs may rely upon to determine the principal reason for a SNF stay or which inpatient procedures were performed. The commenter questioned how SNFs should assess this information if they lack adequate documentation. Additionally, commenters stated that ICD–10–CM and ICD–10–PCS coding require a high level of clinical detail that may be difficult to obtain without clinical information from the prior inpatient stay.

Response: For case-mix classification under the PDPM, SNFs will not be required to collect any information from the hospital where the prior inpatient stay took place beyond that which is required under the current RUG–IV system, except for the procedural information discussed above. The information that SNFs already collect from hospitals should already include sufficient information for the SNF to be able to properly care plan and provide care based on the patient's condition. In order to do this effectively, SNFs should already be receiving documentation and records from the hospital that substantiate the need for care and the type of care that is required for that patient. This level of information, that is essential in developing an appropriate care plan for the patient, should be sufficient for addressing the payment requirements under PDPM. For proper classification and payment under PDPM, facilities will only be required to record the primary reason for SNF care at the time of SNF admission and record the associated ICD–10–CM code and procedural information. As discussed in Chapter 8 of the Medicare Benefit Policy Manual, a beneficiary in a Medicare Part A SNF stay must require skilled nursing care for a condition that was treated during the qualifying hospital stay, or for a condition that arose while in the SNF for treatment of a condition for which the beneficiary was previously treated in the hospital. However, CMS recognizes that in many cases, the primary reason for SNF care may not be the same as the primary reason for the prior inpatient stay. For example, a beneficiary may be treated in a SNF for a secondary condition that arose during the prior inpatient stay but that is different from the condition that precipitated the acute inpatient stay in the first place. PDPM requires facilities to code the diagnosis that corresponds most closely to the primary reason for SNF care (in this case, the secondary condition that arose during the hospital stay) rather than the primary reason for the prior hospitalization. Facilities currently must assess beneficiaries' health status and reason for SNF care at admission in order to treat them appropriately and formulate a patient-centered care plan. PDPM does not require a level of data collection that exceeds the requirements of the existing admission and care planning processes. Therefore, PDPM does not require SNFs to obtain additional clinical information from the inpatient setting, beyond the surgical procedure information discussed above.

Comment: One commenter recommended that CMS allow providers to correct the diagnosis or procedure information recorded at admission any time prior to discharge and to direct Medicare Administrative Contractors, Recovery Audit Contractors, and other contractors to assign low priority to reviewing ICD–10 codes in the medical review process.

Response: We appreciate the commenter's concern and would note that there are existing processes for modifying and correcting MDS assessments, as described in Chapter 5 of the MDS RAI manual. With regard to the comment on CMS directing contractor review activities, we see no reason to assign low priority to any issues at this time.

Comment: One commenter requested additional information about codes listed as ''Return to Provider'' in the PDPM Clinical Category Mapping. Specifically, the commenter requested that CMS provide clarity on why these codes are not accepted as valid primary diagnoses for the purposes of resident classification. Additionally, the commenter requests clarification on

what actions providers are required to take when a code is returned.

Response: As discussed above and in the proposed rule (83 FR 21043), PDPM would use ICD–10–CM diagnosis codes entered in the first line of section I8000 on the MDS assessment to assign residents to clinical categories for classification and payment purposes in three PDPM payment components (PT, OT, and SLP). Codes listed in the PDPM Clinical Category Mapping as ''Return to Provider'' are not deemed appropriate to enter as the primary reason for SNF care. Such codes either lack certainty and specificity required to properly categorize a resident under PDPM or the underlying condition cannot be the main reason of care in SNFs. Therefore, these codes cannot be used to assign a resident to a clinical category for payment purposes under PDPM. When a code is returned to a provider, the provider is to select an appropriate ICD–10–CM diagnosis code from the SNF PDPM Clinical Category Mapping available at CMS' website.

Comment: Another commenter stated that the PDPM Clinical Category Mapping file inappropriately includes ICD–10–CM codes that correspond to an initial encounter. The commenter states that initial encounter codes include ''A'' as the 7th character and can only occur in a hospital where the initial treatment is completed. According to the commenter, initial encounter codes cannot be used in the SNF setting and should be excluded from the clinical category mapping. Additionally, the commenter states that Z codes are not appropriate to assign to patients receiving aftercare for traumatic fractures. These issues, state the commenter, lead to non-traumatic major joint replacements being assigned to Major Joint Replacement while major joint replacements as a result of traumatic injury are assigned to Orthopedic Surgery (Except Major Joint Replacement or Spinal Surgery). The commenter stated that this is inappropriate because aftercare of a traumatic injury resulting in hip replacement needs higher complexity of care than a scheduled non-traumatic hip replacement.

Response: We do not agree with the commenter's assertion that initial encounter codes cannot be used in the SNF and should be excluded from the clinical category mapping. Particularly given the increased focus of some commenters on the ability of PDPM to allow alignment across different payer types, we believe it is possible that some conditions could result as an initial encounter in the SNF. Moreover, as SNF services may be covered for conditions that arise in the hospital or arise in the SNF, we believe that it is important to allow for initial encounter codes to be coded within the SNF and mapped to clinical categories in case such a condition serves as the primary diagnosis for a SNF stay.

With regard to the comment that Z codes are not appropriate for traumatic fractures, as detailed in the ICD–10–CM Official Guidelines for Coding and Reporting, the aftercare codes cover situations when the initial treatment of a disease has been performed and the patient requires continued care during the healing or recovery phase, or for the long-term consequences of the disease. The aftercare Z codes should not be used if treatment is directed at a current, acute disease. Therefore, the aftercare Z codes should not be used for aftercare for traumatic fractures. For aftercare of a traumatic fracture, providers are instructed to assign the acute fracture code with the appropriate 7th character. We agree with the commenter and will update the PDPM mapping accordingly.

Comment: Some commenters expressed concern over the use of MS–DRGs to develop the PDPM clinical categories. Commenters noted that hospital MS–DRGs are unrelated to the reason for SNF admission and are poor predictors of cost in post-acute care. These commenters stated that if SNF MDS coding produces a substantially different set of case-mix adjustments from the case-mix derived from hospital DRG assignments, then the model will produce inappropriate payment rates for the cases which deviate from the ''predicted'' case mix rate. They suggested that CMS should consider retroactively evaluating this case-mix adjustment as soon as it has SNF data following PDPM implementation to correct any inaccurate payments in future updates of the PDPM. A commenter states that PDPM will need significant recalibration due to payment inaccuracies based on the discrepancy between inpatient hospital and SNF reason for admission.

Response: We appreciate the commenters' concerns with the use of MS–DRGs to develop the PDPM clinical categories. We would note, however, that while the MS–DRGs were used to identify patient categories in the SNF, they were not used to determine the cost of treating these types of patients. Given this distinction, while we might expect some difference in the distribution of SNF case-mix based on the potential differences between the prior hospital MS–DRG and SNF-generated diagnosis information under PDPM, we do not believe that using the MS–DRGs compromised the integrity of the clinical categories themselves. In developing PDPM clinical categories, we used MS–DRGs from the prior inpatient stay to define the primary reason for SNF care and assign residents to clinical categories. As stated in section 3.4.1 of the SNF PDPM technical report, we selected this source of diagnosis information because of data quality concerns relating to the principal diagnosis from the SNF claim. At the time the clinical categories were developed, we found that 47 percent of SNF claims assigned generic ICD–9–CM codes, with roughly a third assigned V57.89 ''care involving other specified rehabilitation procedure'', as the principal diagnosis, limiting the usefulness of diagnoses from SNF claims in classifying residents. Per the Medicare Benefit Policy Manual, the SNF reason for admission must be related to a condition treated during the qualifying inpatient stay. Therefore, we believe it is reasonable to use clinical information from the prior inpatient stay to characterize the major types of beneficiaries who receive SNF care. Additionally, the clinical categories were validated by multiple clinicians consulted by CMS and participants at technical expert panels. Therefore, we believe the proposed clinical categories are appropriate to use to classify major clinical types found in the SNF setting. With regard to the possibility that the actual case-mix distribution may be distinct from the ''predicted'' case-mix distribution, we intend to monitor for these types of effects and may make adjustments to the payment rates as may be appropriate. We also appreciate the commenter's suggestion to recalibrate PDPM in the future.

Accordingly, after considering the comments received, for the reasons discussed above and in the proposed rule, we are finalizing our proposals discussed above relating to PT and OT case-mix classification under the PDPM, with the modification discussed below. As discussed above, rather than requiring providers to record the type of inpatient surgical procedure performed during the prior inpatient hospital stay by coding an ICD–10–PCS code in the second line of item I8000 as we proposed, we will instead require providers to select, as necessary, a surgical procedure category in a sub-item within Item J2000 which would identify the relevant surgical procedure that occurred during the patient's preceding hospital stay and which would augment the patient's PDPM clinical category.

(i) Clinical Categories

Once we identified these clinical categories as being generally predictive of resource utilization in a SNF, we then undertook the necessary work to identify those categories predictive of PT and OT costs specifically. As we discussed in the proposed rule (83 FR 21044), we conducted additional regression analyses to determine if any of these categories predicted similar levels of PT and OT as other categories, which may provide a basis for combining categories. As a result of this analysis, for the RCS–I model presented in the ANPRM, we found that the ten inpatient clinical categories could be collapsed into five clinical categories, which predict varying degrees of PT and OT costs. However, as explained in the proposed rule, we received comments on the ANPRM regarding the number of possible case-mix group combinations under RCS–I, so we sought to try and reduce this number of possible case-mix group combinations by further simplifying the model. As part of that effort, we observed similar PT and OT resource utilization patterns in the clinical categories of Non-Orthopedic Surgery and Acute Neurologic and, therefore, proposed to collapse these categories for the purpose of PT and OT classification. Additionally, as reflected in the RCS–I model presented in the ANPRM, we proposed that under PDPM, the remaining clinical categories would be collapsed as follows: Acute infections, cancer, pulmonary, cardiovascular and coagulations, and medical management would be collapsed into one clinical category entitled ''Medical Management'' because their residents had similar PT and OT costs. Similarly, we proposed that orthopedic surgery (except major joint replacement or spinal surgery) and non-surgical orthopedic/musculoskeletal would be collapsed into a new ''Other Orthopedic'' category for equivalent reasons. Finally, the remaining category, Major Joint Replacement, showed a distinct PT and OT cost profile and, thus, we proposed to retain it as an independent category. More information on this analysis can be found in section 3.4.2. of the SNF PMR technical report that accompanied the ANPRM and in section 3.4.2. of the SNF PDPM technical report, both available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*. These proposed collapsed categories, which would be used to categorize a resident initially under the proposed PT and OT case-mix components, were presented in Table 15 of the proposed rule (and are reflected in Table 15 of this final rule).

TABLE 15—COLLAPSED CLINICAL CATEGORIES FOR PT AND OT CLASSIFICATION

PDPM clinical category	Collapsed PT and OT clinical category
Major Joint Replacement or Spinal Surgery	Major Joint Replacement or Spinal Surgery.
Non-Orthopedic Surgery	Non-Orthopedic Surgery and Acute Neurologic.
Acute Neurologic.	
Non-Surgical Orthopedic/Musculoskeletal	Other Orthopedic.
Orthopedic Surgery (Except Major Joint Replacement or Spinal Surgery).	
Medical Management	Medical Management.
Acute Infections.	
Cancer.	
Pulmonary.	
Cardiovascular and Coagulations.	

We received several comments regarding the collapsed PT and OT clinical categories. These comments, along with our responses, appear below.

Comment: A commenter disagreed with the decision to collapse the initial 10 clinical categories into five clinical groupings for purposes of resident classification and payment in the PT and OT components. The commenter stated that the five clinical categories used for resident classification in the PT and OT components are too broad and not representative of the clinical needs of residents. Another commenter recommends that CMS not finalize the proposal to combine the Acute Neurologic and Non-Orthopedic Surgery residents into a single category because patients should be classified based on clinically coherent categories, not on similar cost patterns observed under the current SNF case-mix classification model, for the latter is reflective of current reimbursement incentives to provide therapy based on financial considerations. A commenter suggests that CMS consider separate clinical category for elective major joint replacement of the lower extremity because its cost profile is different from other episode types. The commenter suggests that joint replacements as a result of a fracture could possibly be combined into the Other Orthopedic category.

Response: As described in section 3.4.2 of the SNF PMR technical report that accompanied the 2017 ANPRM, in developing RCS–I (the predecessor to PDPM), we created 10 broad clinical categories to characterize the major patient types found in the SNF setting. In using the CART algorithm to develop resident groups for PT and OT payment, we included the 10 clinical categories as a categorical variable. Allowing the CART algorithm to group the 10 clinical categories into a smaller number of groups resulted in fewer resident groups but a similar R-squared value for predicting costs. In building PDPM we first retained these five collapsed clinical categories to characterize major patient types relevant to predicting PT and OT utilization. As detailed in the proposed rule, we then further collapsed the clinical categories into four categories, in response to comments on the ANPRM regarding the number of possible case-mix group combinations under RCS–I. Based on the greater simplicity achieved in using fewer clinical categories for PT and OT classification and the maintenance in predictive accuracy, we believe using the collapsed four categories is a superior option to capture variation in PT and OT utilization and to characterize the major types of clinical conditions relevant to PT and OT utilization in the SNF population. Non-Orthopedic Surgery and Acute Neurologic are combined into one category based on their similar PT and OT resource utilization pattern, as shown in section 3.4.2 and Table 16 of the SNF PDPM technical report. We recognize that the observed data are reflective of current reimbursement incentives to provide therapy based on financial considerations, which may disguise the relationship between

clinical traits and patient need based on best practice assumptions. We will monitor closely the resource utilization pattern of the 10 clinical categories after the implementation of PDPM. Regarding the elective major joint replacement comment, as detailed in section 3.4.1 of the SNF PMR technical report, we observed that MS–DRG groups with a high percentage of elective surgeries correspond to two types of procedures: Major joint replacements and spinal surgeries, while MS–DRG groups with a high percentage of emergent surgeries include other types of orthopedic surgeries involving extremities, often related to falls. We discovered that average therapy costs per day were similar for resident in a given surgical orthopedic MS–DRG group regardless of whether they received elective or emergent surgery.

Accordingly, after considering the comments received, for the reasons discussed above and in the proposed rule, we are finalizing our proposals without modification relating to the collapsed clinical categories for the PT and OT components.

(ii) Functional Status

As discussed previously in this section and in the proposed rule (83 FR 21044), regression analyses demonstrated that the resident's functional status is also predictive of PT and OT costs in addition to the resident's initial clinical categorization. In the RCS–I model discussed in the ANPRM, we presented a function score similar to the existing ADL score to measure functional abilities for the purposes of PT and OT payment. In response to the ANPRM, we received comments requesting that we consider replacing the functional items used to build the RCS–I function score with newer, IMPACT Act-compliant items from section GG. Therefore, we constructed, and proposed as discussed below, a new function score for PT and OT payment based on section GG functional items.

Under the RUG–IV case-mix system, a resident's ADL or function score is calculated based on a combination of self-performance and support items coded by SNFs in section G of the MDS 3.0 for four ADL areas: Transfers, eating, toileting, and bed mobility. These four areas are referred to as late-loss ADLs because they are typically the last functional abilities to be lost as a resident's function declines. Each ADL is assigned a score of up to four points, with a potential total score as high as 16 points. Under the proposed PDPM, we proposed that section G items would be replaced with functional items from section GG of the MDS 3.0 (Functional Abilities and Goals) as the basis for calculating the function score for resident classification used under PDPM. We explained that section GG offers standardized and more comprehensive measures of functional status and therapy needs. Additionally, we stated that the use of section GG items better aligns the payment model with other quality initiatives. SNFs have been collecting section GG data since October 2016 as part of the requirements for the IMPACT Act. We stated that given the advantages of section GG and of using a more comprehensive measure of functional abilities, we received numerous comments in response to the ANPRM requesting the incorporation of section GG items and of early ADLs items into the function score.

As explained in the proposed rule (83 FR 21045), multiple stakeholders commented on the ANPRM that late-loss items do not adequately reflect functional abilities on their own. These commenters stated that early-loss ADL items also capture essential clinical information on functional status. Therefore, we stated in the proposed rule that in building a new function score based on section GG items, we also investigated the incorporation of early-loss items. To explore the incorporation of section GG items, we evaluated each item's relationship with PT and OT costs. We ran individual regressions using each of the 12 section GG items assessed at admission to separately predict PT and OT costs per day. As explained in the proposed rule, the regression results showed that early-loss items are indeed strong predictors of PT and OT costs, with the exception of two wheeling items. Both wheeling items were excluded from the functional measure due to their weak predictive relationship with PT and OT costs. We observed high predictive ability among the remaining items. In total, we selected ten items for inclusion in the functional measure for the PT and OT components based on the results of the analysis. Thus, under the proposed functional measure for the PT and OT components, a resident's function would be measured using four late-loss ADL activities (bed mobility, transfer, eating, and toileting) and two early-loss ADL activities (oral hygiene and walking). Specifically, the proposed measure includes: Two bed mobility items, three transfer items, one eating item, one toileting item, one oral hygiene item, and two walking items that were all found to be highly predictive of PT and OT costs per day. A list of proposed section GG items that would be included in the functional measure for the PT and OT components was included in Table 18 of the proposed rule (and is shown in Table 18 of this final rule). Section 3.4.1. in the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*) provides more detail on these analyses.

We explained in the proposed rule (83 FR 21045) that, similar to the RUG–IV ADL score, each of these ADL areas would be assigned a score of up to 4 points. However, in contrast to the RUG–IV ADL score, we stated that points were assigned to each response level to track functional independence rather than functional dependence. In other words, higher points are assigned to higher levels of independence. We stated that this approach is consistent with functional measures in other care settings, such as the IRF PPS. Further, under the RUG–IV model, if the SNF codes that the ''activity did not occur'' or ''occurred only once,'' these items are assigned the same point value as ''independent.'' However, as explained in the proposed rule, we observed that residents who were unable to complete an activity had similar PT and OT costs as dependent residents. Therefore, we stated that when the activity cannot be completed, the equivalent section GG responses (''Resident refused,'' ''Not applicable,'' ''Not attempted due to medical condition or safety concerns'') are grouped with ''dependent'' for the purpose of point assignment. For the two walking items, we proposed an additional response level to reflect residents who skip the walking assessment due to their inability to walk. We stated that we believe this is appropriate because this allows us to assess the functional abilities of residents who cannot walk and assign them a function score. We explained that without this modification, we could not calculate a function score for residents who cannot walk because they would not be assessed on the two walking items included in the function score. We further stated that residents who are coded as unable to walk receive the same score as dependent residents to match with clinical expectations. In Tables 16 and 17 of the proposed rule (set forth at Tables 16 and 17 in this final rule), we provided the proposed scoring algorithm for the PT and OT functional measure.

TABLE 16—PT AND OT FUNCTION SCORE CONSTRUCTION

[Except walking items]

Response	Score
05, 06—Set-up assistance, Independent	4
04—Supervision or touching assistance	3
03—Partial/moderate assistance	2
02—Substantial/maximal assistance	1
01, 07, 09, 88—Dependent, Refused, N/A, Not Attempted	0

TABLE 17—PT AND OT FUNCTION SCORE CONSTRUCTION FOR WALKING ITEMS

Response	Score
05, 06—Set-up assistance, Independent	4
04—Supervision or touching assistance	3
03—Partial/moderate assistance	2
02—Substantial/maximal assistance	1
01, 07, 09, 88—Dependent, Refused, N/A, Not Attempted, Resident Cannot Walk*	0

*Coded based on response to GG0170H1 (Does the resident walk?).

We explained in the proposed rule (83 FR 21046) that, unlike section G, section GG measures functional areas with more than one item. We noted that this results in substantial overlap between the two bed mobility items, the three transfer items, and the two walking items. Because of this overlap, we stated that a simple sum of all scores for each item may inappropriately overweight functional areas measured by multiple items. Therefore, to adjust for this overlap, we proposed to calculate an average score for these related items. That is, we would average the scores for the two bed mobility items, the three transfer items, and the two walking items. We stated that the average bed mobility, transfer, and walking scores would then be summed with the scores for eating, oral hygiene, and toileting hygiene, resulting in equal weighting of the six activities. This proposed scoring algorithm produces a function score that ranges from 0 to 24. In section 3.4.1. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*), we provide additional information on the analyses that led to the construction of this proposed function score.

TABLE 18—SECTION GG ITEMS INCLUDED IN PT AND OT FUNCTIONAL MEASURE

Section GG item	Score
GG0130A1—Self-care: Eating	0–4.
GG0130B1—Self-care: Oral Hygiene	0–4.
GG0130C1—Self-care: Toileting Hygiene	0–4.
GG0170B1—Mobility: Sit to lying	0–4 (average of 2 items).
GG0170C1—Mobility: Lying to sitting on side of bed.	
GG0170D1—Mobility: Sit to stand	0–4 (average of 3 items).
GG0170E1—Mobility: Chair/bed-to-chair transfer.	
GG0170F1—Mobility: Toilet transfer.	
GG0170J1—Mobility: Walk 50 feet with 2 turns	0–4 (average of 2 items).
GG0170K1—Mobility: Walk 150 feet.	

We received comments on the use of section GG items as the basis for determining the patient's PDPM functional score for purposes of classifying under the PT and OT components. Those comments, along with our responses, appear below.

Comment: Some comments welcomed the use of IMPACT-Act compliant section GG data to build new function scores for the PT, OT, and nursing components of PDPM, which was a recommendation provided by many commenters on the ANPRM. However, commenters also expressed concern about using section GG data, stating that this data should first be validated and that the results of this validation should be made public. Commenters stated that the first year of section GG data likely contains inaccuracies as providers adjust to the new items. Some commenters therefore stated that it is inappropriate to base resident classification and payment on a single year of section GG data and request that CMS collect a minimum of two years of section GG data to ensure reliability and validity before using this data to determine payment. One commenter suggested that, due to the issues with section GG, CMS should continue to use section G as the basis for functional assessment under the payment system. Another commenter sought clarification regarding whether CMS compared the first 6 months of section GG data to the second 6 months of section GG data to determine whether there were any changes in assessment practices for the new assessment items.

Response: We conducted several investigations to validate the section GG data. First, we verified that the relationship between section G responses and PT and OT utilization was very similar to the relationship between corresponding section GG responses and PT and OT utilization. Second, we determined that section GG items performed similarly to section G items in predicting PT and OT utilization. Finally, we compared coding of section GG items during the first 6 months of FY 2017 to coding of these items during the second 6 months of FY 2017 and found only small

changes in the frequency of responses. Based on the results of these checks, we believe the FY 2017 section GG data are valid and reliable, and therefore, appropriate to use as a basis of resident classification and payment under PDPM.

Comment: One commenter stated that the proposed PDPM function scores ignore missing values for section GG assessment items and urged CMS to map missing values to a function score. Another commenter stated that the function score should incorporate the new response ''10. Not attempted due to environmental limitations''. A few commenters requested that CMS consider assigning a score of 1 to ''dependent'' responses instead of 0, stating that this scoring aligns better with the SNF Quality Reporting Program. These commenters also seek clarification on the rationale for grouping ''dependent'' responses with ''resident refused,'' ''not applicable,'' and ''not attempted due to medical conditions or safety concerns.'' One commenter pointed out that the MDS item GG0170H1 (Does the resident walk) will be retired on September 30, 2018, and recommended that CMS adopt MDS item GG0170I (Walk 10 feet) as a substitute for retired item GG0170H1.

Response: We appreciate the comment that missing values for section GG assessments items are not currently mapped to a point value for computing function score. CMS will follow this suggestion to map all values to a function score by assigning missing section GG responses to receive zero points for the function score calculation as other incomplete responses are also assigned zero points. This is also consistent with the current RUG–IV ADL scoring methodology, which assigns the same point value for missing responses and other incomplete responses. Similarly, we will map the new response of 10: ''Not attempted due to environmental limitations,'' which was highlighted by another commenter, to receive zero points for function score assignment to make sure every response has a corresponding point value. We believe these point value assignments are appropriate as they are consistent with other similar responses that receive zero points for function score assignment, including ''resident refused,'' ''not applicable,'' and ''not attempted due to medical condition or safety concerns''. In response to the comment requesting us to consider assigning 1 point to ''dependent'' responses instead of 0, this suggested scoring would group ''dependent'' responses with ''substantial/maximal assistance'' responses. However, we found that dependent residents have different levels of PT and OT resource utilization than residents receiving substantial/maximal assistance. As described in section 3.4.1 the SNF PDPM technical report, we observed that residents who were unable to complete an activity had similar PT and OT costs as dependent residents. Therefore, we grouped the equivalent section GG responses (''resident refused,'' ''not applicable,'' and ''not attempted due to medical condition or safety concerns'') with ''dependent'' responses for the purpose of point assignment in constructing the function score for PT and OT classification and payment. In terms of alignment with the SNF QRP quality measures, the PDPM function score uses similar scoring logic as the QRP functional outcome measure. As with the PDPM function score, the QRP Change in Self-Care score assigns higher points to higher levels of functional independence and assigns the same point value to ''dependent'' and incomplete responses. The QRP functional outcome measure, however, differs in scale. Whereas the PDPM function score ranges from 0–4, the QRP Change in Self-Care score ranges from 1–6. The QRP functional outcome measure assigns 1 point to ''dependent'' and all ''activity was not attempted'' codes (''resident refused,'' ''not applicable,'' and ''not attempted due to medical condition or safety concerns''), and 2 points to ''substantial/maximal assistance''. This score assignment is very similar to that of the PDPM function score. Additionally, one item currently used to compute function score, MDS GG0170H1 (Does the resident walk), which is used to determine if the resident can walk before proceeding to assess GG0170J1 (Walk 50 Feet with Two Turns) and GG0170K1 (Walk 150 Feet), is set to be retired on September 30, 2018 with the introduction of the newer, more detailed SNF QRP mobility and self-care outcome measure items. CMS concurs with the commenter's suggestion to select a replacement for PDPM implementation. Consistent with the commenter's suggestion, MDS item GG0170I1 (Walk 10 feet) will be used as the substitute for MDS GG0170H1 since the inability to walk at least 10 feet or to complete the assessment for this item suggests a significant mobility impairment that is essentially equivalent to the definition of the retired ''cannot walk'' MDS item. Responses 07: ''resident refused,'' 09: ''not applicable,'' 10: ''not attempted due to environmental limitations,'' or 88: ''not attempted due to medical condition or safety concerns'' from MDS item GG0170I1 will be used to identify residents who cannot walk.

Comment: Commenters also stated that the proposed function scores should be updated to reflect new section GG items for FY 2019. Specifically, they stated that toileting, dressing, and bathing are important activities of daily living that are addressed by occupational therapy, and therefore, should be considered in measuring residents' functional status under PDPM.

Response: In constructing the function score for PT and OT payment, we investigated the use of all existing section GG items. Toileting is one of the items included in the proposed function scores for the PT, OT, and nursing components of PDPM. We are aware that additional section GG items are scheduled to be implemented in FY 2019, including items that measure a resident's dressing and bathing abilities. However, because these new items have not yet been implemented, there is no data available on resource utilization associated with these items. Therefore, it is not appropriate to include these items in the calculation of the PDPM function scores at this time. We will consider adding section GG items that are demonstrated to have a meaningful relationship with utilization of SNF resources as new items are added and an appropriate amount of data (for example, one year) is available to assess this relationship. We will also consider other changes to the function score as necessary to reflect additional updates to the section GG items, for example, the addition, deletion, or modification of particular items or responses.

Comment: One commenter advised CMS to account for weight bearing restrictions among residents who are categorized into the Major Joint Replacement or Spinal Surgery or Other Orthopedic clinical categories. The commenter stated that patients who cannot bear weight have a more complicated post-surgical recovery.

Response: We appreciate the concern of the commenter regarding post-surgical residents who cannot bear weight. However, we believe the ability of a resident to bear weight is adequately captured by the mobility items in MDS item GG0170, which are included in the function score used for classification and payment in the PT and OT components. Therefore, we do not believe additional modifications are necessary at this time.

Comment: One commenter noted that in some cases, PT and OT payment is higher for case-mix groups with higher

functional independence. The commenter said this is counterintuitive because it implies that some residents who are more dependent require less therapy. Another commenter sought clarification on the relationship between function score and average PT and OT costs per day.

Response: The commenter is correct that in some cases payment is higher for residents who have higher levels of functional independence. This reflects the finding that PT and OT utilization is highest for residents with moderate functional independence and lower for residents with both the highest levels of functional dependence and independence. In the first case, this likely reflects residents whose functional abilities are too impaired to receive intensive therapy, while the second case likely corresponds to residents who require less therapy because they already have a high level of functional independence. Therefore, we believe PDPM appropriately assigns payment according to the observed relationship between functional independence and PT/OT utilization.

Comment: One commenter expressed concern regarding the potential for gaming the function score and recommended that CMS remove the function score from use as a patient classifier.

Response: We appreciate this concern for gaming of the function score and plan to monitor closely for any changes in functional coding before and after implementation of PDPM. That being said, we do believe that a patient's functional score is relevant in terms of predicting payment accurately, as described elsewhere in this section. Therefore, we believe it is important to keep function as an aspect of patient classification for payment.

Accordingly, after considering the comments received, for the reasons discussed in the proposed rule and in this final rule, we are finalizing our proposals relating to the use of the section GG items as the basis for determining the patient's PDPM functional score and for classifying the patient under PDPM PT and OT components, with modifications. As discussed above, in response to comments, all missing values for section GG assessment items will receive zero points as a function score. Similarly, the function score will incorporate a new response ''10. Not attempted due to environmental limitations'' and we will assign it a point value of zero. Furthermore, consistent with a commenter's suggestion, we will adopt MDS item GG0170I1 (Walk 10 feet) as a substitute for retired item GG0170H1 (Does the resident walk), and we will use responses 07: ''resident refused,'' 09: ''not applicable,'' 10: ''not attempted due to environmental limitations,'' or 88: ''not attempted due to medical condition or safety concerns'' from MDS item GG0170I1 to identify residents who cannot walk.

(iii) Cognitive Status

Under the RCS–I case-mix model presented in the ANPRM, we used cognitive status to classify residents under the PT and OT components in addition to the primary reason for SNF care and functional ability. As explained in the proposed rule (83 FR 21046) and in greater detail below, after publication of the ANPRM, we removed cognitive status as a determinant of resident classification for the PT and OT components. Still, although cognitive status was not ultimately selected as a determinant of PT and OT classification, it was considered as a possible element in developing the proposed resident groups for these components via the Classification and Regression Trees (CART) algorithm described in greater detail in the proposed rule and below. Because we included cognitive status as an independent variable in the CART analysis used to develop case-mix groups for PT and OT, we stated that we believed it was appropriate to discuss construction of the proposed new cognitive measure here even though it was not ultimately selected as a determinant of payment for PT and OT. Thus, we discussed construction of the instrument used to measure cognitive status under the proposed PDPM in the section addressing case-mix classification under the PT and OT components, rather than introducing it when discussing SLP classification, in which we proposed cognitive status as a determinant of resident classification. Under the current SNF PPS, cognitive status is used to classify a small portion of residents that fall into the Behavioral Symptoms and Cognitive Performance RUG–IV category. For all other residents, cognitive status is not used in determining the appropriate payment for a resident's care. However, as we explained in the proposed rule, industry representatives and clinicians at multiple TEPs suggested that a resident's cognitive status can have a significant impact on a resident's PT and OT costs. Based on this feedback, we explored a resident's cognitive status as a predictor of PT and OT costs.

Under the RUG–IV model, cognitive status is assessed using the Brief Interview for Mental Status (BIMS) on the MDS 3.0. The BIMS is based on three items: ''repetition of three words,'' ''temporal orientation,'' and ''recall.'' These items are summed to produce the BIMS summary score. The BIMS score ranges from 0 to 15, with 0 assigned to residents with the worst cognitive performance and 15 assigned to residents with the highest performance. Residents with a BIMS score less than or equal to 9 classify for the Behavioral Symptoms and Cognitive Performance category. Residents with a summary score greater than 9 but not 99 (resident interview was not successful) are considered cognitively intact for the purpose of classification under RUG–IV.

As we explained in the proposed rule (83 FR 21046), in approximately 15 percent of 5-day MDS assessments, the BIMS is not completed: in 12 percent of cases the interview is not attempted, and for 3 percent of cases the interview is attempted but cannot be completed. The MDS directs assessors to skip the BIMS if the resident is rarely or never understood (this is scored as ''skipped''). In these cases, the MDS requires assessors to complete the Staff Assessment for Mental Status (items C0700 through C1000). The Cognitive Performance Scale (CPS) is then used to assess cognitive function based on the Staff Assessment for Mental Status and other MDS items (''Comatose'' (B0100), ''Makes Self Understood'' (B0700), and the self-performance items of the four late-loss ADLs). The Staff Assessment for Mental Status consists of four items: ''Short-term Memory OK,'' ''Long-term Memory OK,'' ''Memory/Recall Ability,'' and ''Cognitive Skills for Daily Decision Making.'' Only ''Short-term Memory OK'' and ''Cognitive Skills for Daily Decision Making'' are currently used for payment. In MDS 2.0, the CPS was used as the sole measure of cognitive status. A resident was assigned a CPS score from 0 to 6 based on the Staff Assessment for Mental Status and other MDS items, with 0 indicating the resident was cognitively intact and 6 indicating the highest level of cognitive impairment. In addition to the items on the Staff Assessment for Mental Status, MDS items ''Comatose'' (B0100), ''Makes Self Understood'' (B0700), and the self-performance items of the four late-loss ADLs factored into the CPS score. Any score of 3 or above was considered cognitively impaired. The CPS on the current version of the MDS (3.0) functions very similarly. Instead of assigning a score to each resident, a resident is determined to be cognitively impaired if he or she meets the criteria to receive a score of 3 or above on the CPS, based on the MDS items mentioned above. In other words, whereas the MDS 2.0 assigned a CPS

score to each resident, the MDS 3.0 only determines whether a resident's score is greater than or equal to 3 and does not assign a specific score to each resident for whom the CPS is used to assess cognitive status. Residents who are determined to be cognitively impaired based on the CPS are classified in the Behavioral Symptoms and Cognitive Performance category under RUG–IV, if they do not meet the criteria for a higher-paying category.

We stated in the proposed rule (83 FR 21047) that given that the 15 percent of residents who are not assessed on the BIMS must be assessed using a different scale that relies on a different set of MDS items, there is currently no single measure of cognitive status that allows comparison across all residents. To address this issue, Thomas et al., in a 2015 paper, proposed use of a new cognitive measure, the Cognitive Function Scale (CFS), which combines scores from the BIMS and CPS into one scale that can be used to compare cognitive function across all residents (Thomas KS, Dosa D, Wysocki A, Mor V; *The Minimum Data Set 3.0 Cognitive Function Scale.* Med Care. *https://www.ncbi.nlm.nih.gov/pubmed/?term=25763665*). Following a suggestion from the June 2016 TEP, we explored using the CFS as a measure of cognition and found that there is a relationship between the different levels of the cognitive scale and resident costs. Specifically, we observed that as cognitive function declines, PT and OT costs per day decrease, while SLP costs per day more than double. More information on this analysis can be found in section 3.4.1. of the SNF PMR technical report that accompanied the ANPRM available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*. Based on these initial investigations, we used the CFS as a cognitive measure in the RCS–I payment model described in the ANPRM. As we noted above, the RUG–IV system incorporates both the BIMS and CPS score separately, but the CFS blends them together into one measure of cognitive status. Details on how the BIMS score and CPS score are determined using the MDS assessment are described above. The CFS uses these scores to place residents into one of four cognitive performance categories, as shown in Table 19 of the proposed rule (set forth in Table 19 of this final rule). After publication of the ANPRM, we received stakeholder comments questioning this scoring methodology, specifically the classification of a CPS score of 0 as ''mildly impaired.'' Based on a subsequent analysis showing that residents with a CPS score of 0 were similar to residents classified as ''cognitively intact'' under the CFS methodology, as well as clinical feedback, we determined that it was appropriate to reclassify residents with a CPS score of 0 as cognitively intact, consistent with ANPRM feedback. This analysis is described in more detail in section 3.4.1. of the SNF PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*. The scoring methodology for the proposed PDPM cognitive measure was shown in Table 20 of the proposed rule (set forth in Table 20 of this final rule). We would note once again that while we discussed this scoring methodology in section V.D.3.b of the proposed rule (83 FR 21046 through 21047) and this section of the final rule because cognitive status was considered in developing the PT and OT classification, the cognitive score was not proposed as a factor in classification for the PT and OT components under PDPM, as further discussed in the proposed rule (83 FR 21047) and below.

TABLE 19—COGNITIVE FUNCTION SCALE (CFS) SCORING METHODOLOGY

Cognitive level	BIMS score	CPS score
Cognitively Intact	13–15	.....
Mildly Impaired	8–12	0–2
Moderately Impaired	0–7	3–4
Severely Impaired	.....	5–6

TABLE 20—PDPM COGNITIVE MEASURE CLASSIFICATION METHODOLOGY

Cognitive level	BIMS score	CPS score
Cognitively Intact	13–15	0
Mildly Impaired	8–12	1–2
Moderately Impaired	0–7	3–4
Severely Impaired	.....	5–6

(iv) PT and OT Case-Mix Groups

As explained in the proposed rule (83 FR 21047), once each of these variables—clinical reasons for the SNF stay, the resident's functional status, and the presence of a cognitive impairment—was identified, we then used a statistical regression technique called Classification and Regression Trees (CART) to explore the most appropriate splits in PT and OT case-mix groups using these three variables. In other words, CART was used to investigate how many PT and OT case-mix groups should exist under the proposed PDPM and what types of residents or score ranges should be combined to form each of those PT and OT case-mix groups. CART is a non-parametric decision tree learning technique that produces either classification or regression trees, depending on whether the dependent variable is categorical or numeric, respectively. We stated that using the CART technique to create payment groups is advantageous because it is resistant to both outliers and irrelevant parameters. The CART algorithm has been used to create payment groups in other Medicare settings. For example, it was used to determine Case Mix Groups (CMGs) splits within rehabilitation impairment groups (RICs) when the inpatient rehabilitation facility (IRF) PPS was developed. This methodology is more thoroughly explained in section 3.4.2. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*).

As explained in the proposed rule (83 FR 21047), we used CART to develop splits within the four collapsed clinical categories shown in Table 15 of the proposed rule (set forth in Table 15 of

this final rule). Splits within each of these four collapsed clinical categories were based on the two independent variables included in the algorithm: Function score and cognitive status. The CART algorithm split residents into 18 groups for the PT component and 14 groups for the OT component. These splits are primarily based on differences in resident function. As stated in the proposed rule, in the CART-generated groups, cognitive status plays a role in categorizing less than half of the PT groups and only two of the 14 OT groups. In addition, we stated that to create the proposed resident classification for the PT and OT components, we made certain administrative decisions that further refined the PT and OT case-mix classification groups beyond those produced through use of the CART algorithm. For example, while CART may have created slightly different breakpoints for the function score in different clinical categories, we state that we believe using a consistent split in scores across clinical categories improves the simplicity of the case-mix model without compromising its accuracy. Therefore, we used the splits created by the CART algorithm as the basis for the consistent splits selected for the case-mix groups, simplifying the CART output while retaining important features of the CART-generated splits. In our proposed classification for the PT and OT components, we retained function as the sole determinant of resident categorization within each of the four collapsed clinical categories. We created function score bins based on breakpoints that recurred in the CART splits, such as 5, 9, and 23. As noted in the proposed rule (83 FR 21048) and above, we dropped cognitive status as a determinant of classification because of the reduced role it played in categorizing residents within the CART-generated groups. Finally, we used the same function score bins to categorize residents within each of the four collapsed clinical categories for both the PT and OT components. As shown in section 3.4.2. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.htm*), and as explained in the proposed rule, using the proposed case-mix groups for the PT and OT components results in a reduction of 0.005 in the R-squared values for both PT and OT classification models. We stated that this shows that although the proposed case-mix groups improve simplicity by removing one predictor revealed to be less important in categorizing residents (cognitive status) and grouping residents similarly (using the same function score bins) across clinical categories, these decisions have only a minor negative impact on predictive accuracy. These analyses are described in further detail in section 3.4.2. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*).

Based on the CART results and the administrative decisions described above, we proposed 16 case-mix groups to classify residents for PT and OT payment. We noted in the proposed rule (83 FR 21048) that this represents a marked reduction in the number of case-mix groups for PT and OT classification under the RCS–I model discussed in the ANPRM. As discussed in the proposed rule and throughout the sections above, after publication of the ANPRM, we received feedback from stakeholders that the RCS–I payment model was overly complex. In particular, commenters expressed concern about the relatively large number of possible combinations of case-mix groups. Based on this feedback, we sought to reduce the number of resident groups in the PT and OT components. First, as discussed in the proposed rule and in this final rule, because we observed similar PT and OT resource utilization patterns in the clinical categories of Non-Orthopedic Surgery and Acute Neurologic, we decided to collapse these categories for the purpose of PT and OT classification. In addition, as discussed in the proposed rule and in this final rule, we replaced the section G-based functional measure from RCS–I with a new functional measure based on section GG items. We found that the inclusion of the section GG-based functional measure in the CART algorithm resulted in case-mix groups in which cognitive function played a less important role in classification. Based on these results, we determined that we could remove cognitive function as a determinant of PT and OT classification without a notable loss in the predictive ability of the payment model, as discussed above. We also consulted with clinicians who advised CMS during development of PDPM, who confirmed the appropriateness of this decision. We stated in the proposed rule that the decisions to collapse Non-Orthopedic Surgery and Acute Neurologic into one clinical category and remove cognitive status resulted in a large reduction in the number of PT and OT case-mix groups, from the 30 in RCS–I to the 16 in the proposed PDPM provided in Table 21 of the proposed rule (and set forth in Table 21 of this final rule). We provided the criteria for each of these groups along with its CMI for both the PT and OT components in Table 21. As shown in Table 21, two factors would be used to classify each resident for PT and OT payment: Clinical category and function score. Each case-mix group corresponds to one clinical category and one function score range. We proposed classifying each SNF resident into one of the 16 groups shown in Table 21 based on these two factors.

To help ensure that payment reflects the average relative resource use at the per diem level, we stated in the proposed rule (83 FR 21048) that CMIs would be set to reflect relative case-mix related differences in costs across groups. We stated that this method helps ensure that the share of payment for each case-mix group would be equal to its share of total costs of the component. We further explained that CMIs for the PT and OT components were calculated based on two factors. One factor was the average per diem costs of a case-mix group relative to the population average. The other factor was the average variable per diem adjustment factor of the group relative to the population average. In this calculation, average per diem costs equaled total PT or OT costs in the group divided by number of utilization days in the group. Similarly, the average variable per diem adjustment factor equaled the sum of variable per diem adjustment factors corresponding to a given component (PT or OT) for all utilization days in the group divided by the number of utilization days in the group. We calculated CMIs such that they equal the ratio of relative average per diem costs for a group to the relative average variable per diem adjustment factor for the group. In this calculation, relative average per diem costs and the relative average variable per diem adjustment factor were weighted by length of stay to account for the different length of stay distributions across case-mix groups (as further discussed in section 3.11.1. of the SNF PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*). The relative average variable per diem adjustment factors for a given PT group and the corresponding OT group were the same because residents were classified into the same case-mix group under both components. However, relative average per diem costs were different across the two corresponding

PT and OT groups, therefore the resulting CMIs calculated for each group were different, as shown in Table 21. After calculating CMIs as described above, we then applied adjustments to help ensure that the distribution of resources across payment components is aligned with the statutory base rates. We stated that the base rates implicitly allocate resources to case-mix components in proportion to the relative magnitude of the respective component base rates. For example, if the base rate for one component were twice as large as the base rate for another component, this would imply that the component with the larger base rate should receive double the resources of the other component. To ensure that the distribution of resources across payment components was aligned with the statutory base rates, in the proposed rule, we set CMIs such that the average product of the CMI and the variable per diem adjustment factor for a day of care equals 1.0 for each of the five case-mix-adjusted components in PDPM. If the average product of the CMI and the variable per diem adjustment factor for a day of care were different across case-mix components, this would result in allocating resources in a manner inconsistent with the distribution of resources implied by the statutory base rates.

After adjusting the CMIs to align the distribution of resources across payment components with the statutory base rates, a parity adjustment was then applied by multiplying the CMIs by the ratio of case-mix-related payments in RUG–IV over estimated case-mix-related payments in PDPM, as further discussed in section V.J. of the proposed rule. More information on the variable per diem adjustment factors is discussed in section V.D.4. of the proposed rule. The full methodology used to develop CMIs is presented in section 3.11. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*).

TABLE 21—PT AND OT CASE-MIX CLASSIFICATION GROUPS

Clinical category	Section GG function score	PT OT case-mix group	PT case-mix index	OT case-mix index
Major Joint Replacement or Spinal Surgery	0–5	TA	1.53	1.49
Major Joint Replacement or Spinal Surgery	6–9	TB	1.69	1.63
Major Joint Replacement or Spinal Surgery	10–23	TC	1.88	1.68
Major Joint Replacement or Spinal Surgery	24	TD	1.92	1.53
Other Orthopedic	0–5	TE	1.42	1.41
Other Orthopedic	6–9	TF	1.61	1.59
Other Orthopedic	10–23	TG	1.67	1.64
Other Orthopedic	24	TH	1.16	1.15
Medical Management	0–5	TI	1.13	1.17
Medical Management	6–9	TJ	1.42	1.44
Medical Management	10–23	TK	1.52	1.54
Medical Management	24	TL	1.09	1.11
Non-Orthopedic Surgery and Acute Neurologic	0–5	TM	1.27	1.30
Non-Orthopedic Surgery and Acute Neurologic	6–9	TN	1.48	1.49
Non-Orthopedic Surgery and Acute Neurologic	10–23	TO	1.55	1.55
Non-Orthopedic Surgery and Acute Neurologic	24	TP	1.08	1.09

We stated in the proposed rule that, under the proposed PDPM, all residents would be classified into one and only one of these 16 PT and OT case-mix groups for each of the two components. We explained that as opposed to the RUG–IV system that determines therapy payments based only on the amount of therapy provided, these groups classify residents based on the two resident characteristics shown to be most predictive of PT and OT utilization: Clinical category and function score. Thus, we believe that the PT and OT case-mix groups better reflect relative resource use of clinically relevant resident subpopulations, and therefore, provide for more appropriate payment under the SNF PPS.

Commenters submitted the following additional comments related to the proposed rule's discussion of the Physical and Occupational Therapy Case-Mix Classification. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters expressed concern that CMS did not include cognition or swallowing disorders as determinants of payment for the OT component. One commenter stated that the removal of cognitive status as a determinant of PT and OT payment will lead to underpayment because cognitive impairment leads to longer recovery time and an increased need for therapy services, particularly occupational therapy.

Response: As discussed in the proposed rule (83 FR 21046) and in section 3.4.2 of the SNF PDPM technical report, cognitive status was initially considered as a determinant of resident classification and payment in the PT and OT components of PDPM. However, after replacing the section G-based function score for PT and OT classification with a function score based on new, IMPACT Act-compliant section GG items, we reran the CART analysis used to develop possible case-mix groups. We found that after including the section GG-based function score, cognitive status played a minimal role in resident classification. As noted in the proposed rule (83 FR 21047), cognition played a role in categorizing less than half of the 18 CART-generated PT groups and only two of the 14 CART-generated OT groups. Based on the reduced role of cognition in resident classification for PT and OT payment, we decided to remove cognitive status as a determinant of payment for these components. This decision also allowed us to substantially reduce the number of case-mix groups for the PT and OT components from the 30 presented in the 2017 ANPRM to the 16 presented in the proposed rule, contributing to a simplification of the payment model, which was requested by a number of commenters responding to the ANPRM. We also confirmed that the decision to remove cognitive status as a determinant of PT and OT classification had only a minor negative impact on predictive accuracy, reducing the R-squared values of the both the PT and OT classification models by only 0.005.

Comment: One commenter expressed concern about the reliability of the cognitive measure used in PDPM.

Response: As detailed in section 3.4.1 of the SNF PDPM technical report, the PDPM cognitive measure was built based on two existing cognitive measures: The Brief Interview for Mental Status (BIMS) and the Cognitive Performance Scale (CPS). Both measures are used in the current RUG–IV system to determine cognitive impairment. BIMS is used when the resident is able to complete the interview, while CPS is used when the resident is unable to complete the interview and the staff assessment has to be conducted. Thus, the PDPM cognitive measure is based on cognitive measures that have been validated and used for years. It combines the existing scores from BIMS and CPS into one scale that can be used to compare cognitive function across all residents.

Comment: Some commenters stated that CMS should consider including comorbidities related to PT or OT utilization, in particular conditions associated with high therapy intensity or duration. Commenters stated coronary artery disease, congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), asthma, chronic wounds, depression, swallowing disorders and multiple sclerosis are conditions that could be considered as possible comorbidities for the PT or OT components.

Response: As described in section 3.4.1 of the SNF PDPM technical report, we investigated the impact of a broad list of conditions on PT and OT utilization. These conditions were selected for investigation based on comments received in response to the 2017 ANPRM, clinical input, and a literature search. This broad list included several of the conditions mentioned by commenters, including congestive heart failure, diabetes, depression, and swallowing disorders. To focus on conditions that have non-negligible impact on increasing costs, only those that had a positive impact on PT or OT costs per day of $2 or more were selected for further investigation. None of the conditions mentioned by commenters that were included in this investigation (congestive heart failure, diabetes, depression, swallowing disorders, and multiple sclerosis) met this criterion; therefore, they were not selected for inclusion in the payment model. Additionally, as mentioned in section 3.4.1 of the SNF PDPM technical report, we investigated the impact of an even broader range of MDS items, diagnosis-related groups (DRGs), and hierarchical condition categories (HCCs) on PT and OT utilization. Among the conditions included in this analysis were coronary artery disease, COPD, asthma, and various types of wounds/wound care including wound infection, surgical wounds, and surgical wound care. Based on this analysis, we determined that all of these conditions had either a small or statistically insignificant impact on PT costs per day and OT costs per day. As previously stated, because the current system is heavily based on service provision and most residents are classified into the Ultra-High therapy category, there is currently little variance available in PT and OT costs per day to be explained by the presence of comorbidities. For the foregoing reasons, we do not believe it is appropriate to include the conditions mentioned by commenters as comorbidities for PT or OT payment at this time. However, as care practices change over time, we may consider adding comorbidities that have a strong impact on PT or OT utilization.

Comment: Many commenters supported the proposed separation of the PT and OT components, as compared to the RCS–I model that combined these components into a single component. One commenter questioned if therapy would be covered for pain management and wound care treatments as these types of treatments are not explicitly covered under the clinical categories.

Response: We appreciate the support for the decision to separate the PT and OT components. With regard to the question of therapy coverage for certain conditions, we would note that neither the clinical categories, nor any other aspects of PDPM implementation, should be taken to change any coverage guidelines.

Accordingly, after considering the comments received, for the reasons discussed in the proposed rule and in the final rule, we are finalizing the proposed PT and OT components under the PDPM and our proposals relating to the methodology for classifying residents under the PT and OT components, effective October 1, 2019, with the modifications discussed in this section. As discussed above, in response to comments, rather than requiring providers to record the type of inpatient surgical procedure performed during the prior inpatient hospital stay by coding an ICD–10–PCS code in the second line of item I8000 as we proposed, we will instead require providers to select, as necessary, a surgical procedure category in a sub-item within Item J2000 which would identify the relevant surgical procedure that occurred during the patient's preceding hospital stay and which would augment the patient's PDPM clinical category. For purposes of calculating the function score, all missing values for section GG assessment items will receive zero points. Similarly, the function score will incorporate a new response ''10. Not attempted due to environmental limitations'' and we will assign it a point value of zero. Furthermore, consistent with a commenter's suggestion, we will adopt MDS item GG0170I1 (Walk 10 feet) as a substitute for retired item GG0170H1 (Does the resident walk), and we will use responses 07: ''resident refused,'' 09: ''not applicable,'' 10: ''not attempted due to environmental limitations,'' or 88: ''not attempted due to medical condition or safety concerns'' from MDS item GG0170I1 to identify residents who cannot walk.

c. Speech-Language Pathology Case-Mix Classification

As discussed above and in the proposed rule (83 FR 21049), many of the resident characteristics that we found to be predictive of increased PT and OT costs were predictive of lower SLP costs. We stated that as a result of this inverse relationship, using the same set of predictors to case-mix adjust all three therapy components would obscure important differences in variables predicting variation in costs across therapy disciplines and make any model that attempts to predict total therapy costs inherently less accurate. Therefore, we stated that we believe it is appropriate to have a separately adjusted case-mix SLP component that is specifically designed to predict relative differences in SLP costs. As discussed in the proposed rule and in the prior section of this final rule, costs derived from the charges on claims and CCRs on facility cost reports were used as the measure of resource use to develop an alternative payment model. Costs are reflective of therapy utilization as they are correlated to therapy minutes recorded for each therapy discipline.

Following the same methodology we used to identify predictors of PT and OT costs, we explained in the proposed rule that our project team conducted cost regressions with a host of variables from the MDS assessment, prior inpatient claims, and SNF claims that were identified as likely to be predictive of relative increases in SLP costs. The variables were selected with the goal of being as inclusive of the measures recorded on the MDS assessment as possible and also included diagnostic information from the prior inpatient stay. The selection process also incorporated clinical input from TEP panelists, the contractor's clinical staff, and CMS clinical staff. We stated that

these initial costs regressions were exploratory and meant to identify a broad set of resident characteristics that are predictive of SLP resource utilization. The results were used to inform which variables should be investigated further and ultimately included in the payment system. A table of all of the variables considered in this analysis appears in the appendix of the SNF PMR technical report that accompanied the ANPRM (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*).

As we stated in the proposed rule (83 FR 21049), based on these cost regressions, we identified a set of three categories of predictors relevant in predicting relative differences in SLP costs: Clinical reasons for the SNF stay, presence of a swallowing disorder or mechanically-altered diet, and the presence of an SLP-related comorbidity or cognitive impairment. We explained that a model using these predictors to predict SLP costs per day accounted for 14.5 percent of the variation in SLP costs per day, while a very extensive model using 1,016 resident characteristics only predicted 19.3 percent of the variation. We stated that this shows that these predictors alone explain a large share of the variation in SLP costs per day that can be explained with resident characteristics.

As with the proposed PT and OT components, we began with the set of clinical categories identified in Table 14 of the proposed rule (set forth in Table 14 of this final rule) meant to capture general differences in resident resource utilization and ran cost regressions to determine which categories may be predictive of generally higher relative SLP costs. Through this analysis, we found that one clinical category, the Acute Neurologic group, was particularly predictive of increased SLP costs. More detail on this investigation can be found in section 3.5.2. of the SNF PMR technical report that accompanied the ANPRM, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*. Therefore, to determine the initial resident classification into an SLP group under the proposed PDPM, we stated that residents would first be categorized into one of two groups using the clinical reasons for the resident's SNF stay recorded on the first line of Item I8000 on the MDS assessment: Either the ''Acute Neurologic'' clinical category or a ''Non-Neurologic'' group that includes the remaining clinical categories in Table 14 (Major Joint Replacement or Spinal Surgery; Non-Surgical Orthopedic/Musculoskeletal; Orthopedic Surgery (Except Major Joint Replacement or Spinal Surgery); Acute Infections; Cancer; Pulmonary; Non-Orthopedic Surgery; Cardiovascular and Coagulations; and Medical Management).

In addition to the clinical reason for the SNF stay, based on cost regressions and feedback from TEP panelists, we stated in the proposed rule (83 FR 21050) that we also identified the presence of a swallowing disorder or a mechanically-altered diet (which refers to food that has been altered to make it easier for the resident to chew and swallow to address a specific resident need) as a predictor of relative increases in SLP costs. First, we stated that residents who exhibited the signs and symptoms of a swallowing disorder, as identified using K0100Z on the MDS 3.0, demonstrated significantly higher SLP costs than those who did not exhibit such signs and symptoms. Therefore, we considered including the presence of a swallowing disorder as a component in predicting SLP costs. However, when this information was presented during the October 2016 TEP, stakeholders indicated that the signs and symptoms of a swallowing disorder may not be as readily observed when a resident is on a mechanically-altered diet and requested that we also consider evaluating the presence of a mechanically-altered diet, as determined by item K0510C2 on the MDS 3.0, as an additional predictor of increased SLP costs. As we further explained in the proposed rule, our project team conducted this analysis and found that there was an associated increase in SLP costs when a mechanically-altered diet was present. Moreover, we stated that this analysis revealed that while SLP costs may increase when either a swallowing disorder or mechanically-altered diet is present, resident SLP costs increased even more when both of these items were present. More detail on this investigation and these analyses can be found in section 3.5.3. of the SNF PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*. As a result, we agreed with the stakeholders that both swallowing disorder and mechanically-altered diet are important components of predicting relative increases in resident SLP costs, and thus, in addition to the clinical categorization, we proposed classifying residents as having either a swallowing disorder, being on a mechanically altered diet, both, or neither for the purpose of classifying the resident under the SLP component. We also noted that we plan to monitor specifically for any increases in the use of mechanically altered diet among the SNF population that may suggest that beneficiaries are being prescribed such a diet based on facility financial considerations, rather than for clinical need.

As a final aspect of the proposed SLP component case-mix adjustment, we explored how SLP costs vary according to cognitive status and the presence of an SLP-related comorbidity. As we explained in the proposed rule, we observed that SLP costs were notably higher for residents who had a mild to severe cognitive impairment as defined by the PDPM cognitive measure methodology described in Table 20 of the proposed rule (set forth in Table 20 of this final rule) or who had an SLP-related comorbidity present. We stated that for each condition or service included as an SLP-related comorbidity, the presence of the condition or service was associated with at least a 43 percent increase in average SLP costs per day. The presence of a mild to severe cognitive impairment was associated with at least a 100 percent increase in average SLP costs per day. Similar to the analysis conducted in relation to the PT and OT components, the project team ran cost regressions on a broad list of possible conditions. As we stated in the proposed rule (83 FR 21050), based on that analysis, and in consultation with stakeholders during our TEPs and clinicians, we identified the conditions listed in Table 22 of the proposed rule (set forth in Table 22 of this final rule) as SLP-related comorbidities which we believe best predict relative differences in SLP costs. As discussed in the proposed rule, we used diagnosis codes on the most recent inpatient claim and the first SNF claim, as well as MDS items on the 5-day assessment for each SNF stay to identify these diagnoses and found that residents with these conditions had much higher SLP costs per day. Further, we stated that rather than accounting for each SLP-related comorbidity separately, all conditions were combined into a single flag. If the resident has at least one SLP-related comorbidity, the combined flag is turned on. We explained in the proposed rule that we combined all SLP-related comorbidities into a single flag because we found that the predictive ability of including a combined SLP comorbidity flag is comparable to the predictive ability of including each SLP-related comorbidity as an individual predictor. Additionally, we stated that using a combined SLP-

related comorbidity flag greatly improves the simplicity of the payment model. More detail on these analyses can be found in section 3.5.1. of the SNF PMR technical report that accompanied the ANPRM (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*).

TABLE 22—SLP-RELATED COMORBIDITIES

Aphasia.
CVA, TIA, or Stroke.
Hemiplegia or Hemiparesis.
Traumatic Brain Injury.
Tracheostomy Care (While a Resident).
Ventilator or Respirator (While a Resident).
Laryngeal Cancer.
Apraxia.
Dysphagia.
ALS.
Oral Cancers.
Speech and Language Deficits.

Once each of these variables—clinical reasons for the SNF stay, presence of a swallowing disorder or mechanically-altered diet, and the presence of an SLP-related comorbidity or cognitive impairment—found to be useful in predicting resident SLP costs was identified, as we discussed in the proposed rule (83 FR 21050), we used the CART algorithm, as we discussed above in relation to the PT and OT components, to determine appropriate splits in SLP case-mix groups based on CART output breakpoints using these three variables. We stated we then further refined the SLP case-mix classification groups beyond those produced by the CART algorithm. We used consistent criteria to group residents into 18 payment groups across the two clinical categories determined to be relevant to SLP utilization (Acute Neurologic and Non-Neurologic). These groups simplified the SLP case-mix classification by reducing the number of groups while maintaining the CART predictive power in terms of R-squared. This methodology and the results of our analysis are more thoroughly explained in sections 3.4.2. and 3.5.2. of the SNF PMR technical report that accompanied the ANPRM (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*).

Under the original RCS–I SLP component, a resident could be classified into one of 18 possible case-mix groups. Comments received in response to the ANPRM expressed concern over the complexity of the payment model due to the high number of possible combinations of case-mix groups. We stated in the proposed rule (83 FR 21051) that, to reduce the number of possible SLP case-mix groups, we simplified the consistent splits model selected for RCS–I. To accomplish this, we combined clinical category (Acute Neurologic or Non-Neurologic), cognitive impairment, and the presence of an SLP-related comorbidity into a single predictor due to the clinical relationship between acute neurologic conditions, cognition, and SLP comorbidities. We explained in the proposed rule that these three predictors are highly interrelated as acute neurologic conditions may often result in cognitive impairment or SLP-related comorbidities such as speech and language deficits. As we discussed in the proposed rule, using this combined variable along with presence of a swallowing disorder or mechanically-altered diet results in 12 groups. We compared the predictive ability of the simplified model with more complex classification options, including the original RCS–I SLP model. We explained that regression results showed that the reduction in case-mix groups by collapsing independent variables had little to no effect on payment accuracy. Specifically, we noted that the proposed PDPM SLP model has an R-squared value almost identical to that of the original RCS–I SLP model, while reducing the number of resident groups from 18 to 12. Therefore, we determined that 12 case-mix groups would be necessary to classify residents adequately in terms of their SLP costs in a manner that captures sufficient variation in SLP costs without creating unnecessarily granular separations. More information on this analysis can be found in section 3.5.2. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*). We provided the criteria for each of these groups along with its CMI in Table 23 of the proposed rule (set forth in Table 23 of this final rule).

To help ensure that payment reflects the average relative resource use at the per diem level, we stated in the proposed rule (83 FR 21051) that CMIs would be set to reflect relative case-mix related differences in costs across groups. We stated that this method helps ensure that the share of payment for each case-mix group would be equal to its share of total costs of the component. We further explained that CMIs for the SLP component were calculated based on the average per diem costs of a case-mix group relative to the population average. Relative average differences in costs were weighted by length of stay to account for the different length of stay distributions across case-mix groups (as further discussed in section 3.11.1. of the SNF PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*). In this calculation, average per diem costs equaled total SLP costs in the group divided by number of utilization days in the group. Because the SLP component does not have a variable per diem schedule (as further discussed in section 3.9.1. of the SNF PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*), variable per diem adjustment factors were not involved in SLP CMI calculation. We further stated that a parity adjustment was then applied by multiplying the CMI by the ratio of case-mix-related payments in RUG–IV over estimated case-mix-related payments in PDPM, as further discussed in section V.J. of the proposed rule. We stated that this method helps ensure that the share of payment for each case-mix group is equal to its share of total costs of the component and that PDPM is budget neutral relative to RUG–IV. The full methodology used to develop CMIs is presented in section 3.11. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*).

TABLE 23—SLP CASE-MIX CLASSIFICATION GROUPS

Presence of acute neurologic condition, SLP-related comorbidity, or cognitive impairment	Mechanically altered diet or swallowing disorder	SLP case-mix group	SLP case-mix index
None	Neither	SA	0.68
None	Either	SB	1.82
None	Both	SC	2.66

TABLE 23—SLP CASE-MIX CLASSIFICATION GROUPS—Continued

Presence of acute neurologic condition, SLP-related comorbidity, or cognitive impairment	Mechanically altered diet or swallowing disorder	SLP case-mix group	SLP case-mix index
Any one	Neither	SD	1.46
Any one	Either	SE	2.33
Any one	Both	SF	2.97
Any two	Neither	SG	2.04
Any two	Either	SH	2.85
Any two	Both	SI	3.51
All three	Neither	SJ	2.98
All three	Either	SK	3.69
All three	Both	SL	4.19

As with the PT and OT components, we stated that all residents would be classified into one and only one of these 12 SLP case-mix groups under the PDPM. We explained that, as opposed to the RUG–IV system that determines therapy payments based only on the amount of therapy provided, under the PDPM, residents would be classified into SLP case-mix groups based on resident characteristics shown to be predictive of SLP utilization. Thus, we stated that believe the SLP case-mix groups will provide a better measure of resource use and will provide for more appropriate payment under the SNF PPS.

We invited comments on the approach we proposed above to classify residents for SLP payment under the proposed PDPM.

Commenters submitted the following comments related to the proposed rule's discussion of the classification of residents for SLP payment under the PDPM. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters agreed with the SLP-related patient classifiers. Some commenters suggested using a different assessment of cognition than that currently used on the MDS, such as the Montreal Cognitive Assessment (MOCA). One commenter expressed concerns regarding the use of cognition as a first tier classification criterion, as changes in cognition can be difficult to identify and this could impact on the possibility of late or missed IPAs. This commenter suggested moving cognition into the second tier classification criteria.

Response: We appreciate the support for the SLP component classification criteria. With regard to the comment on using a different assessment for assessing cognition, we are not opposed to this idea and would encourage stakeholders to work with CMS in developing potential revisions to the MDS to improve care planning and management. That being said, as the MOCA is not currently in use on the MDS, we must utilize the data and assessment tools to which we currently have access. Finally, with regard to the concern about the interplay between cognition and the IPA, we expect that this concern would be addressed by having the IPA be completed on an optional basis, as described in section V.D.1 of this final rule.

Comment: One commenter expressed concern that having a separate SLP component could result in the overutilization of SLP services, specifically for treating cognitive impairments. The commenter advised CMS to limit the overutilization of SLP services for cognitive impairment issues.

Response: As discussed above, we found that cognitive impairment is a relevant characteristic in predicting SLP resource utilization and costs. However, we understand the concern regarding the potential for providers to overutilize SLP services in certain instances and will monitor the use of SLP services under PDPM to identify any potential consequences of using this payment classifier as part of the SLP component.

Comment: A commenter questioned the accuracy of using the same primary diagnosis to assign clinical category across the PT, OT, and SLP components. This commenter states that multiple diagnoses can contribute to the reason for the SNF stay and proposes distinguishing between PT/OT and SLP diagnoses. Specifically, the commenter suggests allowing providers to enter the clinical reason for PT/OT services in the first two lines of MDS item I8000 and the clinical reason for SLP services in the third line of item I8000. This commenter points to our decision to separate therapy disciplines into different payment components based on our observation that different sets of resident characteristics were predictive of PT and OT costs, on one hand, and SLP costs, on the other. Given that utilization of PT and OT resources and utilization of SLP services are explained by a different set of predictors, this commenter concludes that the clinical reasons for receiving SLP services are distinct from those motivating PT/OT services.

Response: As detailed in the proposed rule (83 FR 21043) and section 3.4.1 of the SNF PDPM technical report, when constructing the ten clinical categories, we explored conditions that are clinically relevant to general SNF resource utilization. Within each component, we further consolidated the ten clinical categories into groups that have significant impact on component-specific resource utilization. We found that the clinical reason for a SNF stay as represented by the clinical categories was highly predictive of PT, OT, and SLP utilization, and thus we do not believe it is necessary to enter separate clinical reasons for PT/OT and SLP services, as suggested by the commenter. For this reason, we believe it is appropriate to include the clinical categories as determinants of resident classification and payment for all three components. We would also emphasize that clinical category is the only predictor shared by the PT/OT and SLP components. The other independent variables are unique to the PT and OT or SLP components and capture other clinical reasons for PT/OT and SLP services. As a result, in many cases, a resident's cognitive status and the presence of SLP-related comorbidities may be as relevant as primary diagnosis in determining resident classification and payment.

Comment: A few commenters stated that the proposed SLP-related comorbidity list is an incomplete reflection of all comorbidities that require SLP treatment. One commenter stated that the SLP comorbidity list should include progressive neurologic disorders that increase SLP resource use. This commenter suggests relabeling the ''ALS'' MDS checkbox item as ''Progressive Neurologic Diseases'' and updating the MDS manual definition for

this item to meet the criteria of specific progressive neurologic diseases.

Response: We appreciate commenters' concerns regarding additional conditions that may be related to SLP utilization. We may consider adding conditions that have a demonstrated relationship to SLP resource use in future revisions to the payment model. To examine the impact of PDPM on residents with chronic neurological conditions, we included this subpopulation in our resident impact analysis and found that PDPM is estimated to slightly increase the payment associated with these residents.

Comment: Some commenters agreed with the use of mechanically altered diet as a payment classifier. One commenter requested that CMS provide evidence that a mechanically altered diet is associated with higher SLP utilization than other nutritional approaches such as personal assistance with feeding. One commenter requested that CMS monitor the use of mechanically altered diets under PDPM to identify any potentially inappropriate use of such diets. One commenter stated that overutilization of such diets can have negative repercussions for patient care.

Response: As described in section 3.5.1 and 3.5.2 of the SNF PMR technical report, besides mechanically altered diet, we additionally explored feeding tube as a determinant of classification and payment for the SLP component. We used CART to test several SLP models with different variables related to swallowing and nutritional approach. This investigation found that mechanically altered diet notably increased the predictive power of the models, whereas feeding tube only had a small impact on predictive ability. While feeding tube was associated with an increase in SLP costs per day, we did not include feeding tube in the payment model because it only had a small impact on the predictive accuracy of the model relative to mechanically altered diet. We also explored the MDS item Eating Self-Performance (G0110H1) as a potential predictor of SLP utilization. While increased eating dependence was associated with higher SLP utilization, when we included Eating Self-Performance as an independent variable in the CART analysis used to explore possible case-mix groups, Eating Self-Performance was only selected as a determinant of classification for half of the 18 groups created by the CART algorithm. As a result, we determined that we could remove Eating Self-Performance from the SLP classification without notably sacrificing predictive ability. As shown in section 3.5.2 of the SNF PMR technical report, removing Eating Self-Performance and combining various independent variables to simplify the classification reduced the R-squared value of the classification by only 0.005. As a result, this classification was used as the basis for the proposed PDPM SLP component.

With regard to the possibility of some providers prescribing mechanically altered diets inappropriately or the possibility of overutilization, we do plan to monitor the use of these diets as part of our general PDPM monitoring strategy.

Accordingly, after considering the comments received, for the reasons discussed in the proposed rule and in this final rule, we are finalizing, without modification, the proposed SLP component of PDPM and our proposals relating to the classification of residents under the SLP component.

d. Nursing Case-Mix Classification

As we explained in the proposed rule (83 FR 21051 through 21052), the RUG–IV classification system first divides residents into ''rehabilitation residents'' and ''non-rehabilitation residents'' based on the amount of therapy a resident receives. We stated that differences in nursing needs can be obscured for rehabilitation residents, where the primary driver of payment classification is the intensity of therapy services that a resident receives. For example, for two residents classified into the RUB RUG–IV category, which would occur on the basis of therapy intensity and ADL score alone, the nursing component for each of these residents would be multiplied by a CMI of 1.56. We stated that this reflects that residents in that group were found, during our previous Staff time measurement (STM) work, to have nursing costs 56 percent higher than residents with a 1.00 index. We noted that while this CMI also includes adjustments made in FY 2010 and FY 2012 for budget-neutrality purposes, what is clear is that two residents, who may have significantly different nursing needs, are nevertheless deemed to have the very same nursing costs, and SNFs would receive the same nursing payment for each. Given the discussion above and in the proposed rule, which noted that approximately 60 percent of resident days are billed using one of three Ultra-High Rehabilitation RUGs (two of which have the same nursing index), we stated that the current case-mix model effectively classifies a significant portion of SNF therapy residents as having exactly the same degree of nursing needs and requiring exactly the same amount of nursing resources. As such, we stated we believed that further refinement of the case-mix model would be appropriate to better differentiate among patients, particularly those who receive therapy services with different nursing needs.

We further explained in the proposed rule (83 FR 21052) that an additional concern in the RUG–IV system is the use of therapy minutes to determine not only therapy payments but also nursing payments. For example, residents classified into the RUB RUG fall in the same ADL score range as residents classified into the RVB RUG. The only difference between those residents is the number of therapy minutes that they received. However, as we stated in the proposed rule, the difference in payment that results from this difference in therapy minutes impacts not only the RUG–IV therapy component but also the nursing component: Nursing payments for RUB residents are 40 percent higher than nursing payments for RVB residents. We stated that as a result of this feature of the RUG–IV system, the amount of therapy minutes provided to a resident is one of the main sources of variation in nursing payments, while other resident characteristics that may better reflect nursing needs play a more limited role in determining payment.

As discussed in the proposed rule (83 FR 21052), the more nuanced and resident-centered classifications in current RUG–IV non-rehabilitation categories are obscured under the current payment model, which utilizes only a single RUG–IV category for payment purposes and has over 90 percent of resident days billed using a rehabilitation RUG. The RUG–IV non-rehabilitation groups classify residents based on their ADL score, the use of extensive services, the presence of specific clinical conditions such as depression, pneumonia, or septicemia, and the use of restorative nursing services, among other characteristics. These characteristics are associated with nursing utilization, and the STRIVE study accounted for relative differences in nursing staff time across groups. Therefore, we proposed to use the existing RUG–IV methodology for classifying residents into non-rehabilitation RUGs to develop a proposed nursing classification that helps ensure nursing payment reflects expected nursing utilization rather than therapy utilization.

For example, in the proposed rule (83 FR 21052), we considered two residents. The first patient classifies into the RUB rehabilitation RUG (on the basis of the

resident's therapy minutes) and into the CC1 non-rehabilitation RUG (on the basis of having pneumonia), while the second classifies into the RUB rehabilitation RUG (on the basis of the resident's therapy minutes) and the HC1 non-rehabilitation RUG (on the basis of the resident having quadriplegia and a high ADL score). Under the current RUG–IV based payment model, the billing for both residents would utilize only the RUB rehabilitation RUG, despite clear differences in their associated nursing needs and resident characteristics. We proposed an approach where, for the purpose of determining payment under the nursing component, the first resident would be classified into CC1, while the second would be classified into HC1 under the PDPM. We stated that believe classifying the residents in this manner for payment purposes would capture variation in nursing costs in a more accurate and granular way than relying on the rehabilitation RUG's nursing CMI.

While resident classification in the proposed PDPM nursing component is guided by RUG–IV methodology, we proposed to make several modifications to the RUG–IV nursing RUGs and classification methodology under the proposed PDPM. First, we proposed under the PDPM to reduce the number of nursing RUGs by decreasing distinctions based on function. We stated that under RUG–IV, residents with a serious medical condition/service such as septicemia or respiratory therapy are classified into one of eight nursing RUGs in the Special Care High category. The specific RUG into which a resident is placed depends on the resident's ADL score and whether the resident is depressed. RUG–IV groups ADL score into bins for simplicity (for example, 2–5 and 6–10). For example, under RUG–IV, a resident in the Special Care High category who has depression and an ADL score of 3 would fall into the 2–5 ADL score bin, and therefore, be classified into the HB2 RUG, which corresponds to Special Care High residents with depression and an ADL score between 2 and 5 (a mapping of clinical traits and ADL score to RUG–IV nursing groups is shown in the appendix of the SNF PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*). To explore options to reduce the number of nursing RUGs, we explained in the proposed rule that we compared average nursing utilization across all 43 RUG–IV nursing RUGs. The dependent variable used in this investigation was the average wage-weighted staff time (WWST) for each nursing RUG from the STRIVE study. WWST is a measure of nursing resource utilization used in the STRIVE study. As discussed in more detail in the proposed rule (83 FR 21052) and in section 3.2.1. of the PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*), we were unable to construct a measure of nursing utilization based on current data because facilities do not report resident-specific nursing costs. As discussed in the proposed rule, we observed that nursing resource use as measured by WWST does not vary markedly between nursing case-mix groups defined by contiguous ADL score bins (for example, 11–14 and 15–16) but otherwise sharing the same clinical traits (for example, classified into Special Care High and depressed). We explained that this suggests that collapsing contiguous ADL score bins for RUGs that are otherwise defined by the same set of clinical traits is unlikely to notably affect payment accuracy. Section 3.6.1. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*) provides more detail on this analysis.

In the Special Care High, Special Care Low, Clinically Complex, and Reduced Physical Function classification groups (RUGs beginning with H, L, C, or P), for nursing groups that were otherwise defined with the same clinical traits (for example, extensive services, medical conditions, depression, restorative nursing services received), we proposed to combine the following pairs of second characters due to their contiguous ADL score bins: (E, D) and (C, B). These characters correspond to ADL score bins (15 to 16, 11 to 14) and (6 to 10, 2 to 5), respectively. We observed that nursing utilization did not vary notably across these contiguous ADL score bins; therefore, we stated that we believe it is appropriate to collapse pairs of RUGs in these classification groups that correspond to contiguous ADL score bins but are otherwise defined by the same clinical traits. For example, HE2 and HD2, which are both in the Special Care High group and both indicate the presence of depression, would be collapsed into a single nursing case-mix group. Similarly, we stated that PC1 and PB1 (Reduced Physical Function and 0 to 1 restorative nursing services) also would be combined into a single nursing case-mix group. Section 3.6.1. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*) provides more detail on this analysis. In the Behavioral and Cognitive Performance classification group (RUGs beginning with B), for RUGs that are otherwise defined by the same number of restorative nursing services (0 to1 or 2 or more), we proposed to combine RUGs with the second character B and A, which correspond to contiguous ADL score bins 2 to 5 and 0 to 1, respectively. We observed that nursing utilization did not vary notably across these contiguous ADL score bins; therefore, we stated that we believe it is appropriate to collapse pairs of RUGs in this classification group that correspond to contiguous ADL score bins but are otherwise defined by the same clinical traits. In other words, BB2 and BA2 would be combined into a single nursing group, and BB1 and BA1 would also be combined into a single nursing group. Section 3.6.1. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*) provides more detail on this analysis. We proposed to maintain CA1, CA2, PA1, and PA2 as separate case-mix groups under the nursing component of the PDPM. We observed that these RUGs do not share similar levels of nursing resource use with RUGs in adjacent ADL score bins that are otherwise defined by the same clinical traits (for example, medical conditions, depression, restorative nursing services received). Rather, we noted that CA1, CA2, PA1, and PA2 are associated with distinctly lower nursing utilization compared to RUGs that otherwise have the same clinical traits (for example, medical conditions, depression, restorative nursing services received) but higher ADL score bins. Section 3.6.1. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*) provides more detail on this analysis. We further stated that ES3, ES2, and ES1 also would be maintained as separate case-mix groups under the nursing component of the proposed PDPM because, although they are defined by the same ADL score bin, they are defined by different clinical traits unlike the pairs of RUGs that were combined. Specifically, ES3, ES2, and ES1 are defined by different combinations of extensive services. We stated that we believe collapsing case-mix groups based on ADL score for the RUGs specified above would reduce

model complexity by decreasing the number of nursing case-mix groups from 43 to 25, which thereby decreases the total number of possible combinations of case-mix groups under the proposed PDPM. Table 26 of the proposed rule (set forth in Table 26 of this final rule) shows the proposed 25 case-mix groups for nursing payment. Section 3.6.1. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*) provides more detail on the analyses and data supporting these proposals.

As explained in the proposed rule (83 FR 21053), the second modification to the RUG–IV nursing classification methodology would update the nursing ADL score to incorporate section GG items. Currently, the RUG–IV ADL score is based on four late-loss items from section G of MDS 3.0: eating, toileting, transfer, and bed mobility. We stated that under the proposed PDPM, these section G items would be replaced with an eating item, a toileting item, three transfer items, and two bed mobility items from the admission performance assessment of section GG. In contrast to the RUG–IV ADL score, the proposed PDPM score assigns higher points to higher levels of independence. Therefore, an ADL score of 0 (independent) corresponds to a section GG-based function score of 16, while an ADL score of 16 (dependent) corresponds to a section GG-based function score of 0. We explained that this scoring methodology is consistent with the proposed PDPM PT and OT function score, as well as functional scores in other care settings, such as the IRF PPS. The proposed nursing scoring methodology also assigns 0 points when an activity cannot be completed (''Resident refused,'' ''Not applicable,'' ''Not attempted due to medical condition or safety concerns''). As described in section V.D.3.c. (PT and OT Case-Mix Classification) of the proposed rule, grouping these responses with ''dependent'' aligns with clinical expectations of resource utilization for residents who cannot complete an ADL activity. The proposed scoring methodology is shown in Table 24 of the proposed rule (set forth in Table 24 of this final rule). As discussed in section V.D.3.c. of the proposed rule, section GG measures functional areas with more than one item, which results in substantial overlap between the two bed mobility items and the three transfer items. To address overlap, we proposed to calculate an average score for each of these related items. That is, we stated we would average the scores for the two bed mobility items and for the three transfer items. This averaging approach was also used in the proposed PT and OT function scores and is illustrated in Table 25 of the proposed rule (set forth in Table 25 of this final rule). We stated that the final score sums the average bed mobility and transfer scores with eating and toileting scores, resulting in a nursing function score that ranges from 0 to 16.

TABLE 24—NURSING FUNCTION SCORE CONSTRUCTION

Response	ADL score
05, 06—Set-up assistance, Independent	4
04—Supervision or touching assistance	3
03—Partial/moderate assistance	2
02—Substantial/maximal assistance	1
01, 07, 09, 88—Dependent, Refused, N/A, Not Attempted	0

TABLE 25—SECTION GG ITEMS INCLUDED IN NURSING FUNCTIONAL MEASURE

Section GG item	ADL score
GG0130A1—Self-care: Eating	0–4.
GG0130C1—Self-care: Toileting Hygiene	0–4.
GG0170B1—Mobility: Sit to lying	0–4 (average of 2 items).
GG0170C1—Mobility: Lying to sitting on side of bed.	
GG0170D1—Mobility: Sit to stand	0–4 (average of 3 items).
GG0170E1—Mobility: Chair/bed-to-chair transfer.	
GG0170F1—Mobility: Toilet transfer.	

In addition to proposing to replace the nursing ADL score with a function score based on section GG items and to collapse certain nursing RUGs, we also proposed (83 FR 21054) to update the existing nursing CMIs using the STRIVE staff time measurement data that were originally used to create these indexes. We explained that under the current payment system, non-rehabilitation nursing indexes were calculated to capture variation in nursing utilization by using only the staff time collected for the non-rehabilitation population. We stated we believe that, to provide a more accurate reflection of the relative nursing resource needs of the SNF population, the nursing indexes should reflect nursing utilization for all residents. To accomplish this, we stated in the proposed rule that we replicated the methodology described in the FY 2010 SNF PPS rule (74 FR 22236 through 22238) but classified the full STRIVE study population under non-rehabilitation RUGs using the RUG–IV classification rules. The methodology set forth in the proposed rule for updating resource use estimates for each nursing RUG proceeded according to the following steps:

(1) Calculate average wage-weighted staff time (WWST) for each STRIVE study resident using FY 2015 SNF wages.

(2) Assign the full STRIVE population to the appropriate non-rehabilitation RUG.

(3) Apply sample weights to WWST estimates to allow for unbiased population estimates. The reason for this weighting is that the STRIVE study was not a random sample of residents. Certain key subpopulations, such as residents with HIV/AIDS, were over-sampled to ensure that there were enough residents to draw conclusions on the subpopulations' resource use. As a result, STRIVE researchers also developed sample weights, equal to the inverse of each resident's probability of selection, to permit calculation of unbiased population estimates.

Applying the sample weights to a summary statistic results in an estimate that is representative of the actual population. The sample weight method is explained in Phase I of the STRIVE study. A link to the STRIVE study is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/TimeStudy.html*.

(4) Smooth WWST estimates that do not match RUG hierarchy in the same manner as the STRIVE study. RUG–IV, from which the nursing RUGs are derived, is a hierarchical classification in which payment should track clinical acuity. It is intended that residents who are more clinically complex or who have other indicators of acuity, including a higher ADL score, depression, or restorative nursing services, would receive higher payment. When STRIVE researchers estimated WWST for each RUG, several inversions occurred because of imprecision in the means. These are defined as WWST estimates that are not in line with clinical expectations. The methodology used to smooth WWST estimates is explained in Phase II of the STRIVE study. A link to the STRIVE study is available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/TimeStudy.html*.

(5) Calculate nursing indexes, which reflect the average WWST for each of the 25 nursing case-mix groups divided by the average WWST for the study population used throughout our research. To impute WWST for each stay in the population, we assigned each resident the average WWST of the collapsed nursing RUG into which they are categorized. To derive the average WWST of each collapsed RUG, we first estimate the average WWST of the original 43 nursing RUGs based on steps 1 through 4 above, then calculate a weighted mean of the average WWST of the two RUGs that form the collapsed RUG. More details on this analysis can be found in section 3.6.3. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*).

Through this refinement, we stated that we believe the nursing indexes under the proposed PDPM better reflect the varied nursing resource needs of the full SNF population. In Table 26 of the proposed rule (set forth in Table 26 of this final rule), we provided the nursing indexes under the proposed PDPM.

To help ensure that payment reflects the average relative resource use at the per diem level, we stated that the nursing CMIs would be set to reflect case-mix related relative differences in WWST across groups. We further stated that Nursing CMIs would be calculated based on the average per diem nursing WWST of a case-mix group relative to the population average. In this calculation, average per diem WWST equaled total WWST in the group divided by number of utilization days in the group. We further explained that because the nursing component does not have a variable per diem schedule (as further discussed in section 3.9.1. of the SNF PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*), variable per diem adjustment factors were not involved in nursing CMI calculation. We then applied a parity adjustment by multiplying the CMI by the ratio of case-mix-related payments in RUG–IV over estimated case-mix-related payments in PDPM, as discussed further in section V.J. of the proposed rule. The full methodology used to develop CMIs is presented in section 3.11. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*).

TABLE 26—NURSING INDEXES UNDER PDPM CLASSIFICATION MODEL

RUG–IV nursing RUG	Extensive services	Clinical conditions	Depression	Number of restorative nursing services	GG-based function score	PDPM nursing case-mix group	Nursing case-mix index
ES3	Tracheostomy & Ventilator.				0–14	ES3	4.04
ES2	Tracheostomy or Ventilator.				0–14	ES2	3.06
ES1	Infection				0–14	ES1	2.91
HE2/HD2		Serious medical conditions e.g. comatose, septicemia, respiratory therapy.	Yes		0–5	HDE2	2.39
HE1/HD1		Serious medical conditions e.g. comatose, septicemia, respiratory therapy.	No		0–5	HDE1	1.99
HC2/HB2		Serious medical conditions e.g. comatose, septicemia, respiratory therapy.	Yes		6–14	HBC2	2.23
HC1/HB1		Serious medical conditions e.g. comatose, septicemia, respiratory therapy.	No		6–14	HBC1	1.85
LE2/LD2		Serious medical conditions e.g. radiation therapy or dialysis.	Yes		0–5	LDE2	2.07
LE1/LD1		Serious medical conditions e.g. radiation therapy or dialysis.	No		0–5	LDE1	1.72
LC2/LB2		Serious medical conditions e.g. radiation therapy or dialysis.	Yes		6–14	LBC2	1.71
LC1/LB1		Serious medical conditions e.g. radiation therapy or dialysis.	No		6–14	LBC1	1.43
CE2/CD2		Conditions requiring complex medical care e.g. pneumonia, surgical wounds, burns.	Yes		0–5	CDE2	1.86
CE1/CD1		Conditions requiring complex medical care e.g. pneumonia, surgical wounds, burns.	No		0–5	CDE1	1.62
CC2/CB2		Conditions requiring complex medical care e.g. pneumonia, surgical wounds, burns.	Yes		6–14	CBC2	1.54
CA2		Conditions requiring complex medical care e.g. pneumonia, surgical wounds, burns.	Yes		15–16	CA2	1.08
CC1/CB1		Conditions requiring complex medical care e.g. pneumonia, surgical wounds, burns.	No		6–14	CBC1	1.34
CA1		Conditions requiring complex medical care e.g. pneumonia, surgical wounds, burns.	No		15–16	CA1	0.94
BB2/BA2		Behavioral or cognitive symptoms		2 or more	11–16	BAB2	1.04
BB1/BA1		Behavioral or cognitive symptoms		0–1	11–16	BAB1	0.99
PE2/PD2		Assistance with daily living and general supervision		2 or more	0–5	PDE2	1.57

TABLE 26—NURSING INDEXES UNDER PDPM CLASSIFICATION MODEL—Continued

RUG–IV nursing RUG	Extensive services	Clinical conditions	Depression	Number of restorative nursing services	GG-based function score	PDPM nursing case-mix group	Nursing case-mix index
PE1/PD1		Assistance with daily living and general supervision		0–1	0–5	PDE1	1.47
PC2/PB2		Assistance with daily living and general supervision		2 or more	6–14	PBC2	1.21
PA2		Assistance with daily living and general supervision		2 or more	15–16	PA2	0.70
PC1/PB1		Assistance with daily living and general supervision		0–1	6–14	PBC1	1.13
PA1		Assistance with daily living and general supervision		0–1	15–16	PA1	0.66

As with the previously discussed components, we stated that all residents would be classified into one and only one of these 25 nursing case-mix groups under the proposed PDPM. As explained in the proposed rule (83 FR 21055), we also used the STRIVE data to quantify the effects of an HIV/AIDS diagnosis on nursing resource use. We controlled for case mix by including the proposed PDPM resident groups (in this case, the nursing RUGs) as independent variables. The results showed that even after controlling for nursing RUG, HIV/AIDS status is associated with a positive and significant increase in nursing utilization. Based on the results of regression analyses, we found that wage-weighted nursing staff time is 18 percent higher for residents with HIV/AIDS. (The estimate of average wage-weighted nursing staff time for the SNF population was adjusted to account for the deliberate over-sampling of certain sub-populations in the STRIVE study. Specifically, we applied sample weights from the STRIVE dataset equal to the inverse of each resident's probability of selection to permit calculation of an unbiased estimate.) Based on these findings, as discussed in the proposed rule, we concluded that the proposed PDPM nursing groups may not fully capture the additional nursing costs associated with HIV/AIDS residents. More information on this analysis can be found in section 3.8.2. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*). Thus, as part of the case-mix adjustment of the nursing component, we proposed an 18 percent increase in payment for the nursing component for residents with HIV/AIDS. We stated that this adjustment would be applied based on the presence of ICD–10–CM code B20 on the SNF claim. In cases where a resident is coded as having this diagnosis, we stated that the nursing component per diem rate for this resident would be multiplied by 1.18, to account for the 18 percent increase in nursing costs for residents with this diagnosis. We also discussed this proposal, as well as its relation to the existing AIDS add-on payment under RUG–IV, in section V.I. of the proposed rule.

We invited comments on the approach we proposed to classify residents for nursing payment under the proposed PDPM.

Commenters submitted the following comments related to the proposed rule's discussion of the classification of residents for nursing payment under the PDPM. A discussion of these comments, along with our responses, appears below.

Comment: One commenter supported the nursing case-mix classification model that would be used under PDPM, specifically citing the nursing function score refinements and using a separate function score for the therapy components than would be used for the nursing component. This commenter also requested that CMS consider aligning the nursing classification under PDPM with certain hospice criteria. Finally, one commenter expressed concern regarding the collapsing of nursing groups to only 25 groups and that these groups may not accurately account for the variety of patient conditions.

Response: We appreciate the support for the nursing component classification criteria. We can examine the hospice criteria specified by the commenter for future consideration. With regard to the comment on the collapsed nursing groups, we believe that, given that we collapsed groups primarily based on functional score bins and did not collapse any of the general nursing group categories (such as extensive services and special care high), we believe that the level of granularity in the nursing classifications is not significantly impacted. As stated in the proposed rule (83 FR 21052) and in section 3.6.1 of the SNF PDPM technical report, we collapsed groups based on function score due to the observation that among nursing RUGs defined by the same clinical traits, nursing resource use is similar across contiguous functional score bins (for example, 11–14 and 15–16). Since WWST does not vary markedly between nursing RUGs defined by contiguous functional score bins, collapsing groups based on functional score bins simplifies the payment model without a notable loss in accuracy. Therefore, we believe that 25 nursing rugs sufficiently captures variation in patient conditions.

Comment: Several commenters questioned the appropriateness of using staff-time measurement data from the STRIVE study to estimate relative differences in nursing utilization across the nursing groups given the age of the data, methodological flaws in the collection of therapy minutes, and small sample sizes for certain resident groups used to estimate CMIs. Additionally, one commenter stated that the STRIVE study underestimates the nursing needs of residents by only measuring the usual nursing time provided to residents in the sampled homes. The commenter further stated that the STRIVE study did not take into account nursing time needed to assure resident safety and maintain resident well-being. The commenter expressed concern that basing nursing payment on STRIVE data will provide inadequate reimbursement, which will result in understaffing. A couple of commenters recommended replacing STRIVE with the Schnelle et al. 2016 simulation model to estimate nursing resource requirements.

Response: Unlike the therapy and NTA charges, nursing charges are reported on SNF claims as part of routine revenue centers, which also include non-case mix services such as room and board, rather than revenue centers specific to nursing. Due to the lack of resident-specific nursing charges, we used WWST from STRIVE data as a measure of nursing resource use in limited instances. Specifically, STRIVE data was not used to select determinants of payment for the nursing component. We only used STRIVE data to update case-mix indexes for the nursing component, so that nursing CMIs were calculated based on the entire SNF population rather than only on non-rehabilitation residents. We conducted a series of investigations into possible changes in resident characteristics from the time of the STRIVE study (2006) to fiscal year 2014

to determine if resident characteristics had changed in a manner that would suggest it would not be appropriate to use data from the STRIVE study in designing payment alternatives. The resident characteristics investigated include, but not limited to, most common Major Diagnostic Categories (MDC), percent of stays with complications or comorbidities in the qualifying inpatient stay, and frequency of MDS section I active diagnoses. The result of the investigations suggest that although there are small changes in prior inpatient hospital stay and SNF stay lengths, there have not been notable changes in resident characteristics or acuity over time. Given the stability of resident characteristics over time, there is no strong evidence of change in the relative resource utilization pattern among nursing groups since the time of STRIVE study in 2006.

In response to the concern about the methodology in collecting therapy minutes, we note that we only used nursing time to estimate CMIs for the nursing component under PDPM. Because therapy minutes were not included in the nursing staff time measure, concerns about how the STRIVE study collected therapy utilization data are not relevant to our use of STRIVE data to estimate nursing CMIs under PDPM.

As for the comments on the small sample sizes of certain resident groups in the STRIVE study, as detailed in section 4.1.2 of the STRIVE Phase II Report available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/TimeStudy.html*, the STRIVE study used several procedures to address these concerns. First, STRIVE researchers deliberately over-sampled certain vulnerable resident groups to obtain more robust estimates of resource utilization for these subpopulations. Second, the STRIVE authors applied sample weights to obtain reliable population estimates. Because the proportion of facilities included in the study varied from state to state, the study population was not truly random. To account for this, the study developed sampling weights equal to the inverse of a resident's probability of selection for inclusion in the study population. The use of sampling weights allows the calculation of unbiased population estimates from the sample data, as described in section 4.1.2 of the STRIVE Phase II Report.

With regard to the comment stating concerns about how the STRIVE study measured nursing time, it is unclear what the commenter means by ''usual nursing time'' and ''nursing time needed to assure resident safety and maintain resident well-being.'' As discussed in the STRIVE Phase I and Phase II reports available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/TimeStudy.html*, the STRIVE study collected three kinds of staff time: Resident Specific Time (RST), Non-Resident Specific Time (NRST), and Non-Study Time (NST). It was not appropriate to include NST in the dependent variable used to measure nursing utilization because these minutes did not benefit residents in the study population. As for NRST, while these minutes did benefit the study population, there are numerous methodological issues involved in including these minutes in the dependent variable. As noted in the STRIVE Phase II Report available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/TimeStudy.html*, for many types of NRST, it is not clear how to allocate these non-resident specific minutes to specific residents. The STRIVE authors note that during development of RUG–III, NRST was allocated to individual residents in proportion to a resident's RST, based on the assumption that a resident's utilization of NRST was proportional to their utilization of RST. However, as the STRIVE authors note, this assumption may not be accurate. Accurate allocation of NRST would have involved extensive additional data collection that was beyond the scope of the STRIVE study. Without confidence in the allocation methodology, including NRST in the dependent variable for nursing would have introduced substantial noise into the dependent variable that could obscure the relationships between resident characteristics and resource utilization. As a result, the STRIVE authors decided to set relative payment weights based on RST alone. However, we disagree with the commenter if they are suggesting that excluding NRST leads us to underestimate nursing utilization. As noted in the STRIVE Phase II Report, the STRIVE study was only used to allocate nursing resources based on estimated relative resource utilization. It did not determine aggregate nursing resources, which are largely determined based on the methodology for setting and updating the federal per diem rates as specified in the Act. Therefore, it is incorrect to assert that relying on the STRIVE data for case-mix adjustment leads to inadequate nursing reimbursement since STRIVE is used to determine allocation of nursing resources rather than total nursing resources.

In response to the alternative data source proposed by commenters, the Schnelle et al. simulation model estimates resource use for nurse aides only; therefore, it is not a comprehensive or appropriate measure of nursing utilization.

Accordingly, after considering the comments received, for the reasons discussed in the proposed rule and in this final rule, we are finalizing our proposals, without modification, relating to the methodology, as described in this section, for classifying patients under the nursing component of PDPM.

e. Non-Therapy Ancillary Case-Mix Classification

Under the current SNF PPS, payments for NTA costs incurred by SNFs are incorporated into the nursing component. This means that the CMIs used to adjust the nursing component of the SNF PPS are intended to reflect not only differences in nursing resource use but also NTA costs. However, as we explained in the proposed rule (83 FR 21055), there have been concerns that the current nursing CMIs do not accurately reflect the basis for or the magnitude of relative differences in resident NTA costs. In its March 2016 Report to Congress, MedPAC wrote: ''Almost since its inception, the SNF PPS has been criticized for encouraging the provision of unnecessary rehabilitation therapy services and not accurately targeting payments for nontherapy ancillary (NTA) services such as drugs (Government Accountability Office 2002, Government Accountability Office 1999, White et al. 2002)'' (available at *http://medpac.gov/docs/default-source/reports/chapter-7-skilled-nursing-facility-services-march-2016-report-.pdf*). In the proposed rule, we stated that while the proposed PT, OT, and SLP components were designed to address the issue related to provision of therapy services raised by MedPAC above, the proposed NTA component was designed to address the issue related to accurately targeting payments for NTA services—specifically, that the current manner of using the RUG–IV case-mix system to determine NTA payment levels inadequately adjusts for relative differences in resident NTA costs.

As noted in the quotation from MedPAC above, MedPAC is not the only group to offer this critique of the SNF PPS. We stated in the proposed rule that just as the aforementioned criticisms that MedPAC cited have existed almost since the inception of the SNF PPS itself, ideas for addressing this concern have a similarly long history. In

response to comments on the 1998 interim final rule which served to establish the SNF PPS, we published a final rule on July 30, 1999 (64 FR 41644). In this 1998 interim final rule, we acknowledged the commenters' concerns about the new system's ability to account accurately for NTA costs, stating that there were a number of comments expressing concern with the adequacy of the PPS rates to cover the costs of ancillary services other than occupational, physical, and speech therapy (non-therapy ancillaries), including such things as drugs, laboratory services, respiratory therapy, and medical supplies. We stated in the 1998 interim final rule that prescription drugs or medication therapy were frequently noted areas of concern due to their potentially high cost for particular residents. Some commenters suggested that the RUG–III case-mix classification methodology did not adequately provide for payments that account for the variation in, or the real costs of, these services provided to their residents. (64 FR 41647)

In response to those comments, we stated in the 1998 interim final rule that ''we are funding substantial research to examine the potential for refinements to the case-mix methodology, including an examination of medication therapy, medically complex patients, and other nontherapy ancillary services'' (64 FR 41648). In the FY 2019 SNF PPS proposed rule (83 FR 21055 through 21056), we proposed a methodology that we believe would case-mix adjust SNF PPS payments more appropriately to reflect differences in NTA costs.

Following the same methodology we used for the proposed PT, OT, and SLP components, the project team ran cost regression models to determine which resident characteristics may be predictive of relative increases in NTA costs. As explained in the proposed rule, the three categories of cost-related resident characteristics identified through this analysis were resident comorbidities, the use of extensive services (services provided to residents that are particularly expensive and/or invasive), and resident age. However, as discussed in the proposed rule, we removed age from further consideration as part of the NTA component based on concerns shared by TEP panelists during the June 2016 TEP. Particularly, some panelists expressed concern that including age as a determinant of NTA payment could create access issues for older populations. Additionally, we state that the CART algorithm used to explore potential resident groups for the NTA component only selected age as a determinant of classification for 2 of the 7 groups created. We noted that we also tested a classification option that used age as a determinant of classification for every NTA group. This only led to a 5 percent increase in the R-squared value of the NTA classification. More information on these analyses can be found in section 3.7.1. of the SNF PMR technical report available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*.

As we explained in the proposed rule (83 FR 21056), with regard to capturing comorbidities and extensive services associated with high NTA utilization, we used multiple years of data (FY 2014 to FY 2017) to estimate the impact of comorbidities and extensive services on NTA costs. This was in response to comments on the ANPRM that the design of the NTA component should be more robust and remain applicable in light of potential changes in the SNF population and care practices over time. We explained in the proposed rule that conditions and services were defined in three ways. First, clinicians identified MDS items that correspond to conditions/extensive services likely related to NTA utilization. However, we stated that since many conditions/extensive services related to NTA utilization are not included on the MDS assessment, we then mapped ICD–10 diagnosis codes from the prior inpatient claim, the first SNF claim, and section I8000 of the 5-day MDS assessment to condition categories from the Part C risk adjustment model (CCs) and the Part D risk adjustment model (RxCCs). The CCs and RxCCs define conditions by aggregating related diagnosis codes into a single condition flag. We use the condition flags defined by the CCs and RxCCs to predict Part A and B expenditures or Part D expenditures, respectively for Medicare beneficiaries. The predicted relationship between the conditions defined in the respective models and Medicare expenditures is then used to risk-adjust capitated payments to Part C and Part D sponsors. Similarly, we explained that our comorbidities investigation aimed to use a comprehensive list of conditions and services to predict resource utilization for beneficiaries in Part A-covered SNF stays. As we stated in the proposed rule, ultimately, the predicted relationship between these conditions/services and utilization of NTA services would be used to case-mix adjust payments to SNF providers, in a process similar to risk adjustment of capitated payments. Given these similarities, we decided to use the diagnosis-defined conditions from the Part C and Part D risk adjustment models to define conditions and services that were not defined on the MDS. Because the CCs were developed to predict utilization of Part A and B services, while the RxCCs were developed to predict Part D drug costs, the largest component of NTA costs, we stated that believe using both sources allows us to define the conditions and services potentially associated with NTA utilization more comprehensively. Lastly, we used ICD–10 diagnosis codes to define additional conditions that clinicians who advised CMS during PDPM development identified as being potentially associated with increased NTA service utilization but are not fully reflected in either the MDS or the CCs/RxCCs. The resulting list was meant to encompass as many diverse and expensive conditions and extensive services as possible from the MDS assessment, the CCs, the RxCCs, and diagnoses. As discussed in the proposed rule, using cost regressions, we found that certain comorbidity conditions and extensive services were highly predictive of relative differences in resident NTA costs. These conditions and services were identified in Table 27 of the proposed rule (set forth in Table 27 in this final rule). More information on this analysis can be found in section 3.7.1. of the SNF PDPM technical report available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*. We noted in the proposed rule that certain conditions that were associated with higher NTA utilization were nevertheless excluded from the list because of clinical concerns. Esophageal reflux was excluded because it is a very common condition in the SNF population and clinicians noted that coding can be discretionary. Migraine headache was also excluded due to clinicians' concerns about coding reliability. Additionally, we noted that clinicians stated that in many cases migraine headache is not treated by medication, the largest component of NTA costs.

Having identified the list of relevant conditions and services for adjusting NTA payments, in the proposed rule (83 FR 21056 through 21057), we considered different options for how to capture the variation in NTA costs explained by these identified conditions and services. We stated that one such method would be merely to count the number of comorbidities and services a resident receives and assign a score to that resident based on this count. We found that this option accounts for the additive effect of having multiple comorbidities and extensive services but

did not adequately reflect the relative differences in the impact of certain higher-cost conditions and services. We also considered a tier system similar to the one used in the IRF PPS, where SNF residents would be placed into payment tiers based on the costliest comorbidity or extensive service. However, we found that this option did not account for the additive effect noted above. To address both of these issues, we proposed basing a resident's NTA score, which would be used to classify the resident into an NTA case-mix classification group, on a weighted-count methodology. Specifically, as shown in Table 27, each of the comorbidities and services that factored into a resident's NTA classification was assigned a certain number of points based on its relative impact on a resident's NTA costs. Those conditions and services with a greater impact on NTA costs were assigned more points, while those with less of an impact were assigned fewer points. The relative impacts are estimated based the coefficients of an ordinary least squares (OLS) regression that used the selected conditions and extensive services to predict NTA costs per day. Points were assigned by grouping together conditions and extensive services with similar OLS regression estimates. More information on this methodology and analysis can be found in section 3.7.1. of the SNF PDPM technical report available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*. We stated that the effect of this methodology was that the NTA component would adequately reflect relative differences in the NTA costs for each condition or service, as well as the additive effect of having multiple comorbidities.

We stated in the proposed rule (83 FR 21057) that a resident's total comorbidity score, which would be the sum of the points associated with all of a resident's comorbidities and services, would be used to classify the resident into an NTA case-mix group. For conditions and services where the source is indicated as MDS item I8000, SNF PDPM NTA Comorbidity Mapping (which accompanied the FY 2019 SNF PPS proposed rule) (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*) provides a crosswalk between the listed condition and the ICD–10–CM codes which may be coded to qualify that condition to serve as part of the resident's NTA classification. MDS item I8000 is an open-ended item in the MDS assessment where the assessment provider can fill in additional active diagnoses that are not explicitly on the MDS for the resident in the form of ICD–10 codes. In the case of Parenteral/IV Feeding, we stated that we observed that NTA costs per day increase as the amount of intake through parenteral or tube feeding increases. For this reason, we proposed to separate this item into a high intensity item and a low intensity item, similar to how it is defined in the RUG–IV system. In order for a resident to qualify for the high intensity category, the percent of calories taken in by the resident by parenteral or tube feeding, as reported in item K0710A2 on the MDS 3.0, must be greater than 50 percent. We further stated that in order to qualify for the low intensity category, the percent of calories taken in by the resident by parenteral or tube feeding, as reported in item K0710A2 on the MDS 3.0, must be greater than 25 percent but less than or equal to 50 percent, and the resident must receive an average fluid intake by IV or tube feeding of at least 501cc per day, as reported in item K0710B2 of the MDS 3.0.

We also noted that the source of the HIV/AIDS diagnosis is listed as the SNF claim. We explained in the proposed rule that this is because 16 states have state laws that prevent the reporting of HIV/AIDS diagnosis information to CMS through the current assessment system and/or prevent CMS from seeing such diagnosis information within that system, should that information be mistakenly reported. We noted that the states are Alabama, Alaska, California, Colorado, Connecticut, Idaho, Illinois, Massachusetts, Nevada, New Hampshire, New Jersey, New Mexico, South Carolina, Texas, Washington, and West Virginia. Given this restriction, it would not be possible to have SNFs utilize the MDS 3.0 as the vehicle to report HIV/AIDS diagnosis information for purposes of determining a resident's NTA classification. We noted that the current SNF PPS uses a claims reporting mechanism as the basis for the temporary AIDS add-on payment which exists under RUG–IV. To address the issue discussed above with respect to reporting of HIV/AIDS diagnosis information under the proposed PDPM, we proposed to utilize this existing claims reporting mechanism to determine a resident's HIV/AIDS status for the purpose of NTA classification. More specifically, we explained that HIV/AIDS diagnosis information reported on the MDS would be ignored by the GROUPER software used to classify a resident into an NTA case-mix group. Instead, we stated that providers would be instructed to locate the HIPPS code provided to the SNF on the validation report associated with that assessment and report it to CMS on the associated SNF claim. Following current protocol, the provider would then enter ICD–10–CM code B20 on the associated SNF claim as if it were being coded to receive payment through the current AIDS add-on payment. The PRICER software, which we use to determine the appropriate per diem payment for a provider based on their wage index and other factors, would make the adjustment to the resident's NTA case-mix group based on the presence of the B20 code on the claim, as well as adjust the associated per diem payment based on the adjusted resident HIPPS code. Again, we noted that this methodology follows the same logic that the SNF PPS currently uses to pay the temporary AIDS add-on adjustment but merely changes the target and type of adjustment from the SNF PPS per diem to the NTA component of the proposed PDPM. We explained that the difference is that while under the current system, the presence of the B20 code would lead to a 128 percent increase in the per diem rate, under the proposed PDPM, the presence of the B20 code would mean the addition of 8 points (as determined by the OLS regression described above) to the resident's NTA score, the categorization of the resident into the appropriate NTA group, and an adjustment to the nursing component, as described in section V.D.3.d. of the proposed rule. Section 1888(e)(12) of the Act enacted a temporary 128 percent increase in the PPS per diem payment for SNF residents with HIV/AIDS and stipulated that the temporary adjustment was to be applied only until the Secretary certifies that there is an appropriate case-mix adjustment to compensate for the increased costs associated with this population. As we explained in the proposed rule, based on this language, we conducted an analysis similar to that used to determine the HIV/AIDS add-on for the nursing component to examine the adequacy of payment for ancillary services (all non-nursing services: PT, OT, SLP, and NTA) for residents with HIV/AIDS under the proposed PDPM. This analysis determined that after accounting for the 8 points assigned for HIV/AIDS in the NTA component and controlling for case-mix classification across the three therapy components and NTA component, HIV/AIDS was not associated with an increase in ancillary costs. We noted that nursing costs were not included in this regression because we separately

investigated the increased nursing utilization associated with HIV/AIDS, as described in section V.D.3.d. of the proposed rule. Based on the results of this investigation, we concluded that the four ancillary case-mix components (PT, OT, SLP, and NTA) adequately reimburse costs associated with residents with HIV/AIDS. Therefore, we stated that we do not believe an HIV/AIDS add-on is warranted for the ancillary cost components. More information on this analysis can be found in section 3.8.2. of the PDPM technical report available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*.

Table 27 provides the proposed list of conditions and extensive services that would be used for NTA classification, the source of that information, and the associated number of points for that condition.

TABLE 27—CONDITIONS AND EXTENSIVE SERVICES USED FOR NTA CLASSIFICATION

Condition/extensive service	Source	Points
HIV/AIDS	SNF Claim	8
Parenteral IV Feeding: Level High	MDS Item K0510A2, K0710A2	7
Special Treatments/Programs: Intravenous Medication Post-admit Code	MDS Item O0100H2	5
Special Treatments/Programs: Ventilator or Respirator Post-admit Code	MDS Item O0100F2	4
Parenteral IV feeding: Level Low	MDS Item K0510A2, K0710A2, K0710B2.	3
Lung Transplant Status	MDS Item I8000	3
Special Treatments/Programs: Transfusion Post-admit Code	MDS Item O0100I2	2
Major Organ Transplant Status, Except Lung	MDS Item I8000	2
Active Diagnoses: Multiple Sclerosis Code	MDS Item I5200	2
Opportunistic Infections	MDS Item I8000	2
Active Diagnoses: Asthma COPD Chronic Lung Disease Code	MDS Item I6200	2
Bone/Joint/Muscle Infections/Necrosis—Except Aseptic Necrosis of Bone	MDS Item I8000	2
Chronic Myeloid Leukemia	MDS Item I8000	2
Wound Infection Code	MDS Item I2500	2
Active Diagnoses: Diabetes Mellitus (DM) Code	MDS Item I2900	2
Endocarditis	MDS Item I8000	1
Immune Disorders	MDS Item I8000	1
End-Stage Liver Disease	MDS Item I8000	1
Other Foot Skin Problems: Diabetic Foot Ulcer Code	MDS Item M1040B	1
Narcolepsy and Cataplexy	MDS Item I8000	1
Cystic Fibrosis	MDS Item I8000	1
Special Treatments/Programs: Tracheostomy Care Post-admit Code	MDS Item O0100E2	1
Active Diagnoses: Multi-Drug Resistant Organism (MDRO) Code	MDS Item I1700	1
Special Treatments/Programs: Isolation Post-admit Code	MDS Item O0100M2	1
Specified Hereditary Metabolic/Immune Disorders	MDS Item I8000	1
Morbid Obesity	MDS Item I8000	1
Special Treatments/Programs: Radiation Post-admit Code	MDS Item O0100B2	1
Highest Stage of Unhealed Pressure Ulcer—Stage 4	MDS Item M0300X1	1
Psoriatic Arthropathy and Systemic Sclerosis	MDS Item I8000	1
Chronic Pancreatitis	MDS Item I8000	1
Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	MDS Item I8000	1
Other Foot Skin Problems: Foot Infection Code, Other Open Lesion on Foot Code, Except Diabetic Foot Ulcer Code.	MDS Item M1040A, M1040B, M1040C.	1
Complications of Specified Implanted Device or Graft	MDS Item I8000	1
Bladder and Bowel Appliances: Intermittent Catheterization	MDS Item H0100D	1
Inflammatory Bowel Disease	MDS Item I8000	1
Aseptic Necrosis of Bone	MDS Item I8000	1
Special Treatments/Programs: Suctioning Post-admit Code	MDS Item O0100D2	1
Cardio-Respiratory Failure and Shock	MDS Item I8000	1
Myelodysplastic Syndromes and Myelofibrosis	MDS Item I8000	1
Systemic Lupus Erythematosus, Other Connective Tissue Disorders, and Inflammatory Spondylopathies.	MDS Item I8000	1
Diabetic Retinopathy—Except Proliferative Diabetic Retinopathy and Vitreous Hemorrhage	MDS Item I8000	1
Nutritional Approaches While a Resident: Feeding Tube	MDS Item K0510B2	1
Severe Skin Burn or Condition	MDS Item I8000	1
Intractable Epilepsy	MDS Item I8000	1
Active Diagnoses: Malnutrition Code	MDS Item I5600	1
Disorders of Immunity—Except: RxCC97: Immune Disorders	MDS Item I8000	1
Cirrhosis of Liver	MDS Item I8000	1
Bladder and Bowel Appliances: Ostomy	MDS Item H0100C	1
Respiratory Arrest	MDS Item I8000	1
Pulmonary Fibrosis and Other Chronic Lung Disorders	MDS Item I8000	1

Given the NTA scoring methodology described in the proposed rule (83 FR 21058 through 21059) and above, and following the same methodology used for the PT, OT, and SLP components, we used the CART algorithm to determine the most appropriate splits in resident NTA case-mix groups. This methodology is more thoroughly explained in sections 3.4.2. and 3.7.2. of the SNF PDPM technical report available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*. Based on the

breakpoints generated by the CART algorithm, we determined that 6 case-mix groups would be necessary to classify residents adequately in terms of their NTA costs in a manner that captures sufficient variation in NTA costs without creating unnecessarily granular separations. As discussed in the proposed rule, we made certain administrative decisions that further refined the NTA case-mix classification groups beyond those produced through use of the CART algorithm but maintained the CART output predictive accuracy. We explained that the proposed NTA case-mix classification departs from the CART comorbidity score bins in grouping residents with a comorbidity score of 1 with residents with scores of 2 instead of with residents with scores of 0. This is to maintain the distinction between residents with no comorbidities and the rest of the population. In addition, we grouped residents with a score of 5 together with residents with scores of 3 to 4 based on their similarity in average NTA costs per day. More information on this analysis can be found in section 3.7.2. of the SNF PDPM technical report available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*. We provided the criteria for each of these groups along with its CMI in Table 28 of the proposed rule (set forth in Table 28 of this final rule).

We stated in the proposed rule (83 FR 21059) that to help ensure payment reflects the average relative resource use at the per diem level, CMIs would be set to reflect relative case-mix related differences in costs across groups. We further stated that this method helps ensure that the share of payment for each case-mix group would be equal to its share of total costs of the component. CMIs for the NTA component were calculated based on two factors. One factor was the average per diem costs of a case-mix group relative to the population average. The other factor was the average variable per diem adjustment factor of the group relative to the population average. In this calculation, average per diem costs equaled total NTA costs in the group divided by number of utilization days in the group. Similarly, the average variable per diem adjustment factor equaled the sum of NTA variable per diem adjustment factors for all utilization days in the group divided by the number of utilization days in the group. We calculated CMIs such that they equaled the ratio of relative average per diem costs for a group to the relative average variable per diem adjustment factor for the group. In this calculation, relative average per diem costs and the relative average variable per diem adjustment factor were weighted by length of stay to account for the different length of stay distributions across case-mix groups (as further discussed in section 3.11.1. of the SNF PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*). After calculating CMIs as described above, we then applied adjustments to ensure that the distribution of resources across payment components was aligned with the statutory base rates as discussed in section V.D.3.b. of the proposed rule. We also applied a parity adjustment by multiplying the CMIs by the ratio of case-mix-related payments in RUG–IV over estimated case-mix-related payments in PDPM, as further discussed in section V.J. of the proposed rule. More information on the variable per diem adjustment factor is discussed in section V.D.4. of the proposed rule. The full methodology used to develop CMIs is presented in section 3.11. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*).

TABLE 28—NTA CASE-MIX CLASSIFICATION GROUPS

NTA score range	NTA case-mix group	NTA case-mix index
12+	NA	3.25
9–11	NB	2.53
6–8	NC	1.85
3–5	ND	1.34
1–2	NE	0.96
0	NF	0.72

We stated in the proposed rule (83 FR 21059) that as with the previously discussed components, all residents would be classified into one and only one of these 6 NTA case-mix groups under the proposed PDPM. We explained that the proposed PDPM would create a separate payment component for NTA services, as opposed to combining NTA and nursing into one component as in the RUG–IV system. This separation would allow payment for NTA services to be based on resident characteristics that predict NTA resource utilization rather than nursing staff time. Thus, we stated that we believe the proposed NTA case-mix groups would provide a better measure of resource utilization and lead to more accurate payments under the SNF PPS.

We invited comments on the approach proposed above to classify residents for NTA payment under the proposed PDPM.

Commenters submitted the following comments related to the proposed rule's discussion of the classification of residents for NTA payment under the PDPM. A discussion of these comments, along with our responses, appears below.

Comment: A few commenters recommended CMS include additional conditions as comorbidities for NTA classification and payment, including: Parkinson's disease, non-refractory epilepsy/seizure disorders, and mental health conditions that bear a strong relationship to NTA utilization. One commenter recommended that CMS include all conditions associated with higher NTA costs, not only the 50 costliest comorbidities. Another commenter suggested implementing a periodic review process to update the NTA comorbidity list based on changes in care practices. One commenter recommended CMS add cardio-respiratory failure and shock, respiratory arrest, pulmonary fibrosis or other chronic lung disorders, oxygen therapy, and non-invasive ventilation (for example, BiPAP/CPAP) to the NTA comorbidity list, as these conditions/services reflect medical complexity and high acuity. Another commenter stated that NTA comorbidities should include wound care and all pressure ulcers, not only stage 4 pressure ulcers.

Response: As described in section 3.7.1 of the SNF PDPM technical report, we investigated a broad list of conditions and services as potential NTA comorbidities, defined using MDS items, ICD–10–CM diagnoses, and CCs and RxCCs from the Medicare Parts C and D risk adjustment models. We used MDS item I5300 to identify residents with Parkinson's disease, RxCC 164 to identify residents with non-refractory epilepsy, CC 84 to identify residents with cardio-respiratory failure and shock, CC 83 to identify residents with respiratory arrest, CC 112 and RxCC 227 to identify residents with pulmonary fibrosis or other chronic lung disorders, MDS item M1200F to identify residents receiving wound care, and MDS item M0300X1 to identify residents with a pressure ulcer. For mental health conditions, we used RxCC 135 to identify residents with anxiety, RxCC 133 to identify residents with specified anxiety, personality, and behavior disorders, RxCC 132 and 134 to identify residents with depression, CC 58 to identify residents with Major Depressive, Bipolar, and Paranoid Disorder, CC 57, RxCC 130 to identify

residents with schizophrenia, CC 54 to identify residents with drug or alcohol psychosis, and CC 55 to identify residents with drug or alcohol dependence. Neither Parkinson's disease, non-refractory epilepsy, pulmonary fibrosis or other chronic lung disorders, nor any mental health condition were among the top 50 costliest conditions/services in terms of NTA utilization. Non-refractory epilepsy was associated with an increase of about $1.60 in NTA costs per day, while Parkinson's disease was associated with an increase of about $2.50 in NTA costs per day and pulmonary fibrosis or other chronic lung disorders were associated with an increase of about $4 per day in NTA costs. Wound care was associated with an increase of about $2 in NTA costs per day, while stage 3 pressure ulcers (the next highest level of severity after stage 4) were associated with an increase of about $1 in NTA costs per day. Among mental health conditions, major depression was the most costly and associated with an increase of about $4 per day in NTA costs. The other mental health conditions were associated with less than $2 in NTA costs per day. In contrast, the least costly comorbidity included in the final list of included comorbidities for NTA classification and payment was associated with an increase of about $4.50 in NTA costs per day. Therefore, these conditions were not included as NTA comorbidities. On the other hand, cardio-respiratory failure and shock, as well as respiratory arrest were found to be among the 50 costliest conditions in terms of NTA utilization. Therefore, these two conditions were included in the final list of NTA comorbidities. As for oxygen therapy and non-invasive ventilation such as BiPAP and CPAP, clinicians advised CMS that it was not appropriate to include these services in the payment model because their inclusion would likely lead to inappropriate provision of these services in excess of clinical need. We do not believe it is appropriate to include conditions/services that do not have a notable impact on NTA costs per day, and therefore, we only included the 50 costliest comorbidities.

Comment: A commenter states that the points assigned to ventilator care should be much higher because this service requires 24-hour assistance. Additionally, this commenter requests CMS modify the term ''ventilator/respirator'' to only ''ventilator'' as the term ''respirator'' is outdated. Another commenter recommended further evaluation of the proposed point assignment, particularly for pressure ulcers, diabetic ulcers, respiratory failure, severe burns, multi-drug resistant organisms, and morbid obesity. According to the commenter, these items require higher resource utilization compared to other conditions/services that are assigned the same number of points.

Response: As described in section 3.7.1 of the SNF PDPM technical report, after determining the 50 costliest comorbidities in terms of NTA utilization, we ran an OLS regression to estimate the increase in NTA costs associated with each included condition or service. We then assigned points to each condition/service in proportion to the associated increase in NTA costs by dividing the coefficient for each condition or service by 10 and then rounding to the nearest integer. Based on this procedure, we assigned 4 points to ventilator/respirator care to reflect our finding that this service was associated with an increase of about $40 in NTA costs per day. Using the same procedure, we assigned 1 point to stage 4 pressure ulcers, diabetic foot ulcers, respiratory failure, severe burns, multi-drug resistant organisms, and morbid obesity as each of these conditions was associated with an increase of roughly $10 in NTA costs per day. Therefore, our analysis does not support increasing the points assigned to these services. The nomenclature used to refer to ventilator/respirator care under PDPM is consistent with the description of this service on the current version of the MDS 3.0 assessment. We appreciate the feedback on the appropriateness of the current name and will consider modifying the name of this item as appropriate to reflect current usage.

Comment: One commenter states that given the theoretical maximum NTA score is 83, the highest NTA score bin should not be 12+. This commenter suggests creating additional score bins at the upper end of the score, such as 12–14, 15–17, and 18+, to more accurately reflect residents with highly complex conditions and multiple extensive services.

Response: While it is true that some stays have very high NTA costs, we find that stays with an NTA comorbidity score of 12 or above are very rare (about 1 percent of all stays). As the number of stays included in each group declines, the magnitude of the standard error associated with the estimate of a group's resource utilization increases, raising concerns about the precision of these estimates. For the foregoing reasons, we do not believe it is appropriate to add additional NTA groups to include residents with extraordinarily high NTA utilization at this time. We will also consider revisiting both the list of included NTA comorbidities and the points assigned to each condition/service based on changes in the resident population and care practices over time.

Comment: Another commenter expressed concern that NTA costs, especially high-cost cases, are impossible to predict through use of existing administrative data due to the small sample size of these high-cost outliers. Since PDPM was developed on data that may fail to account for high-cost outliers, the commenter believes that PDPM is not sufficient to explain NTA utilization and will underpay the actual high-cost cases that cannot be predicted. One commenter questioned the validity of current NTA data, stating that providers do not accurately record NTA costs because these services are not important determinants of payment under RUG–IV. As a result, current data may underestimate NTA costs. Therefore, PDPM may not accurately reimburse NTA utilization.

Response: As shown in section 3.7.1 of the SNF PDPM technical report, average NTA costs per day by comorbidity score varies from around $30 to near $180, which indicates the data being used captures great variations of NTA costs and includes many expensive cases. The NTA comorbidity list as shown in Table 27 of the proposed rule (83 FR 21058) captures comorbidities and services with high NTA costs. Moreover the selected comorbidities and services meet clinical expectations of conditions that are expected to require high NTA utilization. Although the data available may be limited in capturing high-cost cases due to the small sample size of less common comorbidities, the proposed rule (83 FR 21073 through 21077) and section 3.12 of the SNF PDPM technical report show that payments for beneficiaries with high NTA costs will increase notably under PDPM compared with RUG IV. In particular, our impact analysis finds that payment increases by 27.2 percent for residents with 12 or more conditions under PDPM compared to RUG–IV.

Regarding the concern that current administrative data may not fully capture NTA utilization for the SNF population, first, as described in Section 3.2.2. of the SNF PDPM technical report, we checked the quality of self-reported NTA utilization data by comparing charges from cost reports and charges from claims and verifying that these were generally consistent. Second, we used four years of data (FYs 2014–2017) to identify the conditions and services associated with high NTA utilization and assign points to these comorbidities

reflective of their impact on resource use. Using several years of data addresses a key concern of commenters responding to the 2017 ANPRM and ensures a higher level of robustness compared to using a single year of data. Third, if NTA utilization is indeed underreported overall, this should not affect relative NTA resource use across different types of residents, therefore PDPM should still assign payment appropriately based on observed relative differences in NTA utilization. Fourth, clinicians reviewed the proposed NTA classification and verified that it accords with clinical expectations regarding conditions and services that are associated with high NTA utilization. Finally, as SNF care practices and reporting patterns change in response to the new payment model and other factors, we will consider revising elements of PDPM, including the NTA comorbidities, to reflect changes in relative resource use.

Comment: One commenter requested clarification on the NTA comorbidity list change from RCS–I to PDPM.

Response: The change in the comorbidity list from RCS–I to PDPM is due to the following: first, we used 4 years of data (FY2014–FY2017) under PDPM instead of a single year of data under RCS–I to make the list more robust to changes in the SNF population and care practices over time; second, we added Part D condition categories to better capture conditions associated with high medication costs; finally, we expanded the list to the top 50 comorbidities to include more conditions.

Comment: One commenter recommended that PDPM include an NTA default category to accommodate new conditions and services for greater flexibility.

Response: We are not clear on how such a default category would operate, nor what level of reimbursement would be appropriate to set for the addition of new conditions and services. We would need additional information on how such a default category could be constructed.

Comment: One commenter expressed concern regarding access to novel therapies, and encouraged CMS to consider adding a new technology add-on payment, similar to that done for inpatient hospitals, and make additional payments to SNFs when new treatment options become available. One commenter also stated that PDPM does not account for new classes of expensive medications.

Response: The points associated with each NTA comorbidity under the PDPM are based on existing cost data, which may be updated in future years to reflect the costs of new technologies and treatments or new classes of medications. Rather than merely incentivizing new treatments, we expect providers to utilize the best treatments for a given patient, which may or may not be more costly than existing treatments. Further, we note that the inpatient hospital PPS's new technology add-on payment is specifically authorized by sections 1886(d)(5)(K) and (L) of the Act, whereas no similar statutory authority exists under the SNF PPS.

Comment: One commenter expressed concern that using a patient's NTA score as a first tier classification criterion could put providers at risk of late or missing IPAs.

Response: As discussed in section V.D of this final rule, the IPA would be an optional assessment and, as such, not susceptible to late or missed assessment penalties.

Accordingly, after considering the comments received, for the reasons discussed in the proposed rule and in this final rule, we are finalizing the proposed NTA component of the PDPM and the proposed classification methodology for the NTA component, without modification.

f. Payment Classifications Under PDPM

RUG–IV classifies each resident into a single RUG, with a single payment for all services. By contrast, the PDPM classifies each resident into five components (PT, OT, SLP, NTA, and nursing) and provide a single payment based on the sum of these individual classifications. The payment for each component would be calculated by multiplying the CMI for the resident's group first by the component federal base payment rate, then by the specific day in the variable per diem adjustment schedule (as discussed in section V.D.4 of the proposed rule and in section V.D.4 of this final rule). Additionally, for residents with HIV/AIDS indicated on their claim, the nursing portion of payment would be multiplied by 1.18 (as discussed in section V.D.3.d. of the proposed rule and section V.H of this final rule). These payments would then be added together along with the non-case-mix component payment rate to create a resident's total SNF PPS per diem rate under the PDPM. This section describes how two hypothetical residents would be classified into payment groups under the current RUG–IV model and PDPM. To begin, consider two residents, Resident A and Resident B, with the resident characteristics identified in Table 29.

TABLE 29—HYPOTHETICAL RESIDENT CHARACTERISTICS

Resident characteristics	Resident A	Resident B
Rehabilitation Received?	Yes	Yes.
Therapy Minutes	730	730.
Extensive Services	No	No.
ADL Score	9	9.
Clinical Category	Acute Neurologic	Major Joint Replacement.
PT and OT Function Score	10	10.
Nursing Function Score	7	7.
Cognitive Impairment	Moderate	Intact.
Swallowing Disorder?	No	No.
Mechanically Altered Diet?	Yes	No.
SLP Comorbidity?	No	No.
Comorbidity Score	7 (IV Medication and DM)	1 (Chronic Pancreatitis).
Other Conditions	Dialysis	Septicemia.
Depression?	No	Yes.

Currently under the SNF PPS, Resident A and Resident B would be classified into the same RUG–IV group. They both received rehabilitation, did not receive extensive services, received 730 minutes of therapy, and have an

ADL score of 9. This places the two residents into the ''RUB'' RUG–IV group and SNFs would be paid at the same rate, despite the many differences between these two residents in terms of their characteristics, expected care needs, and predicted costs of care.

Under the PDPM, however, these two residents would be classified very differently. With regard to the PT and OT components, Resident A would fall into group TO, as a result of his categorization in the Acute Neurologic group and a function score within the 10 to 23 range. Resident B, however, would fall into group TC for the PT and OT components, as a result of his categorization in the Major Joint Replacement group and a function score within the 10 to 23 range. For the SLP component, Resident A would be classified into group SH, based on his categorization in the Acute Neurologic group, the presence of moderate cognitive impairment, and the presence of Mechanically-Altered Diet, while Resident B would be classified into group SA, based on his categorization in the Non-Neurologic group, the absence of cognitive impairment or any SLP-related comorbidity, and the lack of any swallowing disorder or mechanically-altered diet. For the Nursing component, following the existing nursing case-mix methodology, Resident A would fall into group LBC1, based on his use of dialysis services and a nursing function score of 7, while Resident B would fall into group HBC2, due to the diagnosis of septicemia, presence of depression, and a nursing function score of 7. Finally, with regard to NTA classification, Resident A would be classified in group NC, with an NTA score of 7, while Resident B would be classified in group NE, with an NTA score of 1. This demonstrates that, under the PDPM, more aspects of a resident's unique characteristics and needs factor into determining the resident's payment classification, which makes for a more resident-centered case-mix model while also eliminating, or greatly reducing, the number of service-based factors which are used to determine the resident's payment classification. Because this system is based on specific resident characteristics predictive of resource utilization for each component, we expect that payments will be better aligned with resident need.

4. Variable per Diem Adjustment Factors and Payment Schedule

Section 1888(e)(4)(G)(i) of the Act provides that payments must be adjusted for case mix, based on a resident classification system which accounts for the relative resource utilization of different types of residents. Additionally, section 1888(e)(1)(B) of the Act specifies that payments to SNFs through the SNF PPS must be made on a per-diem basis. Currently under the SNF PPS, each RUG is paid at a constant per diem rate, regardless of how many days a resident is classified in that particular RUG. However, we explained in the proposed rule (83 FR 21060) that during the course of the SNF PMR project, analyses on cost over the stay for each of the case-mix adjusted components revealed different trends in resource utilization over the course of the SNF stay. These analyses utilized costs derived from claim charges as a measure of resource utilization. Costs were derived by multiplying charges from claims by the CCRs on facility-level costs reports. As described in section V.B.3.b. of the proposed rule, costs better reflect differences in the relative resource use of residents as opposed to charges, which partly reflect decisions made by providers about how much to charge payers for certain services. In examining costs over a stay, we stated we found that for certain categories of SNF services, notably PT, OT and NTA services, costs declined over the course of a stay. Based on the claim submission schedule and variation in the point during the month when a stay began, we were able to estimate resource use for a specific day in a stay. Facilities are required to submit monthly claims. Each claim covers the period from the first day during the month a resident is in the facility to the end of the month. If a resident was admitted on the first day of the month, remains in the facility, and continues to have Part A SNF coverage until the end of the month, the claim for that month will include all days in the month. However, if a resident is admitted after the first day of the month, the first claim associated with the resident's stay will be shorter than a month. We stated in the proposed rule that to estimate resource utilization for each day in the stay, we used the marginal estimated cost from claims of varying length based on random variation in the day of a month when a stay began. Using this methodology, we observed a decline in the marginal estimated cost of each additional day of SNF care over the course of the stay. We further stated that to supplement this analysis, we also looked at changes in the number of therapy minutes reported in different assessments throughout the stay. Because therapy minutes are recorded on the MDS, the presence of multiple assessments throughout the stay provided information on changes in resource use. For example, it was clear whether the number of therapy minutes a resident received changed from the 5-day assessment to the 14-day assessment. We explained that the results from this analysis were consistent with the cost from claims analysis and showed that, on average, the number of therapy minutes is lower for assessments conducted later in the stay. This finding was consistent across different lengths of stay. More information on these analyses can be found in section 3.9. of the SNF PDPM technical report and section 3.9. of the SNF PMR technical report that accompanied the ANPRM, both available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*.

As discussed in the proposed rule (83 FR 21060 through 21061), analyses of the SLP component revealed that the per diem costs remain relatively constant over time, while the PT, OT, and NTA component cost analyses indicate that the per diem cost for these three components decline over the course of the stay. We stated in the proposed rule that in the case of the PT and OT components, costs start higher at the beginning of the stay and decline slowly over the course of the stay. By comparison, the NTA component cost analyses indicated significantly increased NTA costs at the beginning of a stay that then drop to a much lower level that holds relatively constant over the remainder of the SNF stay. This is consistent with how most SNF drug costs are typically incurred at the outset of a SNF stay. We stated that these results indicate that resource utilization for PT, OT, and NTA services changes over the course of the stay. More information on these analyses can be found in section 3.9.1. of the SNF PMR technical report that accompanied the ANPRM available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*. As we stated in the proposed rule, we were unable to assess potential changes in the level of nursing costs over a resident's stay, in particular because nursing charges are not separately identifiable in SNF claims, and nursing minutes are not reported on the MDS assessments. However, stakeholders (industry representatives and clinicians) at multiple TEPs indicated that nursing costs tend to remain relatively constant over the course of a resident's stay.

We explained in the proposed rule that constant per diem rates, by

definition, do not track variations in resource use throughout a SNF stay. We stated we believe this may lead to too few resources being allocated for SNF providers at the beginning of a stay. Given the trends in resource utilization over the course of a SNF stay discussed above, and that section 1888(e)(4)(G)(i) of the Act requires the case-mix classification system to account for relative resource use, we proposed adjustments to the PT, OT, and NTA components in the proposed PDPM to account for changes in resource utilization over a stay. These adjustments were referred to as the variable per diem adjustments. We did not propose such adjustments to the SLP and nursing components based on findings and stakeholder feedback, as discussed above, that resource use tends to remain relatively constant over the course of a SNF stay.

As noted above and in the proposed rule (83 FR 21061), and discussed more thoroughly in section 3.9. of the SNF PMR technical report that accompanied the ANPRM (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*), PT and OT costs decline at a slower rate than the decline in NTA costs. Therefore, in addition to proposing a variable per diem adjustment, we further proposed separate adjustment schedules and indexes for the PT and OT components and the NTA component to reflect more closely the rate of decline in resource utilization for each component. Table 30 of the proposed rule provided the adjustment factors and schedule that we proposed for the PT and OT components, while Table 31 of the proposed rule provided the adjustment factors and schedule that we proposed for the NTA component.

In Table 30 of the proposed rule, the adjustment factor for the PT and OT components was 1.00 for days 1 to 20. We explained that this was because the analyses described above indicated that PT and OT costs remain relatively high for the first 20 days and then decline. The estimated daily rates of decline for PT and OT costs relative to the initial 20 days were both 0.3 percent. Thus, we stated that a convenient and appropriate way to reflect this was to bin days in the PT and OT variable per diem adjustment schedules such that payment declines at less frequent intervals, while still reflecting a 0.3 percent daily rate of decline in PT and OT costs. Therefore, we proposed to set the adjustment factors such that payment would decline 2 percent every 7 days after day 20 (0.3 * 7 = 2.1). We explained that the 0.3 percent rate of decline was derived from a regression model that estimates the level of resource use for each day in the stay relative to the beginning of the stay. The regression methodology and results are presented in section 3.9. of the SNF PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*.

As described previously in this section and in the proposed rule (83 FR 21061), NTA resource utilization exhibits a somewhat different pattern. The analyses described above indicate that NTA costs are very high at the beginning of the stay, drop rapidly after the first 3 days, and remain relatively stable from the fourth day of the stay. We stated that starting on day 4 of a stay, the per diem costs drop to roughly one-third of the per diem costs in the initial 3 days. We explained that this suggests that many NTA services are provided in the first few days of a SNF stay. Therefore, we proposed setting the NTA adjustment factor to 3.00 for days 1 to 3 to reflect the extremely high initial costs, then setting it at 1.00 (two-thirds lower than the initial level) for subsequent days. We explained that the value of the adjustment factor was set at 3.00 for the first 3 days and 1.00 after (rather than, for example, 1.00 and 0.33, respectively) for simplicity. The results are presented in section 3.9. of the SNF PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*.

As we described in the proposed rule (83 FR 21061), case-mix adjusted federal per diem payment for a given component and a given day would be equal to the base rate for the relevant component (either urban or rural), multiplied by the CMI for that resident, multiplied by the variable per diem adjustment factor for that specific day, as applicable. Additionally, as described in further detail in section V.D.3.d. of the proposed rule, we stated that an additional 18 percent would be added to the nursing per-diem payment to account for the additional nursing costs associated with residents who have HIV/AIDS. We further explained that these payments would then be added together along with the non-case-mix component payment rate to create a resident's total SNF PPS per diem rate under the proposed PDPM. We invited comments on the proposed variable per diem adjustment factors and payment schedules discussed in this section.

Commenters submitted the following comments related to the proposed rule's discussion of the variable per diem adjustment factors and payment schedules. A discussion of these comments, along with our responses, appears below.

Comment: Some commenters supported the use of the variable per diem adjustment under PDPM. Several commenters stated that PDPM, specifically the variable per diem payment adjustments included in the PT, OT, and NTA components, may negatively affect access for beneficiaries with long stays and complex medical needs. These commenters stated that the variable per diem payment adjustments will encourage early discharges and the provision of fewer services. One commenter stated that residents with chronic conditions may not exhibit a trend of declining NTA utilization over a stay and that resource utilization for these patients is sustained at a relatively constant level throughout the stay. The commenter states that in these cases, variable per diem payment adjustments will incentivize facilities to provide less expensive medications later in the stay, which the commenter states may be harmful to the patient. Finally, one commenter seeks clarification on the rationale for beginning the decline in payment for the PT and OT components after day 20 of a stay.

Response: We note that we investigated the impact of PDPM on various resident subpopulations, including residents with many expensive comorbidities, multiple extensive services, severe cognitive impairment, long stays (utilization days = 100), stroke, IV medication, diabetes, wound infection, amputation/prosthesis care, Alzheimer's, or the presence of addictions, bleeding disorders, behavioral issues, chronic neurological conditions, or bariatric care. CMS investigated the potential impact of the proposed payment model on these subpopulations based on comments received in response to the 2017 ANPRM. For almost all of these subpopulations with complex medical needs, we found that PDPM is estimated to increase payment associated with these residents compared to RUG–IV, as discussed in the proposed rule (83 FR 21075) and section 3.12 of the SNF PDPM technical report. Thus, we do not believe the variable per diem payment will negatively affect access for beneficiaries with expensive comorbidities or complex medical needs. We estimated that payment associated with very long stays (utilization = 100 days) would decline by 1.9 percent under PDPM, and we obtained similar results for stays longer than 90 days. However, this decline in payment is a reflection of the lower resource utilization per day associated

with longer stays. We observed that stays longer than 90 days have lower therapy and NTA costs per day than their shorter counterparts. However, the majority of such long stays are categorized as ultra-high rehabilitation groups in the current case-mix classification suggesting potential overpayment. Nevertheless, given the potential payment reduction for long stays, we plan to monitor provider behavior closely to identify facilities whose beneficiaries experience inappropriate early discharge or provision of fewer services.

Regarding the concern about resource utilization patterns of residents with chronic conditions, we would note that as discussed above, we estimated that PDPM would actually increase overall per-stay payment for many resident subpopulations with chronic conditions. Further, while payment would be highest during the early part of a stay, facilities would have flexibility to allocate this payment to cover costs later in a stay, as they do now. Our research, discussed in the proposed rule (83 FR 21061) and section 3.9 of the SNF PDPM technical report, revealed that for the average SNF stay, NTA utilization declines dramatically after the first 3 days of a stay. Of course, we acknowledge that there are cases that may not match this resource utilization pattern exactly. However, we believe that PDPM, because it is based on the observed relationship between patient characteristics and resource utilization, represents an improvement over the current payment model in terms of payment accuracy. Further, as stated, our investigations show that for many of the specific cases cited by commenters as potential concerns, we expect PDPM actually to increase associated payment compared to RUG–IV. While the variable per diem schedule decreases pay throughout the stay, the overall increase in payment accounts for the treatment cost of chronic conditions, which is costly due to the sustained level of care needed to manage chronic conditions.

As discussed in the proposed rule (83 FR 21060 through 21061) and section 3.9 of the SNF PDPM technical report, we developed a methodology to estimate per-diem resource use over a stay for PT, OT, and NTA. Based on this methodology, we observed that estimated per-diem PT and OT costs remain high for the first 20 days of a stay and decline thereafter. Therefore, we established a variable per diem payment adjustment schedule for the PT and OT components that begins to adjust payment downward beginning on day 21.

Comment: Some commenters suggested that CMS consider creating a waiver from the variable per diem adjustment for NTAs to mitigate potential access issues for patients in SNF stays that exceed 90 days. Additionally, these commenters expressed concern that, for long stays, the variable per diem payment adjustment may erode payments to the point where payment for the stay is below the cost of providing the associated services. Some commenters believe that decreasing payment for PT and OT over the course of the stay without exceptions is not patient-centered and urged CMS to identify certain diagnoses associated with longer duration of high-intensity therapy services as exceptions to the variable per diem schedule. Several commenters requested clarification on if and how CMS intends to monitor the impact of the variable per diem adjustment on patient access and length of stay, expressing concerns that the variable per diem adjustment could have a disproportionate impact on patients with chronic conditions. Finally, one commenter believed that reducing payments over time through the variable per diem adjustment will reduce treatment options for stroke and trauma victims.

Response: With regard to the waiver for either the PT and OT variable per diem adjustment or the NTA variable per diem adjustment in cases of long stays, we do not believe that such a waiver is necessary. While payments do reduce over time, as discussed above, this reduction is to reflect the decrease in patient costs over time. Therefore, given the parallel reductions in costs and payments, over the course of the stay, providers should be adequately reimbursed for the provision of care, even in cases of long stays. With regard to the commenters' concern regarding the impact on stroke and trauma patients, as well as those with chronic conditions, we do plan to monitor closely these types of SNF patients under PDPM to identify any adverse trends which may result from application of the variable per diem adjustment. That being said, given that we proposed to implement PDPM in a budget neutral manner, this means that while the overall sum of monies paid out under the SNF benefit would not change under PDPM, the allocation and distribution of that money to individual SNFs could change. Given that PT, OT, and NTA costs at the beginning of a stay tend to be higher than those at the middle or end of a stay, most notably in the case of long stay patients, maintaining a constant per diem rate will allocate too few funds at the beginning of the stay, thereby increasing the chance that the early portions of a stay may not be adequately reimbursed. By aligning the payments with the cost trends, this produces the best chance to ensure that providers receive adequate and appropriate reimbursement at every point in the stay. Finally, as stated above, we do plan to monitor the impact of this policy and may consider revisions to the policy if there is evidence of adverse trends either systemically or within certain patient populations.

Comment: One commenter questioned if CMS would expect the variable per diem adjustment to continue until the payment reaches zero, for purposes of calculating the UPL for the PT and OT components.

Response: As the variable per diem adjustment was developed based on Medicare Part A data, we cannot speak to the ability of the adjustment factor to be drawn out past the point of the Medicare Part A stay. Moreover, as coverage for a Medicare Part A stay cannot be longer than 100 days, the variable per diem adjustment, for purposes of calculating the UPL, would go as far as Day 100 in Table 30.

Accordingly, after considering the comments received, for the reasons discussed in the proposed rule and in this final rule, we are finalizing our proposal without modification to apply a variable per diem adjustment as part of the PDPM effective October 1, 2019. Table 30 sets forth the final PDPM Variable Per Diem Payment Adjustment Factors and Schedule for the PT and OT components, and Table 31 sets for the final PDPM Variable Per Diem Payment Adjustment Factors and Schedule for the NTA component.

TABLE 30—VARIABLE PER-DIEM ADJUSTMENT FACTORS AND SCHEDULE—PT AND OT

Medicare payment days	Adjustment factor
1–20	1.00
21–27	0.98
28–34	0.96
35–41	0.94
42–48	0.92
49–55	0.90
56–62	0.88
63–69	0.86
70–76	0.84
77–83	0.82
84–90	0.80
91–97	0.78
98–100	0.76

TABLE 31—VARIABLE PER-DIEM ADJUSTMENT FACTORS AND SCHEDULE—NTA

Medicare payment days	Adjustment factor
1–3	3.0
4–100	1.0

D. Use of the Resident Assessment Instrument—Minimum Data Set, Version 3

1. Revisions to Minimum Data Set (MDS) Completion Schedule

Consistent with section 1888(e)(6)(B) of the Act, to classify residents under the SNF PPS, we use the MDS 3.0 Resident Assessment Instrument. Within the SNF PPS, there are two categories of assessments, scheduled and unscheduled. In terms of scheduled assessments, SNFs are currently required to complete assessments on or around days 5, 14, 30, 60, and 90 of a resident's Part A SNF stay, including certain grace days. Payments based on these assessments depend upon standard Medicare payment windows associated with each scheduled assessment. More specifically, each of the Medicare-required scheduled assessments has defined days within which the Assessment Reference Date (ARD) must be set. The ARD is the last day of the observation (or ''look-back'') period that the assessment covers for the resident. The facility is required to set the ARD on the MDS form itself or in the facility software within the appropriate timeframe of the assessment type being completed. The clinical data collected from the look-back period is used to determine the payment associated with each assessment. For example, the ARD for the 5-day PPS Assessment is any day between days 1 to 8 (including Grace Days). The clinical data collected during the look-back period for that assessment is used to determine the SNF payment for days 1 to 14. Unscheduled assessments, such as the Start of Therapy (SOT) Other Medicare Required Assessment (OMRA), the End of Therapy OMRA (EOT OMRA), the Change of Therapy (COT) OMRA, and the Significant Change in Status Assessment (SCSA or Significant Change), may be required during the resident's Part A SNF stay when triggered by certain defined events.

For example, if a resident is being discharged from therapy services, but remaining within the facility to continue the Part A stay, then the facility may be required to complete an EOT OMRA. Each of the unscheduled assessments affects payment in different and defined manners. A description of the SNF PPS scheduled and unscheduled assessments, including the criteria for using each assessment, the assessment schedule, payment days covered by each assessment, and other related policies, are set forth in the MDS 3.0 RAI manual on the CMS website (available at *https://downloads.cms.gov/files/MDS-30-RAI-Manual-v115-October-2017.pdf*).

Table 32 outlines when each of the current SNF PPS assessments is required to be completed and its effect on SNF PPS payment.

TABLE 32—CURRENT PPS ASSESSMENT SCHEDULE

Medicare MDS assessment schedule type	Assessment reference date	Assessment reference date grace days	Applicable standard medicare payment days
Scheduled PPS assessments			
5-day	Days 1–5	6–8	1 through 14.
14-day	Days 13–14	15–18	15 through 30.
30-day	Days 27–29	30–33	31 through 60.
60-day	Days 57–59	60–63	61 through 90.
90-day	Days 87–89	90–93	91 through 100.
Unscheduled PPS assessments			
Start of Therapy OMRA	5–7 days after the start of therapy	Date of the first day of therapy through the end of the standard payment period.	
End of Therapy OMRA	1–3 days after all therapy has ended.	First non-therapy day through the end of the standard payment period.	
Change of Therapy OMRA	Day 7 (last day) of the COT observation period.	The first day of the COT observation period until end of standard payment period, or until interrupted by the next COT–OMRA assessment or scheduled or unscheduled PPS Assessment.	
Significant Change in Status Assessment.	No later than 14 days after significant change identified.	ARD of Assessment through the end of the standard payment period.	

As we explained in the proposed rule (83 FR 21062), an issue which has been raised in the past with regard to the existing SNF PPS assessment schedule is that the sheer number of assessments, as well as the complex interplay of the assessment rules, significantly increases the administrative burden associated with the SNF PPS. We stated that case-mix classification under the proposed SNF PDPM relies to a much lesser extent on characteristics that may change very frequently over the course of a resident's stay (for example, therapy minutes may change due to resident refusal or unexpected changes in resident status), but instead relies on more stable predictors of resource utilization by tying case-mix classification, to a much greater extent, to resident characteristics such as diagnosis information. We explained that in view of the greater reliance of the proposed SNF PDPM (as compared to the RUG–IV model) on resident characteristics that are relatively stable over a stay and our general focus on reducing administrative burden for providers across the Medicare program, we are making an effort to reduce the administrative burden on providers by concurrently proposing to revise the assessments that would be required under the proposed SNF PDPM. Specifically, we proposed to use the 5-day SNF PPS scheduled assessment to classify a resident under the proposed SNF PDPM for the entirety of his or her Part A SNF stay effective beginning FY

2020 in conjunction with the implementation of the proposed PDPM, except as described below. We stated that if we were to finalize this proposal, we would propose revisions to the regulations at § 413.343(b) during the FY 2020 rulemaking cycle so that such regulations would no longer reflect the RUG–IV SNF PPS assessment schedule as of the proposed conversion to the PDPM on October 1, 2019.

We also stated in the proposed rule (83 FR 21062) that we understand Medicare beneficiaries are each unique and can experience clinical changes which may require a SNF to reassess the resident to capture changes in the resident's condition. Therefore, to allow SNFs to capture these types of changes, effective October 1, 2019 in conjunction with the proposed implementation of the PDPM, we proposed to require providers to reclassify residents as appropriate from the initial 5-day classification using a new assessment called an Interim Payment Assessment (IPA), which would be comprised of the 5-day SNF PPS MDS Item Set (Item Set NP). We stated that providers would be required to complete an IPA in cases where the following two criteria are met:

(1) There is a change in the resident's classification in at least one of the first tier classification criteria for any of the components under the proposed PDPM (which are those clinical or nursing payment criteria identified in the first column in Tables 21, 23, 26, and 27 of the proposed rule), such that the resident would be classified into a classification group for that component that differs from that provided by the 5-day scheduled PPS assessment, and the change in classification group results in a change in payment either in one particular payment component or in the overall payment for the resident; and

(2) The change(s) are such that the resident would not be expected to return to his or her original clinical status within a 14-day period.

In addition, we proposed that the Assessment Reference Date (ARD) for the IPA would be no later than 14 days after a change in a resident's first tier classification criteria is identified. We stated that the IPA is meant to capture substantial changes to a resident's clinical condition and not everyday, frequent changes. We believe 14 days gives the facility an adequate amount of time to determine whether the changes identified are in fact routine or substantial. To clarify, we explained that the change in classification group described above refers not only to a change in one of the first tier classification criteria in any of the proposed payment components, but also to one that would be sufficient to change payment in either one component or in the overall payment for the resident. For example, we stated that given the collapsed categories under the PT and OT components, this would mean that a change from the medical management group to the cancer group would not necessitate an IPA, as they are both collapsed under the medical management group for purposes of the PT and OT components. However, we stated a change from the major joint replacement group to the medical management group would necessitate an IPA, as this would change the resident's clinical category group for purposes of categorization under the PT and OT components and would result in a change in payment.

We stated that we believe the proposed requirement to complete an IPA balances the need to ensure accurate payment and monitor for changes in the resident's condition with the importance of ensuring a more streamlined assessment approach under the proposed PDPM.

In cases where the IPA is required and a facility fails to complete one, we proposed that the facility would follow the guidelines for late and missed unscheduled MDS assessments which are explained in Chapters 2.13 and 6.8 of the MDS RAI Manual (*https://downloads.cms.gov/files/MDS-30-RAI-Manual-v115-October-2017.pdf*). Specifically, we stated in the proposed rule (83 FR 21063) that if the SNF fails to set the ARD within the defined ARD window for an IPA, and the resident is still in a Part A stay, the SNF would be required to complete a late assessment. The ARD can be no earlier than the day the error was identified. We explained that if the ARD on the late assessment is set for a date that is prior to the end of the time period during which the assessment would have controlled the payment, had the ARD been set timely, the SNF would bill the default rate for the number of days that the assessment is out of compliance. This is equal to the number of days between the day following the last day of the available ARD window and the late ARD (including the late ARD). We provided an example where a SNF Part A resident, who is in the major joint replacement payment category for the PT and OT components, develops a skin ulcer of such a nature that, in terms of developing a care and treatment plan for this resident, the skin ulcer takes precedence as the resident's primary diagnosis. As a result, the resident's primary diagnosis, as coded in item I8000, is for this skin ulcer, which would cause him to be classified into the medical management category for these components. The facility notes this clinical change on November 10, 2018. However, they do not complete the IPA until November 26, 2018 which is 16 days after the change in criteria was identified and two days after the ARD window. The facility would bill the default rate for the two days that it was out of compliance. We stated that if the SNF fails to set the ARD for an IPA within the defined ARD window for that assessment, and the resident has been discharged from Part A, the assessment is missed and cannot be completed. We noted that all days that would have been paid by the missed assessment (had it been completed timely) are considered provider-liable. Taking the example above, we stated that if the facility recognized the IPA needed to be completed after the resident has left the building, the facility would be liable for all days from November 10, 2018 until the date of the resident's Part A Discharge.

In addition to proposing to require completion of the IPA as described above, we also considered the implications of a SNF completing an IPA on the variable per diem adjustment schedule described in section V.D.4. the proposed rule. More specifically, in the proposed rule, we considered whether an SNF completing an IPA should cause a reset in the variable per diem adjustment schedule for the associated resident. In examining costs over a stay, we found that for certain categories of SNF services, notably PT, OT, and NTA services, costs declined over the course of a stay. Our analyses showed that, on average, the number of therapy minutes is lower for assessments conducted later in the stay. Additionally, we stated that we were concerned that by providing for the variable per diem adjustment schedule to be reset after an IPA is completed, providers may be incentivized to conduct multiple IPAs during the course of a resident's stay to reset the variable per diem adjustment schedule each time the adjustment is reduced. Therefore, in cases where an IPA is completed, we proposed that this assessment would reclassify the resident for payment purposes as outlined in Table 33 of the proposed rule, but that the resident's variable per diem adjustment schedule would continue rather than being reset on the basis of completing the IPA.

Finally, we stated that believe, regardless of the payment system or case-mix classification model used, residents should continue to receive therapy that is appropriate to their care needs, and this includes both the

intensity and modes of therapy utilized. However, we recognized that because the initial 5-day PPS assessment would classify a resident for the entirety of his or her Part A SNF stay (except in cases where an IPA is completed) as outlined above, there would be no mechanism by which SNFs are required to report the amount of therapy provided to a resident over the course of the stay or by which we may monitor that they are in compliance with the proposed 25 percent group and concurrent therapy limit as described in section V.F. of the proposed rule. Therefore, for these reasons, under the proposed PDPM, we proposed to require that SNFs continue to complete the PPS Discharge Assessment, as appropriate (including the proposed therapy items discussed in section V.E.3. of the proposed rule), for each SNF Part A resident at the time of Part A or facility discharge (see section V.E. of this proposed rule for a discussion of our proposed revisions to this assessment to include therapy items). Under the current instructions in the MDS 3.0 RAI manual, the Part A PPS Discharge assessment is completed when a resident's Medicare Part A stay ends, but the resident remains in the facility (MDS 3.0 RAI Manual Chapter 2.5). However, we proposed to require this assessment to be completed at the time of facility discharge for Part A residents as well. Thus, we would continue to collect data on therapy provision as proposed in section V.F. of the proposed rule, to assure that residents are receiving therapy that is reasonable, necessary, and specifically tailored to meet their unique needs. We stated that we believe the combination of the 5-day Scheduled PPS Assessment, the IPA Assessment, and PPS Discharge Assessment would provide flexibility for providers to capture and report accurately the resident's condition, as well as accurately reflect resource utilization associated with that resident, while minimizing the administrative burden on providers under the proposed SNF PDPM.

In addition to these proposed changes, we also examined in the proposed rule (83 FR 21064) the current use of grace days in the MDS assessment schedule. Grace days have been a longstanding part of the SNF PPS. They were created in order to allow clinical flexibility when setting ARD dates of scheduled PPS assessments. In the FY 2012 final rule (76 FR 48519), we discussed that in practice, there is no difference between regular ARD windows and grace days and we encouraged the use of grace days if their use would allow a facility more clinical flexibility or would more accurately capture therapy and other treatments. Thus, we do not intend to penalize any facility that chooses to use the grace days for assessment scheduling or to audit facilities based solely on their regular use of grace days. We may explore the option of incorporating the grace days into the regular ARD window in the future; nevertheless, we will retain them as part of the assessment schedule at the present time consistent with the current policy and the new assessment schedule proposed in the proposed rule.

We proposed, effective beginning October 1, 2019, in conjunction with the proposed implementation of the PDPM, to incorporate the grace days into the existing assessment window. We explained that this proposal would eliminate grace days as such from the SNF PPS assessment calendar and provide for only a standard assessment window. We stated that, as discussed, there is no practical difference between the regular assessment window and grace days and there is no penalty for using grace days. Accordingly, we stated that we believe it would be appropriate to eliminate the use of grace days in PPS assessments.

Table 33 of the proposed rule, set forth at Table 33 of this final rule, sets forth the proposed SNF PPS assessment schedule, incorporating the proposed revisions discussed above, which we stated would be effective October 1, 2019 concurrently with the proposed PDPM.

TABLE 33—PPS ASSESSMENT SCHEDULE UNDER PDPM

Medicare MDS assessment schedule type	Assessment reference date	Applicable standard Medicare payment days
5-day Scheduled PPS Assessment	Days 1–8	All covered Part A days until Part A discharge (unless an IPA is completed).
Interim Payment Assessment (IPA)	No later than 14 days after change in resident's first tier classification criteria is identified.	ARD of the assessment through Part A discharge (unless another IPA assessment is completed).
PPS Discharge Assessment	PPS Discharge: Equal to the End Date of the Most Recent Medicare Stay (A2400C) or End Date.	N/A.

We noted in the proposed rule (83 FR 21064) that, as in previous years, we intend to continue to work with providers and software developers to assist them in understanding changes we proposed to the MDS. Further, we noted that none of the proposals related to changes to the MDS assessment schedule should be understood to change any assessment requirements which derive from the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), which establishes assessment requirements for all nursing home residents, regardless of payer. We invited comments on our proposals to revise the SNF PPS assessment schedule and related policies as discussed above.

We also solicited comment on the extent to which implementing these proposals would reduce provider burden.

Commenters submitted the following comments related to the proposed changes to the MDS assessment schedule and related assessment policies as discussed above. A discussion of these comments, along with our responses, appears below.

Comment: One commenter expressed approval of the proposal to incorporate grace days into the existing assessment window. This commenter agrees that this will simplify things and reduce burden, cost and time for providers. Many commenters agreed with using the 5-day assessment to establish per diem payment for the stay. However, several commenters were concerned that the timing of 5-day assessments may still be difficult for SNFs. These commenters stated that securing clinician sign off and all needed information, such as lab results, will be challenging for SNFs. Several commenters requested an allowance for 5-day assessments to be submitted up until Day 14 of a SNF stay.

Response: We appreciate the support for incorporating grace days into the existing assessment window and for using the 5-day assessment to establish per diem payment for the entirety of the stay, assuming that an IPA is not completed. Regarding the timing of the

5-day assessment under the current RUG–IV system, the 5-day assessment window (which goes until Day 8 of a SNF stay) is no different than that proposed under PDPM. FY 2017 MDS data show that almost 98 percent of 5-day assessments were completed timely. This demonstrates that facilities have been able to complete this assessment with minimal difficulty until now and we do not foresee the new system adding an amount of complexity that would prevent them from completing it going forward. Regarding the suggestion to allow providers to have until Day 14 to submit the initial assessment, we do not believe this is necessary or appropriate, given that, as the data above indicate, there is sufficient time for coding the 5-day assessment and because the 5-day assessment provides a snapshot of the resident closer to the point of admission.

Comment: One commenter questioned if on the 5-day Assessment a facility were to establish a RUG in the Ultra High category for a patient, would that RUG be maintained throughout the entire stay regardless of whether there is a drop in the amount of minutes of therapy provided in an assessment window.

Response: We would note that the proposed changes to the assessment schedule would take place upon implementation of PDPM, and under PDPM, patients would no longer be classified into RUG–IV categories. They would instead be classified into case mix groups (CMGs) based on PDPM classification as described in the proposed rule (83 FR 21034–21061). Once a patient is classified into a CMG, that payment group would be maintained through the entire stay unless an Interim Payment Assessment (IPA), as discussed below, is completed and reclassifies the patient into a different CMG.

Comment: Several commenters were concerned with the proposed reduction in payment assessments. They believe that the reduction in assessments could limit the ability of CMS and surveyors to track changes in status and progress of patients and reduce the amount of data CMS has available to use as a basis for future payment adjustments on. These commenters urged CMS to keep the existing PPS assessments as they are. Several commenters recommended that CMS revise the assessment period and ARD to align more closely with other PAC providers in order to implement standardized patient data elements as required by the IMPACT Act.

Response: We appreciate commenters' concern that a reduction in assessments could limit the ability of CMS and surveyors to track status changes and could reduce the amount of data available for use in future payment policy development. However, PDPM relies on stable characteristics that we do not expect to change significantly over the course of the stay. Therefore, additional SNF PPS payment assessments would not necessarily capture different data throughout the stay. Additionally, the OBRA assessment schedule will remain the same and those assessments would provide needed information and data for surveyors and research purposes. Moreover, if clinical characteristics do change, we would expect facilities to elect the option (as discussed further below) to complete the IPA to track these changes.

We appreciate the recommendation to revise the assessment period and ARD to align more closely with other PAC providers in order to implement standardized patient data elements required by the IMPACT Act. We believe that many of the policies being finalized as part of PDPM serve to improve alignment with other PAC settings such as the utilization of functional measures similar to those in IRFs, and the interrupted stay policy which is similar to the IRF and IPF policies, and we hope to continue to improve this alignment in future refinements. As such, we may consider these recommendations in the future.

Comment: Most commenters supported CMS reducing the number of assessments that are required for SNF payment. These commenters expressed that their support for the reduction of the number of payment assessments is due to burden relief and a desire to align with other PAC settings such as IRFs and Home Health that require far fewer patient assessments than SNFs require. One commenter was concerned that while the number of assessments have been reduced, the MDS itself has become more complex with new reporting requirements and items, leaving administrative burden unchanged. Additionally, most commenters conveyed confusion about the proposed IPA. The first area of confusion arose from which criteria CMS wants SNFs to use to determine whether an IPA needs to be completed. Commenters noted that in the proposed rule (83 FR 21063) we stated that there must be a change in the resident's classification in at least one of the first tier classification criteria for any of the components under the proposed PDPM (which are those clinical or nursing payment criteria identified in the first column in Tables 21, 23, 26, and 27), such that the resident would be classified into a classification group for that component that differs from that provided by the 5-day scheduled PPS assessment, and the change in classification group must result in a change in payment either in one particular payment component or in the overall payment for the resident. Additionally, the commenter stated that later in the proposed rule, we clarified that the change in classification group described above refers to not only a change in one of the first tier classification criteria in any of the proposed payment components, but also to one that would be sufficient to change payment in either one component or in the overall payment for the resident (83 FR 21063). Commenters questioned whether an IPA would be required when there is any clinical change that would cause a payment change for a SNF patient. Many commenters requested a general simplification and more guidance surrounding the IPA criterion. Additionally, several commenters believed that there should be guidance about whether an IPA is needed when a patient's functional status and need for specific services changes and whether the IPA should include section GG in order to capture function change.

Most commenters were concerned about the complexity of the proposed IPA. They believed it would create more burden for providers to have to monitor the clinical changes and subsequent payment changes that would trigger the IPA on a daily basis. Several commenters doubted whether the proposed changes would support CMS' Patients over Paperwork initiative and related Medicare Simplifying Document Requirements. One commenter stated that monitoring the first tier changes in each of the case-mix adjusted components would be just as burdensome as the current assessment schedule and is too high a bar, particularly for NTAs. Furthermore, some commenters communicated that the complexities and uncertainties of the IPA would cause providers not to do them and the aim of CMS to provide SNFs with satisfactory reimbursement would not come to fruition. Similarly, some commenters expressed that because of the confusion and burden related to the IPA, this would unnecessarily increase the risk of provider error and potential medical review. This, in turn, would cause facilities to complete fewer IPAs and consequently this could lead to less quality care provided to patients who otherwise would have needed it had it

been identified appropriately using the IPA. Some commenters are concerned that the IPA will likely require MDS coordinators to take on more of a care coordination role which would require additional operating costs for SNFs.

Response: We are pleased that so many commenters support the proposal to reduce the number of payment assessments in SNFs. We agree that alignment across PAC settings is very important and anticipate that the reduction of assessments will further this alignment. We also agree that the reduction of assessments will significantly decrease the burden for providers.

We disagree with the commenter that stated that even though the number of assessments have been reduced, the MDS itself has become more complex with new reporting requirements and items, leaving administrative burden unchanged. Section VII. of this final rule discusses burden associated with the changes we are making and our calculations show that there is a significant reduction in administrative burden to providers under PDPM.

We thank the commenters for calling our attention to their questions and confusion about the IPA. We continue to believe that it is necessary for SNFs to continually monitor the clinical status of each and every patient in the facility regularly regardless of payment or assessment requirements and we believe that there should be a mechanism in place that would allow facilities to do this. However, we also believe that providers may be best situated, as in the case of the Significant Change in Status Assessment, to determine when a change has occurred that should be reported through the IPA. Therefore, to further ease the administrative burden associated with PDPM and improve clarity on when an IPA should be completed, we have decided to make the IPA an optional assessment. Facilities will be able to determine when IPAs will be completed for their patients to address potential changes is clinical status and what criteria should be used to decide when an IPA would be necessary. We are not finalizing the proposed criteria for the triggering of the IPA, but rather we will seek additional stakeholder input on this issue. We note that we are finalizing the proposal surrounding IPA completions and the variable per diem adjustment schedule (including the NTA variable per diem, that is, the completion of an IPA will not reset the variable per diem adjustment schedule)) even though the IPA will now be optional. However, because the IPA will be optional and providers can determine their own criteria for when an IPA is completed, we are revising the ARD criteria we proposed. The ARD for the IPA will be the date the facility chooses to complete the assessment relative to the triggering event that causes a facility to choose to complete the IPA. Payment based on the IPA will begin the same day as the ARD. The IPA will not be susceptible to assessment penalties, given the optional nature of the assessment. We reiterate that we expect facilities to complete IPAs as they deem necessary to address clinical changes throughout a SNF stay and that the removal of the requirement to complete these assessments does not in any way negate the need to provide excellent skilled nursing and rehabilitative care and continually monitor and document patient status.

Comment: Many comments addressed the IPA criteria that ''. . . the resident would not be expected to return to his or her original clinical status within a 14-day period.'' Commenters stated that this is a very subjective determination and that it is difficult for providers to predict the course of recovery for patients who have an acute clinical change and providers would not necessarily know if this episode would or would not resolve in a 2-week period. On the other hand, several other commenters expressed that the 14-day period seemed excessive since the average of most SNF stays is currently around 19 or 20 days and CMS estimates the majority of the stays under PDPM will be between 1–15 days. Some commenters recommend that CMS shorten the timeframe to 3 days consistent with the proposed interrupted stay policy. Other commenters suggested that this time period should be reduced to 7 days. One commenter recommended that CMS should use an approach similar to the change in status policy in the home health setting (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/oasis/downloads/qandadocument0909.pdf*). Many comments requested more examples that show various scenarios in which an IPA would be required. Additionally, several commenters requested CMS to describe when an IPA would be used versus a Significant Change in Status Assessment.

Response: Given that the IPA will now be an optional assessment under PDPM and we are not finalizing criteria for when an IPA should be completed, but rather, will seek additional stakeholder input on this issue, we will take all of the comments regarding these criteria under consideration for future policy making.

Comment: One commenter requested clarification on the nursing classification change that would trigger an IPA. This commenter questioned what constitutes a substantial change versus a titration of services. Another commenter requested clarification as to what would constitute a first tier change in the nursing component. Another commenter requested clarification on what a first tier change in the SLP Case-Mix classification would look like.

Response: We appreciate the requests for clarification on the IPA triggers. However, because the IPA will now be an optional assessment, we will allow facilities to determine on their own when IPAs are necessary. As such, we will seek additional stakeholder feedback on this issue in the future.

Comment: Many commenters supported the addition of the IPA; with several commenters supporting the variable per diem adjustment policy relating to the IPA, stating that this would reduce the incentive for providers to complete multiple IPAs over the course of a SNF stay each time payment was reduced based on the adjustment. Some commenters disagreed and stated that the variable per diem for the NTA component should be reset following the completion of an IPA, while other commenters supported the variable per diem adjustment but had concerns about the NTA per diem rate following the completion of an IPA. These commenters suggested the variable per diem rate be reset for NTA services when an IPA is completed. Some commenters stated they recognize CMS' concern that providers might be incentivized to complete multiple IPAs in order to reset the NTA rate during one SNF stay. However, these commenters were concerned that in cases where IPAs are legitimately completed and the result is a change in NTA use, the potential financial loss could be significant or could result in re-hospitalization if facilities do not end up providing NTAs that patients need because of financial considerations. Commenters offered several solutions to this concern. One commenter suggested that the NTA variable per diem adjustment schedule be reset for patients who experience adverse changes in status resulting in the completion of an IPA. Another commenter suggested that CMS use the points associated with NTAs to develop a threshold of additional NTA points that would allow facilities to reset the NTA variable per diem rate to Day 1. One commenter suggested a physician verified post-stay process for patients to dispute the variable per diem

adjustment when their need for PT, OT, or NTAs would substantially increase from what was originally anticipated.

Response: We are pleased that so many commenters supported the addition of the IPA, and appreciate the support for not resetting the variable per diem adjustment when an IPA is completed. We disagree with those commenters who suggested that the variable per diem be reset every time an IPA is completed. As stated in the proposed rule (83 FR 21060), in examining costs over a stay, we found that for certain categories of SNF services, notably PT, OT and NTA services, costs declined over the course of a stay. Our analyses showed that, on average, the number of therapy minutes is lower for assessments conducted later in the stay.

We believe that the ability to reset the variable per diem would incentivize providers to complete IPAs every time the variable per diem was reduced. We also believe it is possible that providers may refrain from coding certain conditions on an initial assessment and then code other conditions on later assessments to justify the variable per diem adjustment reset.

With regard to the ideas presented by commenters for when the variable per diem should be reset, we do not believe that the variable per diem should be reset except in cases of an entirely new SNF stay (we also refer readers to section V.F. of this final rule for a discussion of our interrupted stay policy). We understand that some commenters are concerned that unless the variable per diem adjustment schedule is reset, a patient's per diem rate may not reflect changes in NTA use identified in an IPA that is completed during a patient's stay. However, we note that if a new condition is coded on an IPA during a SNF stay, the SNF PPS per diem payment for the patient may in fact increase to reflect changes in the patient's clinical condition if the new condition results in a change to the patient's case-mix group. Thus, a patient's case-mix group and associated payment could change within a stay to reflect a change in NTA use on the IPA. However, we do not think that resetting the variable per diem adjustment would be appropriate each time such a change occurs. As we explained above, we found that for PT, OT, and NTA services, costs generally decline over the course of a stay and we believe the variable per diem adjustment appropriately accounts for this decline in costs. Furthermore, as the SNF PPS is a prospective payment system, it is not intended to reimburse for each additional condition or service separately, but rather provides a predictive payment based on a snapshot of the patient's condition. Resetting the variable per diem adjustment in each case of a change in the patient's condition would be more akin to a traditional fee-for-service model, providing additional payment for each additional service or condition, which is precisely the opposite of the goals of implementing PDPM.

Commenters were also concerned that there might be financial implications to not re-setting the variable per diem for NTAs and that this might result in facilities not providing the drugs that patients require because of financial reasons. However, we do not believe that the variable per diem adjustment creates new financial implications that would affect patient care, as this incentive also exists under the current payment system that utilizes a constant per diem rate and we have no evidence that SNF patients are being denied necessary medications or services. Further, we would note that there are quality safeguards in place such as readmission penalties and quality metrics such as the SNF QRP quality measures that should provide a disincentive against providers engaging in this type of stinting behavior.

Comment: Several commenters requested that CMS consider adding additional assessments to capture changes in patient need during the SNF stay. These commenters explained their concern that PDPM does not differentiate between processes designed to adjust payment and the continuous need to assess patient care needs. Additionally, these commenters believe that status changes-especially of the functional nature-that may not rise to the level of a required IPA might be missed, especially in longer stay patients. These commenters stated that therapy assessments may not be documented frequently enough to capture serious status changes of patients under PDPM. Specifically, they noted that patient care needs must be documented through an additional assessment after day 20 and they are apprehensive that the change in the variable per diem payment after Day 20 of a SNF stay may directly affect patient care if these assessments are not completed. These commenters suggested that CMS add an additional assessment after Day 20 of the stay that would specifically capture therapy needs.

Response: We appreciate the commenters' concerns regarding how assessments relate to functional change, the ongoing need to assess patient care needs, and the necessity to capture therapy needs throughout the stay, especially during long stays. It is our expectation that the optional nature of the IPA will allow facilities to capture all of these changes as they occur during a SNF stay. Facilities will determine when IPAs should be completed, and we expect them to pay special attention to clinical and functional changes. It should be noted that, even absent an IPA requirement, we expect SNFs to constantly evaluate, capture, document and treat clinical and functional changes that occur in patients throughout a SNF stay. We defer to the judgment of clinicians and expect that the care they are providing is always evaluative in nature, meaning that therapists are continually assessing the needs of the patient and changing interventions as needed throughout the course of the therapy regimen, and we note that the absence or presence of a required assessment tool should not change this.

Accordingly, after considering the comments received, for the reasons discussed in the proposed rule and in this final rule, we are finalizing our proposed changes to the MDS assessment schedule and related assessment policies as discussed in the proposed rule, with the following modifications. As discussed above, rather than making the IPA a required assessment as we proposed, this assessment will be optional, and providers may determine whether and when an IPA is completed. In addition, because the IPA is an optional assessment and providers can determine their own criteria for when an IPA is completed, we are revising the ARD criteria such that the ARD will be the date the facility chooses to complete the IPA relative to the triggering event that causes the facility to choose to complete the IPA. Payment based on the IPA would begin the same day as the ARD. These changes will be effective October 1, 2019 in conjunction with the implementation of the PDPM.

2. Item Additions to the Swing Bed PPS Assessment

As noted previously in section IV.C of this final rule, section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute or SNF care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, such services furnished by non-CAH rural hospitals are paid under the SNF PPS, effective

with cost reporting periods beginning on or after July 1, 2002. A more detailed discussion of this provision appears in section IV.C of the proposed rule.

For purposes of the proposed PDPM, we proposed to add three items to the Swing Bed PPS Assessment. Until now, these additional items have not been part of the Swing Bed PPS Assessment form because they have not been used for payment. However, we stated in the proposed rule (83 FR 21064) that presence of each of these items would be used to classify swing bed residents under the proposed SNF PDPM as explained in section V.D. of the proposed rule. Thus, we stated that believed it was necessary and appropriate to include these items in the Swing Bed PPS Assessment beginning October 1, 2019, in conjunction with the proposed implementation of the PDPM. The items we proposed to add to the Swing Bed PPS assessment are provided in Table 34 of the proposed rule (also set forth in Table 34).

Commenters submitted the following comments related to the proposed addition of three items to the Swing Bed PPS assessment. A discussion of these comments, along with our responses, appears below.

Comment: Commenters supported the addition of the three proposed items to the Swing Bed PPS assessment and stated that these items will be important to establish the SLP and NTA component case-mix rates.

Response: We are pleased that commenters support the addition of these items to the Swing Bed PPS Assessment. We agree that these items are necessary to determine the SLP and NTA case-mix rates. We will continue to consider additions to the Swing Bed PPS Assessment as it becomes necessary to ensure consistency between swing bed and non-swing bed providers.

Accordingly, after considering the comments received, for the reasons discussed in the proposed rule and in this final rule, we are finalizing the addition of the items in Table 34 to the Swing Bed PPS Assessment as proposed without modification, effective October 1, 2019 in conjunction with the implementation of the PDPM.

TABLE 34—ITEMS TO ADD TO SWING BED PPS ASSESSMENT

MDS Item No.	Item name	Related PDPM payment component
K0100	Swallowing Disorder	SLP
I4300	Active Diagnoses: Aphasia	SLP
O0100D2	Special Treatments, Procedures and Programs: Suctioning, While a Resident	NTA

3. Items To Be Added to the PPS Discharge Assessment

Under the MDS 3.0, the Part A PPS Discharge assessment is completed when a resident's Medicare Part A stay ends, but the resident remains in the facility (MDS 3.0 RAI Manual Chapter 2.5). The PPS Discharge Assessment uses the Item Set NPE and does not currently contain section O of the MDS 3.0. The therapy items in section O of the MDS allow CMS to collect data from providers on the volume, type (physical therapy, occupational therapy and speech-language pathology), and mode (individual, concurrent, or group therapy) of the therapy provided to SNF residents. As noted in comments received on the ANPRM in relation to therapy provision, this data would be particularly important to monitor. Specifically, a significant number of commenters expressed concerns that the amount of therapy provided to SNF residents, were RCS–I to have been implemented, would drop considerably as compared to the amount currently delivered under RUG–IV. Commenters noted that this is because the incentive to provide a high volume of therapy services to SNF residents (to achieve the highest resident therapy group classification) would no longer exist under RCS–I, potentially leading providers to reduce significantly the amount of therapy provided to SNF residents.

We stated in the proposed rule (83 FR 21065) that, given that the RCS–I model and PDPM both present the potential for providers to reduce significantly the amount of therapy provided to SNF residents as compared to RUG–IV, we believe that the same potential result may occur under the proposed PDPM as commenters identified with RCS–I. To better track therapy utilization under PDPM, and to better ensure that residents continue to receive an appropriate amount of therapy commensurate with their needs, given the reduction in the frequency of resident assessments required under the proposed PDPM, we proposed to add therapy collection items to the PPS Discharge assessment and to require providers to complete these items beginning October 1, 2019, in conjunction with the proposed implementation of the PDPM.

Specifically, we proposed to add the items listed in Table 35 of the proposed rule (as set forth in Table 35 of this final rule) to the PPS Discharge Assessment.

TABLE 35—ITEMS TO ADD TO SNF PPS DISCHARGE ASSESSMENT

MDS Item No.	Item name
O0400A5	Special Treatments, Procedures and Programs: Speech-Language Pathology and Audiology Services: Therapy Start Date.
O0400A6	Special Treatments, Procedures and Programs: Speech-Language Pathology and Audiology Services: Therapy End Date.
O0400A7	Special Treatments, Procedures and Programs: Speech-Language Pathology and Audiology Services: Total Individual Minutes.
O0400A8	Special Treatments, Procedures and Programs: Speech-Language Pathology and Audiology Services: Total Concurrent Minutes.
O0400A9	Special Treatments, Procedures and Programs: Speech-Language Pathology and Audiology Services: Total Group Minutes.
O0400A10	Special Treatments, Procedures and Programs: Speech-Language Pathology and Audiology Services: Total Days.
O0400B5	Special Treatments, Procedures and Programs: Occupational Therapy: Therapy Start Date.
O0400B6	Special Treatments, Procedures and Programs: Occupational Therapy: Therapy End Date.
O0400B7	Special Treatments, Procedures and Programs: Occupational Therapy: Total Individual Minutes.
O0400B8	Special Treatments, Procedures and Programs: Occupational Therapy: Total Concurrent Minutes.

TABLE 35—ITEMS TO ADD TO SNF PPS DISCHARGE ASSESSMENT—Continued

MDS Item No.	Item name
O0400B9	Special Treatments, Procedures and Programs: Occupational Therapy: Total Group Minutes.
O0400B10	Special Treatments, Procedures and Programs: Occupational Therapy: Total Days.
O0400C5	Special Treatments, Procedures and Programs: Physical Therapy: Therapy Start Date.
O0400C6	Special Treatments, Procedures and Programs: Physical Therapy: Therapy End Date.
O0400C7	Special Treatments, Procedures and Programs: Physical Therapy: Total Individual Minutes.
O0400C8	Special Treatments, Procedures and Programs: Physical Therapy: Total Concurrent Minutes.
O0400C9	Special Treatments, Procedures and Programs: Physical Therapy: Total Group Minutes.
O0400C10	Special Treatments, Procedures and Programs: Physical Therapy: Total Days.

We stated that for the proposed items, which refer to the total number of minutes for each therapy discipline and each therapy mode, this would allow CMS both to conduct reviews of changes in the volume and intensity of therapy services provided to SNF residents under the proposed PDPM compared to that provided under RUG–IV, as well as to assess compliance with the proposed group and concurrent therapy limit discussed in section V.F of the FY 2019 SNF PPS proposed rule. We further stated that the proposed ''total days'' items for each discipline and mode of therapy would further support our monitoring efforts for therapy, as requested by commenters on the ANPRM, by allowing us to monitor not just the total minutes of therapy provided to SNF residents under the proposed PDPM, but also assess the daily intensity of therapy provided to SNF residents under the proposed PDPM, as compared to that provided under RUG–IV. As we explained in the proposed rule, ultimately, these proposed items would allow facilities to easily report therapy minutes provided to SNF residents and allow us to monitor the volume and intensity of therapy services provided to SNF residents under the proposed PDPM, as suggested by commenters on the ANPRM. We stated that if we discovered that the amount of therapy provided to SNF residents did change significantly under the proposed PDPM, if implemented, then we would assess the need for additional policies to ensure that SNF residents continued to receive sufficient and appropriate therapy services consistent with their unique needs and goals.

Commenters submitted the following comments related to the proposed rule's discussion of the SNF PPS Discharge Assessment. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters opposed the addition of items and the reporting of therapy services in section O of the SNF PPS Discharge Assessment. These commenters acknowledged that the fundamental design of PDPM (which will no longer tie payment to the amount of therapy a patient receives, as occurs under the current RUG–IV payment system) could perhaps cause some patients appropriately to receive less therapy. The commenters stated that this would be a positive anticipated outcome for many residents considering that the recurring concern of RUG–IV has been that the model may incentivize SNFs to provide therapy services beyond what patients need. These commenters noted that while they recognize the importance of monitoring the impacts of policy changes especially in the initial stages of the implementation, they were disappointed that CMS appears to be interested in collecting this data merely in order to monitor changes in volume of services and that CMS did not discuss evaluating this aspect of PDPM in relation to quality and outcomes measures (such as through the SNF Quality Reporting Program) that are normally associated with effective therapy provision. These commenters noted that the MDS should be used for care-planning and case-mix payment determination and that since therapy time is not relevant to the case-mix methodology under PDPM, this proposed addition of therapy collection of items serves no purpose on the MDS. These commenters suggested that instead of collecting therapy provision information on the MDS, facilities should gather and report therapy provision information on claims on a line-item, date-of-service basis that would be in line with Medicare Part B and other payers and limit provider burden.

Response: We agree with commenters that it is possible that, in some cases, less therapy will be provided under PDPM than under RUG–IV and that this would be a positive development in those cases where therapy was provided regardless of patient need and simply because of higher payments for higher volumes of therapy. However, we continue to be concerned that under PDPM, providers may reduce the amount of therapy provided to SNF patients because of financial considerations. We agree with commenters that quality and outcomes measures (like those in the SNF Quality Reporting Program) would be a positive way to evaluate the efficacy of therapy provision, and we will take this into consideration for future policy development. However, we disagree that the collection of these items is not relevant to case-mix determination. While the days and minutes of therapy provided will not be a determining factor in the therapy case-mix classification under PDPM, the need to ensure beneficiary protection under this payment system is very relevant to the therapy case-mix classification, and the ability to collect this data will safeguard the integrity of the case-mix classification and help ensure that patients receive an appropriate amount of therapy services. Should we discover that the amount of therapy under PDPM is distinctly different from the amount of therapy under RUG–IV, we will evaluate the potential reasons for this change and consider potential actions, either at the provider or systemic level, to address these issues.

We appreciate the commenters' suggestion of using claims information as the basis for therapy reporting, but would note that this mechanism would be more complicated and not provide the same level of detail in the data as is currently reported in section O of the MDS. Further, as providers are already familiar with the section O items, we believe that this method will provide the simplest transition for providers.

Comment: Many commenters supported the proposal to add therapy collection items to the SNF PPS Discharge Assessment in order to monitor compliance with the group and concurrent therapy limits. One commenter stated that they believed this proposal may protect against therapists being pressured to provide an unreasonable amount of group or concurrent therapy. Several commenters, however, were concerned that the monitoring effort proposed is

not strong enough to enforce the aforementioned limits. One commenter suggested that based on CMS' assertion that ''services furnished to SNF residents may be considered reasonable and necessary insomuch as services are consistent with 'the individual's particular medical needs,' '' (83 FR 21068) they question whether excessive group and concurrent therapy serves as justification to deny SNF coverage. This commenter proposed that rather than a ''warning edit'' that would notify providers that they have exceeded the group and concurrent threshold, CMS should decide whether these occurrences violate coverage requirements and if it is determined that they do, payment should be denied for the claim. Many commenters suggested that in addition to monitoring the therapy provision, CMS should monitor resident outcomes. One commenter recommended that CMS utilize the four new SNF QRP section GG outcome measures, and current readmission measures and qualitatively measure the current the effectiveness of therapy provided in the SNF.

Response: We appreciate the comments we received in support of the proposal to add therapy collection items to the SNF PPS Discharge Assessment. We agree that this proposal would enable us to monitor group and concurrent therapy compliance and will hopefully help prevent therapists from feeling pressured to provide an unreasonable amount of group and/or concurrent therapy. We appreciate the concern that the monitoring effort proposed is not strict enough to enforce the concurrent and group therapy limits. We would note that the monitoring plan is intended for this exact reason. As stated in the proposed rule (83 CFR 21067), as part of our regular monitoring efforts on SNF Part A services, we would monitor group and concurrent therapy utilization under the proposed PDPM and consider making future proposals to address abuses of this proposed policy or flag providers for additional review should an individual provider be found to consistently exceed the proposed threshold after the implementation of the proposed PDPM.

We appreciate the suggestion to deny claims if the threshold is exceeded and we may consider this option further in the future. As stated in the FY 2019 SNF PPS proposed rule (83 FR 21068), services furnished to SNF residents may be considered reasonable and necessary insomuch as the services are consistent with the individual's particular medical needs and that excessive levels of group and/or concurrent therapy could constitute a reason to deny SNF coverage for such stays. We appreciate the suggestion to monitor patient outcomes in addition to collecting therapy provision data, as well as the recommendation to specifically use the four new SNF QRP section GG outcome measures and current readmission measures to measure the effectiveness of therapy provided in SNFs. We may consider these suggestions in future policy making decisions.

Accordingly, after considering the comments received, for the reasons discussed in the proposed rule and in this final rule, we are finalizing the addition of the items in Table 35 to the PPS Discharge Assessment as proposed, without modification, effective October 1, 2019 in conjunction with the implementation of the PDPM.

E. Revisions to Therapy Provision Policies Under the SNF PPS

Currently, almost 90 percent of residents in a Medicare Part A SNF stay receive therapy services. Under the current RUG–IV model, therapy services are case mix-adjusted primarily based on the therapy minutes reported on the MDS. As discussed in the proposed rule (83 FR 21065), when the original SNF PPS model was developed, most therapy services were furnished on an individual basis, and the minutes reported on the MDS served as a proxy for the staff resource time needed to provide the therapy care. Over the years, we have monitored provider behavior and have made policy changes as it became apparent that, absent safeguards like quality measurement to ensure that the amount of therapy provided did not exceed the resident's actual needs, there were certain inherent incentives for providers to furnish as much therapy as possible. Thus, for example, in the SNF PPS FY 2010 final rule (74 FR 40315 through 40319), we decided to allocate concurrent therapy minutes for purposes of establishing the RUG–IV group to which the patient belongs, and to limit concurrent therapy to two patients at a time who were performing different activities.

As we explained in the proposed rule (83 FR 21066), following the decision to allocate concurrent therapy, using STRIVE data as a baseline, we found two significant provider behavior changes with regard to therapy provision under the RUG–IV payment system. First, there was a significant decrease in the amount of concurrent therapy that was provided in SNFs. Simultaneously, we observed a significant increase in the provision of group therapy, which was not subject to allocation at that time. We concluded that the manner in which group therapy minutes were counted in determining a patient's RUG–IV group created a payment incentive to provide group therapy rather than individual therapy or concurrent therapy, even in cases where individual therapy (or concurrent therapy) was more appropriate for the resident. Thus, we stated that we made two policy changes regarding group therapy in the FY 2012 SNF PPS final rule (76 FR 48511 through 48517). We defined group therapy as exactly four residents who are performing the same or similar therapy activities. Additionally, we allocated group therapy among the four patients participating in group therapy—meaning that the total amount of time that a therapist spent with a group will be divided by 4 (the number of patients that comprise a group) to establish the RUG–IV group to which the patient belongs.

We stated in the proposed rule (83 FR 21066) that since we began allocating group therapy and concurrent therapy, these modes of therapy (group and concurrent) represent less than one percent of total therapy provided to SNF residents. Table 36, which appeared in the FY 2014 SNF PPS Proposed Rule (78 FR 26464) (and was also presented in the FY 2019 SNF PPS proposed rule) and sets forth our findings with respect to the effect of policies finalized in the FY 2012 SNF PPS Final Rule, demonstrates the change in therapy provision between the STRIVE study and the implementation of the therapy policy changes in FY 2012. As we noted in the proposed rule, the distribution of therapy modes presented in Table 36 reflecting therapy provision in FY 2012 is also an accurate reflection of current therapy provision based on resident data collected in the QIES Database and continued monitoring of therapy utilization.

TABLE 36—MODE OF THERAPY PROVISION

	STRIVE (%)	FY 2011 (%)	FY 2012 (%)
Individual	74	91.8	99.5
Concurrent	25	0.8	0.4
Group	<1	7.4	0.1

As we explained in the proposed rule (83 FR 21066), based on our prior experience with the provision of concurrent and group therapy in SNFs, we again were concerned that if we were to implement the proposed SNF PDPM, providers may base decisions regarding the particular mode of therapy to use for a given resident on financial considerations rather than on the clinical needs of SNF residents. We stated that because the proposed SNF PDPM would not use the minutes of therapy provided to a resident to classify the resident for payment purposes, we were concerned that SNFs may once again become incentivized to emphasize group and concurrent therapy, over the kind of individualized therapy which is tailored to address each beneficiary's specific care needs which we believe is generally the most appropriate mode of therapy for SNF residents. As we stated in the FY 2012 proposed rule (76 FR 26387), while group therapy can play an important role in SNF patient care, group therapy is not appropriate for either all patients or for all conditions, and is primarily effective as a supplement to individual therapy, which we maintain should be considered the primary therapy mode and standard of care in therapy services provided to SNF residents. We stated in the FY 2012 proposed rule that, as evidenced by the application of a cap on the amount of group therapy services that may be provided to SNF residents, we do not believe that a SNF providing the preponderance of therapy in the form of group therapy would be demonstrating the intensity of therapy appropriate to this most frail and vulnerable nursing home population.

We stated in the FY 2019 SNF PPS proposed rule (83 FR 21066) that since the inception of the SNF PPS, we have limited the amount of group therapy provided to each SNF Part A resident to 25 percent of the therapy provided to them by discipline. We referred to the FY 2000 final rule (64 FR 41662), where we stated that although we recognize that receiving PT, OT, or ST as part of a group has clinical merit in select situations, we do not believe that services received within a group setting should account for more than 25 percent of the Medicare resident's therapy regimen during the SNF stay.

We explained that although we recognize that group and concurrent therapy may have clinical merit in specific situations, we also continue to believe that individual therapy is generally the best way of providing therapy to a resident because it is most tailored to that specific resident's care needs. As such, we stated that individual therapy should represent the majority of the therapy services received by SNF residents both from a clinical and payment perspective. As we stated in the FY 2012 proposed rule (76 CFR 26372), even under the previous RUG–53 model, it was clear that the predominant mode of therapy that the payment rates were designed to address was individual therapy rather than concurrent or group therapy.

We stated in the proposed rule (83 FR 21066) that to help ensure that SNF residents would receive the majority of therapy services on an individual basis, if we were to implement the proposed PDPM, we believed concurrent and group therapy combined should be limited to no more than 25 percent of a SNF resident's therapy minutes by discipline. In combination, this limit would ensure that at least 75 percent of a resident's therapy minutes are provided on an individual basis. We stated that because the change in how therapy services would be used to classify residents under the proposed PDPM gives rise to the concern that providers may begin to utilize more group and concurrent therapy due to financial considerations, we proposed to set a combined 25 percent limit on concurrent therapy and group therapy for each discipline of therapy provided. For example, if a resident received 800 minutes of physical therapy, no more than 200 minutes of this therapy could be provided on a concurrent or group basis. Finally, we noted that under RUG–IV, we currently allocate minutes of therapy because we pay for therapy based on therapy minutes and not resident characteristics. We stated that given that therapy minutes would no longer be a factor in determining payment classifications for residents under the proposed PDPM, we would utilize the total, unallocated number of minutes by therapy mode reported on the MDS, to determine compliance with the proposed limit. We explained that utilizing unallocated therapy minutes also serves to underscore the patient-driven nature of the PDPM, as it focuses the proposed limit on concurrent and group therapy on the way in which the therapy is received by the beneficiary, rather than furnished by the therapist, and would better ensure that individual therapy represents at least a vast majority of the therapy services received by a resident.

In the proposed rule (83 FR 21067), we considered other possible limits, and even no limit, on group and concurrent therapy. For example, we considered placing no limit on group or concurrent therapy, in order to afford providers the greatest degree of flexibility in designing a therapy program for each SNF resident. However, even in response to this option to have no limit on concurrent and group therapy, many commenters on the ANPRM expressed concerns regarding the lack of appropriate safeguards for ensuring that SNF residents continue to receive an appropriate level of therapy under the revised case-mix model. We stated in the proposed rule that we agree with these commenters and believe that there should be some limit on the amount of group and concurrent therapy that is provided to residents in order to ensure that residents receive an appropriate amount of individual therapy that is tailored to their specific needs. Also, in the ANPRM, we discussed the possibility of proposing a 25 percent limit on each of concurrent and group therapy, allowing for up to 50 percent of therapy services provided in the SNF to be provided in a non-individual modality. We stated in the proposed rule that this option sought to balance the flexibility afforded to therapists in designing an appropriate therapy plan that meets the needs and goals of the specific resident with the importance of ensuring that SNF residents receive an appropriate level of individual therapy. However, we were concerned that a separate 25 percent limit for group and concurrent therapy would not provide sufficient assurance that at least a majority of a resident's therapy would be provided on an individual basis.

Therefore, we stated that we believe the separate 25 percent limits on concurrent and group therapy discussed in the ANPRM, or any option which would impose a higher limit on group and concurrent therapy, would not provide the necessary protection for SNF residents. By contrast, we stated that we believe a combined 25 percent limit on group and concurrent therapy would provide sufficient assurance that at least a majority of each resident's therapy would be provided on an individual basis, consistent with our position that individual therapy is generally the best way of providing therapy to SNF residents because it is most tailored to their care needs. We noted that, assuming that existing therapy delivery patterns (as set forth in Table 36) are accurate and they reflect the individually-tailored needs of SNF residents currently being treated under the SNF benefit, the number of group and concurrent minutes that have been reported by SNFs thus far are significantly lower than the limit described in our proposal. In other words, we stated that, based on the data presented in Table 36, the proposed limit on group and concurrent therapy affords a significantly greater degree of flexibility on therapy modality than appears to be required to meet the needs of SNF residents, given that less than one percent of therapy currently being delivered is either group or concurrent therapy. Therefore, we concluded that a combined limit of 25 percent for group and concurrent therapy should provide SNFs with more than enough flexibility with respect to therapy mode to meet the care needs of their residents.

As discussed in the proposed rule (83 FR 21067), we believe that individual therapy is usually the best mode of therapy provision as it permits the greatest degree of interaction between the resident and therapist, and should therefore represent, at a minimum, the majority of therapy provided to an SNF resident. However, we recognized that, in very specific clinical situations, group or concurrent therapy may be the more appropriate mode of therapy provision, and therefore, we stated we would want to allow providers the flexibility to be able to utilize these modes. We continued to stress that group and concurrent therapy should not be utilized to satisfy therapist or resident schedules, and that all group and concurrent therapy should be well documented in a specific way to demonstrate why they are the most appropriate mode for the resident and reasonable and necessary for his or her individual condition.

Currently the RUG–IV grouper calculates the percentage of group therapy each resident receives in the SNF based on the algorithms described in section 6.6 of the MDS RAI Manual (found at *https://downloads.cms.gov/files/MDS-30-RAI-Manual-v115-October-2017.pdf*). When a resident is found to have exceeded the 25 percent group therapy limit, the minutes of therapy received in excess are not counted towards the calculation of the RUG–IV therapy classification. We explained that because the proposed PDPM would not use the minutes of therapy provided to a resident to classify the resident for payment purposes, we would need to determine a way under the proposed PDPM to address situations in which facilities exceed the combined 25 percent group and concurrent therapy limit.

Therefore, we proposed that at a component level (PT, OT, SLP), when the amount of group and concurrent therapy exceeds 25 percent within a given therapy discipline, that providers would receive a non-fatal warning edit on the validation report that the provider receives when submitting an assessment which would alert the provider that the therapy provided to that resident exceeded the threshold. To explain, a fatal error in the QIES ASAP system occurs when one or more items in the submitted record fail to pass the requirements identified in the MDS data submission specifications. A warning error occurs when an item or combination of items in the submitted record trigger a non-fatal edit in the QIES ASAP system. We stated that the non-fatal warning would serve as a reminder to the facility that they are out of compliance with the proposed limit for group and concurrent therapy. We also stated that, as part of our regular monitoring efforts on SNF Part A services, we would monitor group and concurrent therapy utilization under the proposed PDPM and consider making future proposals to address abuses of this proposed policy or flag providers for additional review should an individual provider consistently be found to exceed the proposed threshold after the implementation of the proposed PDPM. We noted that as the proportion of group and/or concurrent therapy (which are, by definition, non-individual modes of therapy provision) increases, the chances that the provider is still meeting the individualized needs of each resident would diminish. We stated that given that meeting the individualized needs of the resident is a component of meeting the coverage requirements for SNF Part A services, as described in section 1814(a)(2)(B) of the Act and further described in section 30 of Chapter 8 of the Medicare Benefit Policy Manual (accessible at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c08.pdf*), where it states that services furnished to SNF residents may be considered reasonable and necessary insomuch as the services are consistent with ''the individual's particular medical needs'', excessive levels of group and/or concurrent therapy could constitute a reason to deny SNF coverage for such stays. We invited comments on this proposed compliance mechanism.

Commenters submitted the following comments related to the proposed revisions to the therapy policies under the PDPM. A discussion of these comments, along with our responses, appears below.

Comment: The vast majority of commenters supported the proposal to limit concurrent and group therapy to 25 percent. Several stated that the combined limit is not restrictive enough and recommended that CMS implement further real-time efforts (beyond the warning edit outlined in the proposed rule) to ensure that patients are receiving the therapy they need, monitor compliance, and have stricter enforcement outcomes. Conversely, several commenters supported the notion that CMS could possibly raise the group and concurrent therapy limit following close monitoring of utilization and determining that patients are indeed receiving the individualized therapy they need even in group and concurrent sessions, and that SNFs are not taking advantage of the financial incentives that providing group and concurrent therapy offer. These commenters stated that they were in favor of the idea that providers would be reporting and counting the patients' time in therapy rather than the therapists' allocated time to determine compliance with the proposed group and concurrent therapy limit under PDPM since this is more consistent with the concept of patient-centered care and best clinical practice.

Response: We are pleased that the vast majority of commenters supported the proposal to limit concurrent and group therapy to 25 percent. We appreciate both the concern that 25 percent may not be restrictive enough and the concern that it is too restrictive, and we will continue to track the amount of therapy provided via the different modes in conjunction with our monitoring efforts described throughout section V. of this final rule. We will determine whether group and

concurrent therapy are being over or underutilized and we will consider revising the policy and enforcement efforts as necessary. Because therapy minutes would no longer be a factor in determining case-mix classification under the PDPM, as it is under RUG–IV, we agree with the commenters that using the total, unallocated number of minutes by therapy mode reported on the MDS versus therapists' allocated time makes the most sense in determining compliance with the group and concurrent therapy limit, and we appreciate that the commenters recognized the patient-centered nature of the proposal.

Comment: Several commenters stated that the current policy regarding group and concurrent therapy allocation has increased provider costs. Specifically, these comments stated that concurrent and group therapy are more cost-effective modes than individual therapy and that the 25 percent drop in the delivery of concurrent and group therapy from FY 2011 until now demonstrates a significant increase in provider costs. These commenters believe that restoring flexibility in therapy service under PDPM will permit SNFs to develop more cost-effective innovative approaches to care.

Response: We disagree with the assertion that the current policy to allocate group and concurrent therapy increases cost. As we stated in the FY 2012 final rule (76 FR 48515), to fulfill our responsibilities to ensure appropriate payment based on resource utilization and cost, we proposed the allocation of group therapy minutes, which equalizes the reimbursement incentives across modes of therapy. Although case-mix classification under PDPM is not based primarily on volume of services provided, as is the case with the RUG–IV payment system, it is still important that there are equal financial incentives to provide the different modes of therapy. Further, given that the payment incentives are equal among the various therapy modes because of the allocation of minutes and that over 99 percent of therapy minutes are reported as individual therapy, this provides evidence that the mode of therapy that providers believe is most effective in addressing a beneficiary's needs is individual therapy. Regarding the need to restore flexibility in therapy service under PDPM, we think that the 25 percent cap will allow for flexibility in therapy services. As mentioned above, since currently, over 99 percent of therapy minutes are delivered individually, SNFs should continue to have adequate leeway to provide the mode of therapy which is most appropriate for the patients even with the revised cap. Nevertheless, to the extent that provider costs have increased, these cost increases have been captured as part of the data analysis used to set the case-mix weights under PDPM. To the extent that these costs change as a result of PDPM, more specifically changes in the mode of therapy service delivery, we can consider revising the case-mix weights to reflect these changes in provider costs.

Comment: Several commenters opposed the proposed limitations on group and concurrent therapy and expressed concern that even though there is a lack of data demonstrating what the most appropriate threshold is for each individual patient, the combined 25 percent group and concurrent therapy limit is an arbitrary amount and would restrict therapists' ability to make appropriate treatment decisions. These commenters also stated that setting a limit on group and concurrent therapy may also restrict some patients from receiving the most appropriate mode of therapy for their individual need and that group or concurrent therapy might indeed be the most appropriate mode of therapy for a patient. These commenters stressed the importance of trusting the professional judgment of therapists in deciding which combination of each mode of therapy is appropriate for each patient in conjunction with Medicare guidelines for skilled therapy and medical necessity.

Response: We agree that therapists are the most appropriate professionals to determine the mode of therapy a patient should receive and that professional judgment must be trusted and used in SNFs. However we do not agree that 25 percent is an arbitrary amount. As stated in the proposed rule, (83 FR 21066), since we began allocating group therapy and concurrent therapy, these modes of therapy (group and concurrent) represent less than one percent of total therapy provided to SNF residents. Further, we do not agree that data do not exist with regard to the appropriate threshold for each individual patient, as over 99 percent of therapy services are currently reported as individual. This would suggest that a much lower threshold for concurrent and group therapy would likely be acceptable and appropriate, though we also believe that added flexibility is important under a new payment system. Therefore, we believe it is appropriate to use the 25 percent combined therapy limit for concurrent and group therapy.

We also do not agree that setting a limit on group and concurrent therapy may restrict some patients from receiving the most appropriate mode of therapy for their individual needs. We currently have a 25 percent limit in place for group therapy and, based on our data, this limit has not restricted patients from receiving what we assume is the most appropriate amount of therapy for their individual needs. Given the stakeholders' comments that individual therapy is the most costly form of therapy along with the evidence of therapy being furnished to SNF patients on the basis of financial considerations rather than patient need, the extremely high prevalence of individual therapy would indicate that the amount of individual therapy, despite being the most costly, is the most effective for beneficiaries, which would comport with our reasons for supporting either the limit we proposed or a lower such limit. To hold otherwise would indicate that the minutes currently being reported are an inaccurate representation of the way in which therapy is currently being delivered, which could potentially constitute fraud on the part of some SNF providers. Based on the MDS assessment data mentioned above that demonstrate that almost no group or concurrent therapy is being reported on the MDS currently, the commenters' characterization of the proposed limit (which is far above the current level of furnishing such services) as insufficiently flexible would actually beg the question of why commenters would appear to believe that group and concurrent therapy would be better suited to address patient needs under PDPM rather than under RUG–IV.

Given the historical precedent of 25 percent as a therapy threshold and the very limited amount that group and concurrent therapy that has actually been reported in SNFs, we believe it is an appropriate threshold. That being said, using the new items in section O of the PPS Discharge Assessment, we will monitor therapy provision as discussed in section V.D of this final rule and we will consider policy changes as we receive data and see how therapy is being furnished under PDPM.

Comment: Some commenters suggested that CMS revise the group therapy definition to include two to four participants while many commenters suggested that CMS revise the definition to include two to six participants doing the same or similar activities. In addition to better aligning with other settings such as Inpatient Rehabilitation Facilities (IRFs), commenters stated that this revision would allow increased flexibility so that patients in smaller SNFs could utilize and benefit from

group therapy. One commenter stated that the CMS definition of concurrent therapy is arbitrary and does not reflect therapists' preferred practice. This commenter urged us to redefine concurrent therapy. Several commenters requested that CMS reconsider the ''rigid'' documentation requirements that accompany group therapy provision, stating a preference as a practitioner to use group therapy when patients can benefit from it. One commenter requested that we provide additional guidance to providers and MACs related to the level of appropriate documentation required for participation in group or concurrent therapy.

Response: We recognize the importance of alignment across settings. We may consider changing the definition of group therapy and/or concurrent therapy to align with other PAC settings in future rulemaking efforts.

With regard to the ''rigid'' documentation requirements, we would like to remind the commenter that we did not impose new documentation requirements on SNFs with regard to concurrent and group therapy. Rather, in the FY 2012 proposed rule, we simply clarified certain already-established documentation standards (76 FR 26387 through 26388). As we wrote in the FY 2012 final rule in response to comments, since we simply clarified existing expectations, we did not agree that these documentation guidelines would increase or create undue burden on therapists, or that these guidelines create a disincentive for clinicians to perform group therapy due to increased paperwork. We stated that there should be no additional burden to provide this documentation, as it should be a standard part of any documentation. We agreed with those commenters who stated that rehabilitation professionals need to support the work they do through documentation, and that the documentation should reflect the need for skilled care and the mode of therapy provided, as well as demonstrate how the therapy provision will support patients' needs and goals. (76 FR 48516).

We continue to believe that it is vital for SNFs to document services appropriately in order to demonstrate the skilled nature and the fact that the services are reasonable and necessary. This will be especially important when the 25 percent cap on concurrent and group therapy is in place after the implementation of PDPM. We will monitor the mode of therapy given and we will be interested to see how facilities document the therapy used so we can determine whether we will increase, decrease or maintain the limit following extensive monitoring.

Regarding the request to provide additional guidance related to documentation of group and concurrent therapy, we remind commenters of the guidance provided in the FY2012 proposed rule (76 FR 26388) regarding group therapy: Because group therapy is not appropriate for either all patients or all conditions, and in order to verify that group therapy is medically necessary and appropriate to the needs of each beneficiary, SNFs should include in the patient's plan of care an explicit justification for the use of group, rather than individual or concurrent, therapy. This description should include, but need not be limited to, the specific benefits to that particular patient of including the documented type and amount of group therapy; that is, how the prescribed type and amount of group therapy will meet the patient's needs and assist the patient in reaching the documented goals. In addition, we believe that the above documentation is necessary to demonstrate that the SNF is providing services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident in accordance with section 1819(b)(2) of the Act.

While the above guidance was provided in relation to group therapy, we believe that it applies to concurrent therapy as well.

Comment: Some commenters disagreed with the proposal of a combined limit of 25 percent for concurrent and group therapy, with one commenter stating that this contradicted the discussion in the ANPRM that considered a 25 percent limit on concurrent therapy and a separate 25 percent limit on group therapy. This commenter pointed out that we stated, we believe that individual therapy is usually the best mode of therapy provision as it permits the greatest degree of interaction between the resident and therapist, and should therefore represent, at a minimum, the majority of therapy provided to an SNF resident (82 FR 21004). This commenter and several others requested that CMS return to the separate 25 percent caps for concurrent therapy and for group therapy, as discussed in the ANPRM. According to these commenters, prior to CMS allocating concurrent and group therapy in FY 2011 and FY 2012, respectively, the average amount of concurrent and group therapy that was furnished to all residents combined was about 26 percent. These commenters believe this means that there were many residents who received higher amounts than an average of 25 percent group and concurrent therapy and others who received lower amounts based on their clinical status and need. According to these commenters, CMS has not produced any evidence the quality of care changed dramatically since FY 2011 and FY 2012, which would suggest the quality of care furnished in FY 2010 and earlier was meeting individual resident needs of patients. One commenter suggested that we implement a 25 percent combined cap for group and concurrent therapy at a facility level rather than at a per-patient level. One commenter requested that CMS consider having providers report ''individual'' and ''non-individual'' therapy, rather than separately reporting group and concurrent therapy.

Response: We do not agree that there is a contradiction between the ANPRM and our current proposal. We continue to believe that individual therapy should represent a majority of therapy provided in a SNF. We continue to contend that although group and concurrent therapy may have clinical merit in specific situations, we believe that individual therapy is generally the best way of providing therapy to a resident because it is most tailored to that specific resident's care needs. As such, we believe that individual therapy should represent at least the majority of the therapy services received by SNF residents. (82 FR 21004).

Our latest (FY 2017) data indicate that individual therapy was provided 99.77 percent of the time, meaning that group and concurrent therapy combined was reported as having been provided 0.23 percent of the time. If therapy continues to be provided in the same way, there is no reason to believe that a combined 25 percent limit on group and concurrent therapy is not a generous limit given the amount of group and concurrent therapy that has been provided under RUG IV. Therefore, we do not agree with the request to implement the separate 25 percent caps for group and concurrent therapy discussed in the ANPRM. We further disagree that CMS put restrictions on the ''ability to furnish concurrent and group therapy.'' We did not change any restrictions in FY 2011 and FY 2012 on the amount or type of therapy provided. The 25 percent cap on group therapy was in place since the inception of the SNF PPS. Rather, we allocated first concurrent therapy in FY 2011 (74 FR 40315–40319) and then group therapy in FY 2012 (76 FR 48511–48517) as a way to equalize payment across therapy modes and remove any financial

incentives for providing a certain therapy mode, which appeared to drive at least some portion of the approximately 1,000 percentage increase in the amount of group therapy provided under the SNF Part A benefit in FY 2011. This was not an effort to restrict any mode of therapy. As we wrote in the FY 2012 final rule (76 FR 48513, 48514), by allocating group therapy among the four group therapy participants, we are also equalizing the reimbursement incentive across the modes of therapy. We stated we believe this would once again encourage clinicians to choose the mode of therapy based on clinical rather than financial reasons. We stated in the FY 2012 final rule that the purpose of our allocation policy is to provide payment that better reflects resource utilization and cost, and that we do not believe this policy should affect clinical determinations regarding the appropriate mode of therapy provided to a patient.

We appreciate the suggestion to implement a combined 25 percent group and concurrent therapy limit at the facility level rather than the patient level; however, given that a significant part of the reason we proposed a limit on group and concurrent therapy is so that patients receive therapy that reflects their individualized needs, we believe that implementing a facility based limit on concurrent and group therapy would defeat the purpose. With regard to a facility level limit, as opposed to the patient-level limit, we believe that therapy decisions should be driven by clinical standards and judgment related to an individual patient and not in relation to all patients within a facility. Utilizing a facility-level cap may allow for certain patients to receive excessive levels of group or concurrent therapy, which we do not believe would be advisable for any patient.

With regard to the comment that providers not be required to report group and concurrent therapy separately, while we have a combined cap, we believe that it is important to understand which of the two modes of therapy, concurrent or group therapy, is actually occurring in relation to this cap. Given that some commenters requested separate caps on group and concurrent therapy, we would not be in a position to assess the need for this separation in the future if group and concurrent therapy were reported under a single heading.

Comment: Several commenters expressed concern with how the combined group and concurrent therapy limit would interplay with student supervision in SNFs. One commenter stated the following, ''Students' minutes are often counted as concurrent therapy when the clinical instructor is also treating a patient and we anticipate residents being treated by students will quickly exceed the 25 percent threshold.'' The commenters went on to explain that the 25 percent limitation on group and concurrent therapy minutes could make it inefficient for the treating therapist or assistant and could deter facilities from taking students. One commenter was concerned that ''CMS currently requires that student treatment must be labeled as ''concurrent,'' and therefore, this would fall under the 25 percent limitation on group and concurrent therapy. They stated that positive clinical education experiences in post-acute settings often translate into quality therapists and assistants getting jobs in those settings upon graduation. One commenter explained that if a SNF accepts more students, ''the average of 1 percent for group and concurrent therapy represented in CMS data may not prove accurate.'' They described a scenario where SNFs that prefer to have higher than average volumes of students may deliver concurrent therapy in excess of 25 percent and that the combined 25 percent limit of group and concurrent therapy could be a deterrent to SNFs taking therapy students One commenter recommended that CMS create a reporting requirement that would delineate between student and therapist/assistant minutes so that those minutes could be separated from the total of group and concurrent therapy minutes.

Response: We appreciate the concern that these commenters raised. We agree that our policies should not deter SNFs from taking students, and we agree that the therapy student internship is crucial to ensuring that students gain valuable SNF experience that would cause quality therapist and assistant graduates to pursue employment at SNFs when they eventually graduate. We appreciate the candor with which the commenters have described how they provide concurrent therapy at the same time as their therapy students consistent with current policy allowances. We would like to clarify that CMS does not require that student therapy be labeled as concurrent. The following is written in the MDS 3.0 RAI Manual (Chapter 3, section O):

> When a therapy student is involved with the treatment, and one of the following occurs, the minutes may be coded as concurrent therapy: The therapy student is treating one resident and the supervising therapist/assistant is treating another resident, and both residents are in line of sight of the therapist/assistant or student providing their therapy.

This instruction is describing one possible scenario. We would like to reiterate that CMS does not require students to do concurrent therapy. As stated in the FY 2012 final rule (76 FR 48511), as the therapy student is under the direction of the supervising therapist (even if no longer required to be under line-of-sight supervision), the time the student spends with a patient will continue to be billed as if it were the supervising therapist alone providing the therapy. In other words, the therapy student, for the purpose of billing, is treated as simply an extension of the supervising therapist rather than being counted as an additional practitioner.

We suspect that, as noted in the FY 2012 final rule referenced above, because we do not allow facilities to count therapy students' independent time on the MDS, many facilities rely on the MDS instructions above (allowing a therapist or assistant and a student to treat one patient each while both residents are in line of sight of the therapist/assistant or student providing their therapy) to permit them to count student concurrent therapy time. However, this should in no way be considered mandatory practice and like all concurrent therapy, should be used sparingly.

Further, as mentioned above, our most recent (FY 2017) data show that individual therapy was provided 99.77 percent of the time, meaning that group and concurrent therapy combined was reported as having been provided 0.23 percent of the time. It concerns us that commenters have stated that they are providing so much concurrent therapy with students that the 25 percent cap would be too low for them, because this would suggest that either the comments were provided mistakenly or that facilities are falsely reporting concurrent therapy as individual therapy. While we agree with commenters that the opportunity to supervise student therapists in SNFs is valuable to the education of future therapists and assistants, our data indicate that a 25 percent combined cap on group and concurrent therapy should not deter facilities from taking more therapy students. We believe the recommendation to monitor student therapy minutes along with just therapist/assistant minutes has merit and it is something we will consider for future policy making.

Comment: Some commenters expressed concern with CMS' implication that clinical decisions about

therapy are principally driven by ''. . . financial considerations rather than the clinical needs of the SNF residents''.

Response: The available data support our assertion that at least some SNFs principally utilize financial considerations, rather than relying on clinical judgment, when making decisions regarding the manner and amount of care to provide to SNF residents. In 2016, CMS released the Skilled Nursing Facility Utilization and Payment Public Use File (Skilled Nursing Facility PUF) (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/SNF.html*). The Skilled Nursing Facility PUF contained information on utilization, payment (allowed amount, Medicare payment and standard payment), submitted charges, and beneficiary demographic and chronic condition indicators organized by CMS Certification Number (6-digit provider identification number), Resource Utilization Group (RUG), and state of service. The SNF PUF included information on the number of provider assessments where residents were classified into an Ultra-High Rehabilitation RUG or a Very-High Rehabilitation RUG. It also included the percentage of those assessments that were within ten minutes of the minimum threshold used to classify a resident into that Rehabilitation RUG category (that is, between 500–510 minutes for RV RUGs and 720–730 minutes for RU RUGs). Based on this information, we found the following:

- 51 percent of all RV assessments showed therapy provided between 500 and 510 minutes.
- 65 percent of all RU assessments showed therapy provided between 720 and 730 minutes.
- For 88 providers, all of their RV assessments showed therapy provided between 500 and 510 minutes.
- For 215 providers, all of their RU assessments showed therapy provided between 720 and 730 minutes.
- More than one in five providers had more than 75 percent of both RU and RV assessments that showed therapy provided within 10 minutes of the minimum threshold.

This clear evidence of thresholding behavior supports our assertion regarding SNFs that are driven by payment considerations rather than therapy needs of patients. Furthermore, we received a significant number of comments from stakeholders on the proposed rule who believe that the quality and volume of therapy services are likely to diminish under PDPM. This belief is, itself, predicated on the notion that SNFs will continue to utilize financial considerations as the basis for care planning decisions. However, with better and more reliable patient diagnosis and characteristic data and given the removal of therapy service volume as a component of the payment system, we expect that we will be better positioned under PDPM to exercise our authority to make case-mix creep adjustments under section 1888(e)(4)(F) of the Act, as may be appropriate, to address any changes in payment which are merely the result of changes in the coding or classification of SNF patients that do not reflect actual changes in case mix. This type of analysis will also be a part of CMS monitoring efforts under PDPM.

Comment: One commenter recommended that, in the future, CMS consider whether it would be reasonable to track rehabilitative versus maintenance therapy, similar to how it is done in the home health setting.

Response: We appreciate this suggestion and may take it into consideration for future policy making decisions.

Accordingly, after considering the comments received, for the reasons discussed in the proposed rule and in this final rule, we are finalizing our proposal, without modification, to set a combined 25 percent limit on group and concurrent therapy per discipline. Additionally, we are finalizing our proposal, without modification, to implement a non-fatal warning edit on the validation report upon submission when the amount of group and concurrent therapy exceeds 25 percent within a given therapy discipline, which would alert the provider to the fact that the therapy provided to that resident exceeded the threshold.

F. Interrupted Stay Policy

Under section 1812(a)(2)(A) of the Act, Medicare Part A covers a maximum of 100 days of SNF services per spell of illness, or ''benefit period.'' A benefit period starts on the day the beneficiary begins receiving inpatient hospital or SNF benefits under Medicare Part A. (See section 1861(a) of the Act; § 409.60). SNF coverage also requires a prior qualifying, inpatient hospital stay of at least 3 consecutive days' duration (counting the day of inpatient admission but not the day of discharge). (See section 1861(i) of the Act; § 409.30(a)(1)). Once the 100 available days of SNF benefits are used, the current benefit period must end before a beneficiary can renew SNF benefits under a new benefit period. For the current benefit period to end so a new benefit period can begin, a period of 60 consecutive days must elapse throughout which the beneficiary is neither an inpatient of a hospital nor receiving skilled care in a SNF. (See section 1861(a) of the Act; § 409.60). Once a benefit period ends, the beneficiary must have another qualifying 3-day inpatient hospital stay and meet the other applicable requirements before Medicare Part A coverage of SNF care can resume. (See section 1861(i); § 409.30)

While the majority of SNF benefit periods, approximately 77 percent, involve a single SNF stay, it is possible for a beneficiary to be readmitted multiple times to a SNF within a single benefit period, and such cases represent the remaining 23 percent of SNF benefit periods. For instance, a resident can be readmitted to a SNF within 30 days after a SNF discharge without requiring a new qualifying 3-day inpatient hospital stay or beginning a new benefit period. SNF admissions that occur between 31 and 60 days after a SNF discharge require a new qualifying 3-day inpatient hospital stay, but fall within the same benefit period. (See sections 1861(a) and (i) of the Act; §§ 409.30, 409.60)

Other Medicare post-acute care (PAC) benefits have ''interrupted stay'' policies that provide for a payment adjustment when the beneficiary temporarily goes to another setting, such as an acute care hospital, and then returns within a specific timeframe. In the inpatient rehabilitation facility (IRF) and inpatient psychiatric facility (IPF) settings, for instance, an interrupted stay occurs when a patient returns to the same facility (or in the case of an IPF, the same or another IPF) within 3 days of discharge. The interrupted stay policy for long-term care hospitals (LTCHs) is more complex, consisting of several policies depending on the length of the interruption and, at times, the discharge destination: An interruption of 3 or fewer days is always treated as an interrupted stay, which is similar to the IRF PPS and IPF PPS policies; if there is an interruption of more than 3 days, the length of the gap required to trigger a new stay varies depending on the discharge setting. In these three settings, when a beneficiary is discharged and returns to the facility within the interrupted stay window, Medicare treats the two segments as a single stay.

As we explained in the proposed rule (83 FR 21068), while other Medicare PAC benefit categories have interrupted stay policies, the SNF benefit under the RUG–IV case-mix model had no need for such a policy because, given a resident's case-mix group, payment did not change over the course of a stay. In other words, assuming no change in a

patient's condition or treatment, the payment rate was the same on Day 1 of a covered SNF stay as it is at Day 7. Accordingly, a beneficiary's readmission to the SNF—even if only a few days may have elapsed since a previous discharge—could essentially be treated as a new and different stay without affecting the payment rates.

However, as described in section V.D of the proposed rule (83 FR 21068) and section V.C.4 of this final rule, we stated that the PDPM would adjust the per diem rate across the length of a stay (the variable per diem adjustment) to better reflect how and when costs are incurred and resources used over the course of the stay, such that earlier days in a given stay receive higher payments, with payments trending lower as the stay continues. In other words, the adjusted payment rate on Day 1 and Day 7 of a SNF stay may not be the same. Although we stated that we believe this variable per diem adjustment schedule more accurately reflects the increased resource utilization in the early portion of a stay for *single-stay benefit periods* (which represent the majority of cases), we considered whether and how such an adjustment should be applied to payment rates for cases involving multiple stays per benefit period. In other words, in the proposed rule, we considered instances in which a resident has a Part A stay in a SNF, leaves the facility for some reason, and then is readmitted to the same SNF or a different SNF; and how this readmission should be viewed in terms of both resident classification and the variable per diem adjustment schedule under the proposed PDPM. We explained that application of the variable per diem adjustment is of particular concern because providers may consider discharging a resident and then readmitting the resident shortly thereafter to reset the resident's variable per diem adjustment schedule and maximize the payment rates for that resident.

We stated in the proposed rule (83 FR 21068) that, given the potential harm which may be caused to the resident if discharged inappropriately, and other concerns outlined previously in this section and in the proposed rule, we discussed in last year's FY 2018 ANPRM the possibility of adopting an interrupted stay policy under the SNF PPS in conjunction with the implementation of the RCS–I case-mix model. Several commenters expressed support for this interrupted stay policy in responding to the ANPRM, saying that the interrupted stay policy is in alignment with similar policies in other post-acute settings, and that a similar policy would likely be implemented under any cross-setting PAC payment system.

Thus, we proposed to implement an interrupted stay policy as part of the SNF PPS, effective beginning FY 2020 in conjunction with the proposed implementation of the SNF PDPM. Specifically, in cases where a resident is discharged from a SNF and returns to the same SNF by 12:00 a.m. at the end of the third day of the interruption window (as defined below), we proposed treating the resident's stay as a continuation of the previous stay for purposes of both resident classification and the variable per diem adjustment schedule. In cases where the resident's absence from the SNF exceeds this 3-day interruption window (as defined below), or in any case where the resident is readmitted to a different SNF, we proposed treating the readmission as a new stay, in which the resident would receive a new 5-day assessment upon admission and the variable per diem adjustment schedule for that resident would reset to Day 1. We stated in the proposed rule (83 FR 21068 through 21069) that, consistent with the existing interrupted stay policies for the IRF and IPF settings, we would define the interruption window as the 3-day period starting with the calendar day of discharge and additionally including the 2 immediately following calendar days. We stated that for the purposes of the interrupted stay policy, the source of the readmission would not be relevant. That is, the beneficiary may be readmitted from the community, from an intervening hospital stay, or from a different kind of facility, and the interrupted stay policy would operate in the same manner. We explained that the only relevant factors in determining if the interrupted stay policy would apply are the number of days between the resident's discharge from a SNF and subsequent readmission to a SNF, and whether the resident is readmitted to the same or a different SNF.

In the proposed rule (83 FR 21069), we presented the following examples, which we believed aided in clarifying how this policy would be implemented:

Example A: A beneficiary is discharged from a SNF on Day 3 of the stay. Four days after the date of discharge, the beneficiary is then readmitted (as explained above, this readmission would be in the same benefit period) to the same SNF. The SNF would conduct a new 5-day assessment at the start of the second admission and reclassify the beneficiary accordingly. In addition, for purposes of the variable per diem adjustment schedule, the payment schedule for the second admission would reset to Day 1 payment rates for the beneficiary's new case-mix classification.

Example B: A beneficiary is discharged from a SNF stay on Day 7 and is readmitted to the *same* SNF within the 3-day interruption window. For the purposes of classification and payment, this would be considered a continuation of the previous stay (an interrupted stay). The SNF would not conduct a new 5-day assessment to reclassify the patient and for purposes of the variable per diem adjustment schedule, the payment schedule would continue where it left off at the rate for the day of discharge; we stated in the proposed rule that, in this case, the first day of the second stay would be paid at the Day 8 per diem rates under that schedule.

Example C: A beneficiary is discharged from a SNF stay on Day 7 and is readmitted to a *different* SNF within the 3-day interruption window. The SNF would conduct a new 5-day assessment at the start of the second admission and classify the beneficiary accordingly. In addition, for purposes of the variable per diem adjustment schedule, the payment schedule for the second admission would reset to Day 1 payment rates for the beneficiary's new case-mix classification.

We note two clarifications to the preceding examples. In each of the above examples, when the beneficiary is discharged from the SNF stay, the SNF would complete the required PPS Discharge Assessment (see Table 33: PPS Assessment Schedule under PDPM). Additionally, in Example B, we inadvertently indicated in the proposed rule that the first day of the second stay would be paid at the Day 8 per diem rates. However, the first day of the second stay would actually be paid at the rate for the day of discharge, Day 7. These points are further addressed in our responses to comments below.

We also stated in the proposed rule (83 FR 21069) that we considered alternative ways of structuring the interrupted stay policy. For example, we considered possible ranges for the interrupted stay window other than the 3 calendar day window proposed. For example, we considered windows of fewer than 3 days (for example, 1 or 2 day windows for readmission), as well as windows of more than 3 days (for example, 4 or 5 day windows for readmission). However, we stated we believe that 3 days represents a reasonable window after which it is more likely that a resident's condition and resource needs will have changed. We also stated that we believe

consistency with other payment systems, like that of IRF and IPF, is helpful in providing clarity and consistency to providers in understanding Medicare payment systems, as well as making progress toward standardization among PAC payment systems.

In addition, we explained that, to determine how best to operationalize an interrupted stay policy within the SNF setting, we considered three broad categories of benefit periods consisting of multiple stays. The first type of scenario, SNF-to-SNF transfers, is one in which a resident is transferred directly from one SNF to a different SNF. The second case we considered, and the most common of all three multiple-stay benefit period scenarios, is a benefit period that includes a readmission following a new hospitalization between the two stays—for instance, a resident who was discharged from a SNF back to the community, re-hospitalized at a later date, and readmitted to a SNF (the same SNF or a different SNF) following the new hospital stay. The last case we considered was a readmission to the same SNF or a different SNF following a discharge to the community, with no intervening re-hospitalization.

We further explained that, to simplify the analysis, we primarily examined benefit periods with two stays. We stated that benefit periods with exactly two stays account for a large majority (70 percent) of all benefit periods with multiple stays, and benefit periods with more than two stays represent a very small portion (less than 7 percent) of all benefit periods overall. We therefore assume the data for cases where there are exactly two stays in a benefit period are representative of all benefit periods with multiple stays. We noted that, of cases where there are exactly two stays in a benefit period, over three quarters (76.4 percent) consist of re-hospitalization and readmission (to the same SNF or a different SNF). Discharge to the community and readmission without re-hospitalization cases represent approximately 14 percent of cases, while direct SNF-to-SNF transfers represent approximately 10 percent.

For each of these case types, in which a resident was readmitted to a SNF after discharge, we explained that we examined whether (1) the variable per diem adjustment schedule should be ''reset'' back to the Day 1 rates at the outset of the second stay versus ''continuing'' the variable per diem adjustment schedule at the point at which the previous stay ended, and (2) a new 5-day assessment and resident classification should be required at the start of the subsequent SNF stay.

With regard to the first question above, specifically whether or not a readmission to a SNF within the proposed 3-day interruption window would reset the resident's variable per diem adjustment schedule, we stated that in each of the cases described above, we were concerned generally that an interrupted stay policy that ''restarts'' the variable per diem adjustment schedule to Day 1 after readmissions could incentivize unnecessary discharges with quick readmissions. We explained that this concern is particularly notable in the second and third cases described above, as the beneficiary may return to the same facility. As we discussed in the proposed rule (83 FR 21069), to investigate this question, we conducted linear regression analyses to examine changes in costs in terms of both PT/OT and NTA costs per day from the first to second admission for the three scenarios described above (SNF-to-SNF direct transfers, readmissions following re-hospitalization, and readmissions following community discharge). As discussed in section V.D.4. of the proposed rule (83 FR 21060 through 21061) and in section V.C.4 of this final rule, investigations revealed that utilization of PT, OT, and NTA services changes over the course of a stay. Based on both empirical analysis and feedback from multiple technical expert panels, we determined that SLP and nursing utilization remained fairly constant over a stay. Therefore, we proposed variable per diem adjustment schedules for the PT, OT, and NTA components but not for the SLP or nursing components. We stated in the proposed rule that, because the analysis of changes in costs across two stays in a single benefit period is relevant to determining how the variable per diem payment adjustments should apply to benefit periods with multiple stays, we restricted our analysis to the three payment components for which we are proposing variable per diem adjustments (PT, OT, and NTA). For this analysis, both the re-hospitalization and community discharge cases were separated into two sub-cases: When the resident returns to the same SNF, and when the resident is admitted to a different SNF. By definition, SNF-to-SNF transfer cases always have different providers for the first and second stays. We stated in the proposed rule that the regression results showed that PT/OT costs from the first to second admission were very similar for SNF-to-SNF transfers and for readmissions to a different provider following re-hospitalization or discharge to community, suggesting that the second admission is comparable to a new stay. NTA costs from the first to second admission also were very similar for SNF-to-SNF transfers. We stated that, for readmissions following re-hospitalization or discharge to community, NTA costs for readmissions to the same provider were notably less than NTA costs for readmissions to a different provider. We explained that, overall, these results suggest that a readmission to a *different* SNF, regardless of whether it was a direct SNF-to-SNF transfer, or whether the beneficiary was re-hospitalized or discharged to the community before the second admission, are more comparable to a new stay than an interrupted stay. Thus, we proposed to always reset the variable per diem adjustment schedule to Day 1 whenever residents are discharged and readmitted to a different SNF. We acknowledged that this could lead to patterns of inappropriate discharges and readmissions that could be inconsistent with the intent of this policy; for example, we stated we would be concerned about patients in SNF A consistently being admitted to SNF B to the exclusion of other SNFs in the area. We explained that should we discover such behavior, we would flag these facilities for additional scrutiny and review and consider potential policy changes in future rulemaking. However, based on the results of our regression analyses, and because of the concern that a SNF provider could discharge and promptly readmit a resident to reset the variable per diem adjustment schedule to Day 1, we stated that in cases where a resident returns to the *same* provider we were proposing to allow the payment schedule to reset only when the resident has been out of the facility for at least 3 days. As previously mentioned, we stated that believe 3 days represents a reasonable window after which it is more likely that a resident's condition and resource needs will have changed, and this 3-day requirement is also consistent with the interrupted stay policies of similar Medicare PAC benefits. Moreover, we stated that while we found that PT and OT costs for cases where the gap is longer than 3 days are similar to PT and OT costs for cases where the gap is shorter than 3 days, NTA costs are notably higher for cases where the gap is longer than 3 days. We explained that this provides further support for resetting the variable per diem schedule for cases where the gap is longer than 3 days (as costs tend to be higher, similar to a new stay). More information on these analyses can be found in section 3.10.3. of the SNF PMR technical report available at *https://*

www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html.

We explained in the proposed rule (83 FR 21070) that with regard to the question of whether or not SNFs would be required to complete a new 5-day assessment and reclassify the resident after returning to the SNF within the proposed 3-day interruption window, we investigated changes in resident characteristics from the first to the second stay within a benefit period. First, we looked at changes in clinical categories from the first to second stay for residents with an intervening re-hospitalization. We explained that this analysis could only be conducted for residents with a re-hospitalization because, as described in section 3.10.2. of the SNF PMR technical report, for research purposes, classification into clinical categories was based on the diagnosis from the prior inpatient stay. We stated that for those residents who had a re-hospitalization and were readmitted to a SNF (either the same or a different SNF), and therefore, could be reclassified into a new clinical category (because of new diagnostic information as a result of the intervening re-hospitalization), we found that a majority had the same clinical category for both the first and second admission. We further explained that because we could not conduct this investigation for SNF-to-SNF transfers or community discharge cases (as they lack a new hospitalization), we separately investigated changes in function from the first to second stay for SNF-to-SNF transfers and for readmissions following community discharge. We found that in a large majority of cases, there was no change in function from the first to second stay, regardless of whether the second provider was the same or different as the first provider. Thus, we stated we believe it would be appropriate to maintain the classification from the first stay for those residents returning to the same SNF no more than 3 calendar days after discharge from the same facility. However, we stated that because we proposed to exclude from the interrupted stay policy readmissions to a different SNF (regardless of the number of days between admissions) and readmissions to the same SNF when the gap between admissions is longer than 3 days, and to treat these readmissions as new stays for purpose of the variable per diem adjustment schedule, we believe it would be appropriate and consistent to treat these cases as new stays for purposes of clinical classification and to require a new 5-day PPS assessment. More information on these analyses can be found in section 3.10.2. of the SNF PMR technical report available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html.* Additionally, we noted that under the approach discussed in section V.E.1. of the proposed rule, providers would be afforded the flexibility to use the IPA, which would allow for resident reclassification under certain circumstances.

We also noted that we believe that frequent SNF readmissions may be indicative of poor quality care being provided by the SNF. Given this belief, we stated we plan to monitor the use of this policy closely to identify those facilities whose beneficiaries experience frequent readmission, particularly facilities where the readmissions occur just outside the 3-day window used as part of the proposed interrupted stay policy. We stated that should we discover such behavior, we would flag these facilities for additional scrutiny and review and consider potential policy changes in future rulemaking.

We invited comments on the proposals outlined above. Commenters submitted the following comments related to the proposed rule's discussion of the proposed interrupted stay policy under the PDPM. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters pointed out a potential adverse incentive associated with the interaction between the interrupted stay policy, the proposed Interim Payment Assessment (IPA), and the variable per diem adjustment. Specifically, these comments were concerned with issues that could arise because an IPA does not return the NTA component to day 1 payment rates under the variable per diem adjustment schedule. Commenters stated that if a patient requires a new high cost medication or piece of equipment, the inability to return to day 1 of the variable per diem adjustment schedule could result in an array of unintended issues. Commenters noted that these unintended issues include incentivizing unnecessary discharges to a hospital followed by quick readmissions (which, the commenter pointed out, was a risk CMS had specifically considered and attempted to avoid in crafting the proposed interrupted stay policy) and reluctance to admit patients who are at high risk of changes in care needs. One commenter stated that CMS has not aligned the planned monitoring of unnecessary discharges with existing quality measures, and instead has created an incentive for unnecessary discharges and readmissions just outside the 3-day interruption window by prohibiting providers from returning patients to days one through three of the variable per diem adjustment schedule for typically high cost NTAs when an IPA is conducted or in the instance of interrupted stays of 3 or less days.

Response: While we appreciate the commenters' concerns regarding the potential for an adverse incentive, we believe that frequent SNF readmissions may be indicative of poor quality care being provided by the SNF. CMS plans to monitor the use of this policy closely to identify those facilities whose beneficiaries experience frequent readmission, particularly facilities where the readmissions occur just outside the 3-day window used as part of the proposed interrupted stay policy. Should we discover such behavior, we will flag these facilities for additional scrutiny and review and consider potential policy changes in future rulemaking.

We do not believe that facilities have cause for reluctance to admit patients who are at high risk of changes in care needs. The optional IPA allows for patients to be reclassified in cases of significant changes in care needs.

With regard to the question of the IPA resetting the variable per diem adjustment, this issue is addressed in our responses to comments in section V.D. of this final rule.

With regard to the question of interruptions of 3 or less days resetting the variable per diem adjustment, as we stated in the proposed rule, our analyses found that some costs, specifically NTA costs, are notably higher for cases where the gap is longer than 3 days, compared to cases where the interruption is 3 or less days, where costs are more similar to uninterrupted stays. We believe this supports the use of a 3-day gap as the metric for when to reset the variable per diem adjustment.

Regarding any current alignment of quality measures and the monitoring of unnecessary discharges, we interpret the commenter to be suggesting that CMS does not currently have in place quality measures that address unnecessary discharges to the hospital during the SNF Stay. We disagree with this assertion in that CMS has developed and implemented a hospital readmission measure for SNF.

Comment: Commenters requested clarification as to whether the readmission of a patient under the interrupted stay policy (for example, within the 3-day window) would trigger an IPA.

Response: As discussed in section V.D. of this final rule, the IPA under PDPM would be an optional assessment. Therefore, readmission after an interrupted stay would not trigger an IPA. If the provider believes, even in the case of a short absence from the facility, that an IPA is warranted, then we would encourage the provider to complete an IPA in that instance.

Comment: Several commenters requested clarification about completing initial evaluations for therapy upon readmission of a patient in an interrupted stay under the interrupted stay policy. Commenters questioned whether CMS has an expectation that therapists will always complete a new evaluation upon the resident's return to a SNF as currently instructed in the MDS RAI Manual, or whether CMS would defer to the clinical judgment of the therapist in a way that is more like the EOT/EOT–R practice. Commenters also questioned whether CMS would require SNFs to indicate on the claim form when a resident has been readmitted and/or when an evaluation was complete after the resident was readmitted. Commenters pointed out that, per the current instruction in section O of the MDS RAI Manual, ''If a resident returns from a hospital stay, an initial evaluation must be performed after entry to the facility, and only those therapies that occurred since admission/reentry to the facility and after the initial evaluation shall be counted.'' (MDS 3.0 Chapter 3, section O, V1.15, page O–19). On the other hand, commenters pointed out that the premise for the interrupted stay policy is similar to the policy for the End-of Therapy (EOT) Other Medicare Required Assessment (OMRA), which leaves it to the clinician's judgment whether or not a new therapy evaluation should be completed. Commenters stated that when therapy is the primary skill, and the patient misses 3 consecutive calendar days of therapy, the provider must complete an EOT OMRA, which effectively changes the payment resource utilization group (RUG). Commenters pointed out that in cases where therapy resumes after the EOT–OMRA is performed and the resumption of therapy date is no more than 5 consecutive calendar days after the last day of therapy provided, and the therapy services have resumed at the same RUG–IV classification level, and with the same therapy plan of care that had been in effect prior to the EOT OMRA, an EOT OMRA with Resumption (EOT–R) may be completed. Commenters noted that in these cases, it is left to the clinician's judgment whether or not a new therapy evaluation should be completed.

Response: Given that an interrupted stay does not prompt the need for a new 5-day PPS assessment and continues the stay from the point when the interruption occurred, providers should not be required to always complete an evaluation upon the resident's readmission after an interrupted stay. Per the proposed interrupted stay policy, a new 5-day assessment must be completed only if the interruption lasts longer than 3 days (or if the beneficiary is readmitted to a different SNF). If the interruption was less than 3 days but patient care needs have changed significantly, clinicians may complete an IPA at their discretion. The instructions in the MDS RAI Manual will be updated accordingly as part of the implementation of PDPM.

With regard to whether providers would be required to report on the claim form when a patient is readmitted or an evaluation is completed for such a patient, we do not anticipate such changes in claims reporting, though we would have providers report on the claim when an interrupted stay occurred.

Comment: Many commenters had questions and concerns related to discharge practices under the interrupted stay policy, and requested clarification of the requirements surrounding the PPS Part A Discharge (NPE) when beneficiaries meet the criteria of an interrupted stay. One commenter stated that it is unclear in the proposed rule whether the NPE would be completed in example B in the FY 2019 SNF PPS proposed rule (83 FR 21069). Assuming that an NPE would be required once the resident has been out of the facility for 24 hours, whether the resident returns within 1 day or 3 days, commenters questioned how the facility would manage the assessment schedule versus the payment schedule. Other commenters questioned whether CMS expects SNFs to wait to see whether the beneficiary returns before completing the discharge assessment. Commenters questioned what the implications would be for setting the Assessment Reference Date (ARD) approximately 4 to 5 days after discharge in cases when the beneficiary does not return within the 3-day window. Commenters stated that as currently defined, doing this would be considered a late assessment, and could subject the SNF to penalties. Commenters also stated that if this discharge assessment is required, then this adds to the administrative burden, which is contradictory to CMS' stated goals.

Response: As is the current policy, SNFs would be expected to complete the PPS discharge assessment and/or OBRA discharge assessment upon any discharge and within currently established timeframes, regardless of any expectation as to whether or not a patient might be readmitted and/or whether the readmission would be considered an interrupted stay. This does not add administrative burden beyond what SNFs are currently expected to do. This information is also important in our ability to assess instances in which facilities may abuse the interrupted stay policy.

With regard to managing the assessment schedule and payment schedule, we would refer commenters to the assessment schedule discussed in section V.D of this final rule, which outlines both the assessment calendar and payment timeline for each assessment under PDPM.

Comment: Some commenters sought clarification as to how the SNF should count the total volume, mode, and type of therapy to report in section O of the MDS for purposes of the discharge assessment when a resident's stay included one or more interrupted stays. Would they count it from Day 1, the original admission date, even though there was an interrupted stay, or would this discharge assessment only include the volume, mode, and type of therapy delivered since the time of return to discharge?

Response: In cases where a resident is discharged and then readmitted to a SNF in a manner that triggers an interrupted stay under the interrupted stay policy, only those therapies that occurred since the readmission would be included in section O of the MDS for each discharge assessment.

Comment: A commenter expressed concerns related to the use of the length of an interruption in days (for example, less than or equal to 3 days) as the trigger for a 5-day assessment. The commenter stated appreciation for CMS efforts to reduce the number of 5-day assessments, but stated that no reduction in burden is achieved by not requiring a 5-day assessment for patients returning following 3 or fewer days, assuming that SNFs must still conduct a patient assessment upon readmission for all patients. Also, the commenter believes not performing a 5-day assessment for all returning patients creates unneeded risk for patients and SNFs. The commenter recommended performing the 5-day assessment after every readmission, the result of which—not the number of days in the interruption—should determine whether the patient's condition has

changed and new care needs are present that would warrant resetting the variable per diem rate. Commenters stated that the number of days in an interruption is irrelevant to costs of treatment and it is the patient's condition upon return from the interruption that should determine whether the payment resets to day 1 per diem rates or not.

Response: Contrary to the commenter's assertion, we believe that a reduction in burden is, in fact, achieved by not requiring a 5-day assessment for patients returning following 3 or fewer days. While SNFs may be required to complete OBRA assessments and other statutorily required assessments beyond the scope of SNF PPS payment, it will no longer be the case that SNFs must conduct a patient assessment upon readmission for all patients for the purposes of PPS payment. As discussed above, in conjunction with the implementation of the PDPM, CMS will reduce the assessment schedule significantly to ease provider burden (see section V. E. and Table 33 of the proposed rule). The Start of Therapy OMRA, the assessment that would have previously been required for PPS payment upon a readmission, is no longer required. The new schedule utilizes the 5-day Assessment and PPS Discharge Assessments as the only required assessments, with IPAs being optional at clinician discretion.

We disagree that not performing an assessment for all returning patients creates unneeded risk. We believe that the new assessment schedule we proposed achieves efficiencies in terms of provider burden while still providing enough data to accurately monitor provider behavior, changes in patient condition, and outcomes via the 5-day assessment, IPA assessments, and discharge assessments. While a 5-day assessment would not be required upon readmission in the case of an interrupted stay, the provider has the option of completing an IPA as it determines appropriate to assess whether the patient's condition and care needs have changed.

While we appreciate the commenter's concern, we believe the use of the number of days between discharge and readmission to determine whether there is an interrupted stay is appropriate. As described in the proposed rule, our analyses found that some types of costs, notably NTA costs, tend to be higher for cases where the gap is longer than 3 days, suggesting that such stays are more like new stays than continuing stays and thus supporting the 3-day metric for resetting the variable per diem schedule. The length of the interruption is also used in determining whether there is an interrupted stay in other Medicare post-acute payment systems and we expect that its use here will be just as effective.

With regard to the commenters' recommendation that a 5-day assessment be completed upon readmission after an interrupted stay, we believe that this would constitute an unnecessary burden on providers, particularly given the provider's option to complete an IPA upon readmission to the SNF. We also do not believe a 5-day assessment is necessary upon readmission after an interrupted stay of 3 days or less. While we found that PT and OT costs for cases where the gap is longer than 3 days are similar to PT and OT costs for cases where the gap is shorter than 3 days, NTA costs are notably higher for cases where the gap is longer than 3 days. We explained that this provides further support for resetting the variable per diem schedule for cases where the gap is longer than 3 days (as costs tend to be higher, similar to a new stay). As discussed in section 3.10 of the SNF PMR technical report, our analyses also showed that clinical category (in cases with an intervening re-hospitalization) and functional status (in cases involving SNF-to-SNF transfers and readmissions following community discharge) tended not to change between the first stay and the second stay in an interrupted stay of 3 days or less. Thus, we believe our research suggests that stays with interruptions of 3 days or less are more similar in cost to uninterrupted stays and are less likely to involve significant changes in patient condition or function. Therefore, we do not agree that a 5-day assessment should be required upon readmission after an interrupted stay, or that it is appropriate to reset the variable per diem adjustment schedule to day 1 after an interrupted stay.

We agree with the commenter that the patient's condition should be the most relevant factor in determining the need for a new assessment, and CMS has given providers the option of performing an IPA at their discretion based on changing conditions. As we explained previously, if a new condition is coded on an IPA, the SNF PPS per diem payment for the patient could increase to reflect changes in the patient's clinical condition if there is a change in the patient's case-mix group.

Comment: A commenter stated that CMS does not explicitly discuss discharge to the community and the interrupted stay policy, and requested clarification.

Response: In the FY 2019 SNF PPS proposed rule (83 FR 21068 through 21069), we discussed discharge to the community and the interrupted stay policy. The beneficiary may be readmitted *from the community,* from an intervening hospital stay, or from a different kind of facility, and the interrupted stay policy would operate in the same manner. The interrupted stay policy would operate in the same manner for discharges to the community.

Comment: One commenter commented that the RAI User's Manual instructions for A2400A, on page A–32, are to code 1, yes, if the resident has had a Medicare Part A covered SNF stay since the most recent admission/entry or reentry. The commenter stated that providers also use the Medicare Stay End Date Algorithm on page A–37 of the RAI User's Manual to correctly code A2400C, the end of the Medicare SNF stay. A2400C is also used to determine whether the PPS Part A Discharge assessment is required. The commenter referenced Example B on page 21069 of the proposed rule, which describes a beneficiary who is discharged on day 7 and is readmitted to the same SNF within the 3-day interruption window. The example states a SNF would not conduct a new 5-day assessment, and for the purposes of payment, this would be considered a continuation of the previous stay. The commenter expressed concern that, even though the Example B beneficiary is considered a continuation of the previous stay for payment purposes, A2400 on the MDS would still be coded as two separate Medicare stays. The commenter stated that when the resident is discharged on day 7, this date would be considered the end of the Medicare stay at A2400C. The entry record completed when the resident returned would have a new Medicare start date (A2400B) that would equal the reentry date. The commenter stated that this could lead to unmatched stays and inaccurate SNF QRP measures.

Response: We appreciate the comments on the potential revisions needed to the MDS manual or any technical specifications associated with SNF programs to implement the interrupted stay policy, and will consider these issues when making revisions to these materials as part of implementing the PDPM and related policies. With regard to the commenter's concern about the alignment of individual stays in the SNF QRP and the PDPM, we are aware of the issue and will revise the codes so that a hospital admission and return to the SNF does

not trigger a new Medicare stay for purposes of the SNF QRP.

Comment: A commenter expressed concern regarding how the interrupted stay policy will operate in situations where the SNF provided the resident with the Notice of Medicare Non-Coverage (NOMNC), which is required to be provided prior to a discharge to the community. The commenter requested clarification on how or if issuance of the NOMNC or SNFABN would have any effect on the interrupted stay policy. Their concern was that if a resident meets the criteria of an interrupted stay following a discharge where denial notices were issued, the resident would be considered a new admission to the SNF. The commenter stated the cost of an admission in this situation is more like that of a new admission than a readmission. They recommended that the interrupted stay policy not be applied following a discharge with issuance of denial notices.

Response: The basic purpose of the interrupted stay policy is to ensure that when two segments of a resident's stay in the facility are separated by only a brief absence, the variable per diem payment adjustment is not inappropriately reset to Day 1 upon the resident's return. We do not believe that the mere issuance of a denial notice such as a NOMNC or SNFABN prior to the resident's departure would, in itself, have any effect on the nature of the care needed by the resident upon subsequent resumption of SNF care, the costs of readmission, or the way in which providers would be paid under the PDPM, and, accordingly, we are not adopting the commenter's suggestion.

Comment: A commenter expressed concern about the impact an OBRA Discharge Return Not Anticipated assessment would have on the interrupted stay policy. The commenter stated that currently, when a resident discharges to the community with the intent not to return, the SNF is required to complete the OBRA Discharge Return Not Anticipated assessment and would combine this assessment with the PPS Part A Discharge. The commenter stated that the OBRA Discharge Return Not Anticipated ends the resident's ''episode of care.'' The commenter stated that if this resident were to be readmitted to the SNF within the interruption window, this would be considered a new admission, require an admission type of entry record, and start a new ''episode of care.'' Furthermore, the commenter stated that this discharge would end all of the resident's orders, meaning that a new admission order is required, along with new physician certification of skilled care and new therapy evaluations. The commenter was highly concerned that the interrupted stay policy would apply following an OBRA Discharge Return Not Anticipated assessment, when the resident is considered a ''new admission'' for all other regulations. The commenter stated that the cost of an admission in this situation is more like that of a new admission than a readmission. The commenter recommended that the interrupted stay policy not be applied following a Discharge Return Not Anticipated.

Response: We appreciate this concern though we do not agree that the interrupted stay policy should not apply in cases where the resident is discharged return not anticipated. While the provider may have prepared a discharge plan for this patient based on the notion that the patient would not return, the patient's return to the SNF within that 3-day window would suggest that either the patient was not adequately prepared for discharge or may have been discharged too early from the facility. Further, providers should consider the possibility that a patient may return before finalizing the precise discharge type coded on the MDS. Finally, we believe that exempting such discharges from the interrupted stay policy could incentivize providers to merely code discharges in this manner only for this purpose and without sufficient basis.

Comment: One commenter stated that currently a Medicare Part A stay in the SNF will end if the resident has been discharged to the community, has been admitted to the hospital, or is on a hospital observation stay or emergency room visit that spans midnight and exceeds 24 hours. The commenter stated that the interrupted stay policy would consider any readmission within the 3-day interruption window as a continuation of the previous stay, therefore changing the number of Medicare stays the facility would have had prior to this proposal. One commenter expressed concern that the reduction in Medicare stays has the potential to affect the SNF QRP measures adversely by resulting in a higher number of unmatched stays and potential errors with SNF QRP measure calculation. The commenter referenced the Skilled Nursing Facility Quality Reporting Program Measure Calculation and Reporting User's Manual 1.0 (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNF-QM-Users-Manual-V10-FINAL-5-22-17.pdf*) and the instructions on how to identify a Medicare Part A stay for SNF QRP: Start by sorting assessments in reverse order during the 12-month target period. If the most recent assessment is a PPS Part A Discharge assessment, look for the next qualifying assessment; if the assessment is a 5-day, this is a matched assessment, and if not a 5-day, the stay is unmatched. The commenter expressed concern for potential negative impact to the SNF QRP measures, regardless of whether the Discharge Assessment NPE is required with the discharge prior to the interrupted stay, with the following reasoning.

The commenter described a sequence of assessments and events that the commenter stated would occur under the current payment system if Example B on page 21069 were to occur: 5-day assessment, NPE, discharge of less than 3 days, 5-day assessment, and final NPE. This would be counted as two Medicare stays for SNF QRP.

The commenter then described how this sequence might differ under the new system, depending on whether the NPE is required or not. In Example B, if the NPE was required on day 7 when the resident was discharged, but a new 5-day assessment was not required when the resident returned within the interruption window, then the sequence of assessments and events would be: 5-day assessment, NPE, interrupted stay, NPE. This would result in one unmatched stay (between the return from the interrupted stay to the final NPE) and one matched stay.

In Example B, if the NPE is not required on day 7 when the resident discharges for less than 3 days, the sequence would be: 5-day assessment, interrupted stay, NPE. This would result in only one Medicare stay.

The commenter requested clarification on how the Medicare stays will be calculated with the interrupted stay policy, presumably for the purposes of the QRP, and recommended evaluation by the SNF QRP CMS team to evaluate any further risks, errors, or concerns that may arise from this proposed policy.

Response: We agree with the commenter's description of how the current matching occurs for assessments. As previously discussed, we are aware that admissions and discharges are currently coded for purposes of the SNF QRP in a way that might conflict with how stays will be captured under the new PDPM. We intend to revise the codes so that a Medicare stay is captured the same way for purposes of the SNF QRP and the PDPM.

Comment: One commenter stated concerns with the suggestion that CMS

would monitor this interrupted stay policy for frequent readmission, particularly facilities where the readmissions occur just outside the 3-day window used as part of the proposed interrupted stay policy. The commenter stated that SNFs already are the most highly regulated and monitored profession in health care. They stated a new policy with additional scrutiny and risk increases provider burden. They pointed out that CMS has programs in place to monitor and penalize SNFs for rehospitalization. The commenter stated that the SNF Rehospitalization VPB Program reduces all SNF rates by 2 percent. The commenter further stated that SNFs may earn a portion of these funds back by keeping rehospitalization rates low. Also, the commenter pointed out that SNF performance on return to community and related quality measures under the SNF QRP are publicly reported. The commenter stated that SNFs that perform poorly on QRP measures are less likely to be included in Medicare Advantage Plan or Accountable Care Organization provider networks. Thus, the commenter concluded that heightened scrutiny for poor performance already is in place. They recommended that SNF re-admissions to hospitals under the existing program—presumably meaning the SNF Rehospitalization VPB Program—should serve as the monitoring tool. They stated that, as with the SNF VBP Program, QRP performance also will serve a monitoring tool. They added that poorly performing SNFs will be penalized by the market, so that no additional government action is needed.

Response: We acknowledge that these monitoring tools exist and will utilize these existing tools to the fullest extent possible, but will also monitor specifically for inappropriate behavior in the context of the interrupted stay policy and decide the appropriate form of administrative action for whatever behavior is identified.

Comment: One commenter stated that CMS should develop a policy specific to the interrupted stay and the calculation of group/concurrent minutes. An interrupted stay could prevent the individual therapy minutes from being provided, and therefore, result in exceeding the 25 percent threshold. For example, if a resident is admitted to a facility and receives 100 percent group therapy on Day 1 of their SNF stay, with the full intent to move the resident to individual therapy in the days that follow, and then an interrupted stay occurs on Day 2 of the resident's stay; what would be the resulting impact to the facility from the resident receiving over the allowed 25 percent group therapy?

Response: As noted in section V.E of this final rule, there currently is no penalty associated with the group and concurrent therapy limits; instead, providers will receive a non-fatal warning edit on the validation report. We stated that we would monitor and evaluate how group and concurrent therapy are used under PDPM and consider making future proposals to address abuses of this policy or flag providers for additional review should a provider be found to consistently exceed the threshold. That being said, in terms of calculating adherence with the concurrent and group therapy limit, such a calculation is, as described in section V.E. of this final rule, completed at the stay level. Therefore, in cases of an interrupted stay, the therapy minutes over the course of the entire stay, both before and after the interruption, would be used to calculate the proportion of therapy time furnished within a concurrent or group setting. We believe this is the fairest option, as to calculate the proportion of such minutes based on only one portion of the stay may unduly identify a given provider as having failed to adhere to the established limit only because that particular portion of the stay had a larger amount of a given therapy mode.

Comment: Several commenters pointed out a discrepancy in the Medicare days count in Example B in the FY 2019 SNF PPS proposed rule (83 FR 21069). Specifically, commenters highlighted that Example B states that the resident is discharged on day 7 and that ''the first day of the second stay would be paid at the Day 8 per diem rates under that schedule.'' This implies that if a SNF resident has an interrupted stay, for the purposes of determining day in the stay for the per diem payment, when the patient returns to the SNF after the interruption, the stay resumes on the *next day* of the stay. For example, if a SNF resident is on day 7 of a stay which is then interrupted, when the resident returns within a certain time frame the day in the stay would be day 8. If the resident is discharged on day 7 of the stay, the SNF would be unable to bill for this day, resulting in the beneficiary using only 6 of the Medicare days. This would be unfair for both the resident and the SNF. Commenters recommended that CMS clarify the policy so that providers are paid for the day when a resident leaves a SNF in the case of an interrupted stay. Commenters said that under the policy as proposed, providers would not be paid for the day the resident leaves the SNF and so would lose one day of reimbursement.

Response: We agree with commenters regarding this typographical error and that payments should resume at the rate of the day *of* discharge, rather than the day after discharge. In other words, if a SNF resident is on day 7 of a stay which is interrupted, when the resident is readmitted, the payment rate would resume at day 7, not day 8, as Example B incorrectly stated.

The day of discharge in an interrupted stay would not be counted against the beneficiary's count of 100 days of covered Part A care in a benefit period. SNFs are not currently paid for the day of discharge, even with an anticipated leave of absence, unless the patient returns to the SNF before midnight of the same day. We do not believe there is anything about the interrupted stay policy that warrants changing this.

Comment: Multiple commenters expressed general support for the interrupted stay policy as proposed. Commenters supported the implementation of a SNF interrupted stay policy that is consistent with the policies in other post-acute care settings. Commenters recognized that with the proposed changes under the PDPM, which include variable per diem payment adjustments that provide higher payments at the beginning of the stay, implementing an interrupted stay policy will be appropriate for SNFs. As a further point of support, commenters noted that under the current system, rates of discharge to institutions (such as acute hospital or emergency department) are monitored very closely. Commenters expected that the proposed interrupted stay policy would allow for short term discharges where medically necessary while allowing for appropriate payment across a patient's stay.

Response: We agree with the commenters that the PDPM will benefit from the interrupted stay policy proposed.

Accordingly, after considering the comments received, for the reasons discussed in the proposed rule and in this final rule, we are finalizing our proposed interrupted stay policy without modification, to be effective October 1, 2019 in conjunction with the implementation of the PDPM.

G. Relationship of the PDPM to Existing Skilled Nursing Facility Level of Care Criteria

As discussed in the proposed rule (83 FR 21070), the establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-

mix adjustment aspect of the SNF PPS has been based, in part, on the beneficiary's need for skilled nursing care and therapy, we have coordinated claims review procedures with the existing resident assessment process and case-mix classification system. This approach includes an administrative presumption that utilizes a beneficiary's initial classification in one of the upper 52 RUGs of the 66-group RUG–IV system to assist in making certain SNF level of care determinations.

As further discussed below, in the proposed rule (83 FR 21070–72), we proposed to adopt a similar approach under the PDPM effective October 1, 2019, by retaining an administrative presumption mechanism that would utilize the initial assignment of one of the case-mix classifiers that we designate for this purpose to assist in making certain SNF level of care determinations. This designation would reflect an administrative presumption under the PDPM that beneficiaries who are correctly assigned one of the designated case-mix classifiers on the initial 5-day, Medicare-required assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date on the 5-day Medicare required assessment.

We stated that, as under the existing RUG–IV administrative presumption, a beneficiary who is not assigned one of the designated classifiers would not automatically be classified as either meeting or not meeting the level of care definition, but instead would receive an individual level of care determination using the existing administrative criteria. We stated that the use of the administrative presumption reflects the strong likelihood that those beneficiaries who are assigned one of the designated classifiers during the immediate post-hospital period require a covered level of care, which would be less likely for other beneficiaries.

In the ANPRM (82 FR 21007), we discussed some potential adaptations of the RUG–IV model's administrative presumption to accommodate specific features of the RCS–I model, including the possible designation of the following case-mix classifiers for purposes of the administrative presumption:

- Continued designation of the same nursing (non-rehabilitation) groups that currently comprise the Extensive Services, Special Care High, Special Care Low, and Clinically Complex categories under RUG–IV, as those groups would crosswalk directly from RUG–IV to the RCS–I model we were considering;
- In addition, designation of the most intensive functional score (14 to 18) under the RCS–I model's combined PT/OT component, as well as the uppermost comorbidity score (11+) under its NTA component.

In response, a number of comments expressed concern that the possible adaptations of the presumption could adversely affect access to care for some beneficiaries. Others questioned whether using the PT/OT component's highest functional score bin (14 to 18) as a trigger for the presumption would be appropriate, inasmuch as the residents that typically require the most therapy are those with only moderate functional impairments. In addition, commenters questioned the discussion's inclusion of the RCS–I model's NTA component as a possible classifier under the presumption, as well as its omission of RCS–I's SLP component.

Regarding the commenters' concerns about access to care, we noted in the proposed rule that we have indicated in the ANPRM and in previous rulemaking that the actual purpose of the level of care presumption has always been to afford a streamlined and simplified administrative procedure for readily identifying those beneficiaries with the *greatest likelihood* of meeting the level of care criteria; however, we have also emphasized that in focusing on such beneficiaries, this approach in no way serves to disadvantage *other* beneficiaries who may *also* meet the level of care criteria. As we noted in the ANPRM, an individual beneficiary's inability to qualify for the administrative presumption would not in itself serve to disqualify that resident from receiving SNF coverage. While such residents are not automatically presumed to require a skilled level of care, neither are they automatically classified as requiring nonskilled care; rather, any resident who does not qualify for the presumption would instead receive an individual level of care determination using the existing administrative criteria (82 FR 21007). As we further explained in the FY 2016 SNF PPS final rule (80 FR 46406, August 4, 2015), structuring the presumption in this manner serves specifically to ensure that the presumption does not disadvantage such residents, by providing them with an individualized level of care determination that fully considers all pertinent factors.

As for concerns about the appropriateness of certain classifiers, including the possible use of the PT/OT component's highest functional score bin (14 to 18) for this purpose under RCS–I, we noted in the proposed rule that the case-mix classification model for PT and OT that we were proposing in connection with the PDPM would essentially reconfigure the PT/OT component from the RCS–I model. As discussed in section V.D.3.b. of the proposed rule, the proposed PDPM would divide the RCS–I model's combined PT/OT component into two separate case-mix adjusted components, under which each resident would be assigned separate case-mix groups for PT and OT payment. Those groups would classify residents based on clinical category and function score, the two resident characteristics shown to be most predictive of PT and OT utilization.

The proposed rule's discussion also cited section III.B.4. of the ANPRM (''Variable Per Diem Adjustment Factors and Payment Schedule''), as well as section V.D.4. of the proposed rule itself, which indicated that our initial analyses revealed that in contrast to the SLP component—where per diem costs remain relatively constant over time—costs for the PT, OT, and NTA components typically are highest at the outset and then decline over the course of the stay. The proposed rule noted that our research to date continues to show a strong correlation between the dependent variables used for the proposed separate PT and OT components and a similarity in predictors, in that the associated costs for both therapy disciplines remain highest in the initial (and typically most intensive) portion of the SNF stay. We stated that this heightened resource intensity during the initial part of the SNF stay under the PT, OT, and NTA components, in turn, more closely reflects the distinctive utilization patterns that served as the original foundation for the level of care presumption itself—that is, the tendency as noted in the FY 2000 SNF PPS final rule for SNF stays to be at their most intensive and unstable immediately following admission as justifying a presumption of coverage at the very outset of the SNF stay (64 FR 41667, July 30, 1999). We also stated that we believe this would make the most intensive classifiers within each of these three proposed components well-suited to serve as clinical proxies for identifying those beneficiaries with the most intensive care needs and greatest likelihood of requiring an SNF level of care.

Accordingly, for purposes of the administrative presumption under the proposed PDPM, we proposed to continue utilizing the same designated nursing (non-rehabilitation) categories under the PDPM as had been used to

date under RUG–IV. We noted that the most direct crosswalk between the existing RUG–IV model and the proposed PDPM would involve nursing services, for which, under the proposed PDPM, each resident would continue to be classified into one of the groups that fall within the existing non-rehabilitation RUG–IV categories. (As explained in section V.D.3.d. of the proposed rule, while the PDPM would streamline the total number of nursing case-mix groups from the current 43 under RUG–IV down to 25 through the consolidation of similar groups *within* individual categories, the overall number and structure of the nursing categories themselves would remain the same.) Under our proposal, effective in conjunction with the proposed implementation of the PDPM (that is, as of October 1, 2019), we stated that the administrative presumption would apply to those groups encompassed by the same nursing categories as have been designated for this purpose under the existing RUG–IV model:

- Extensive Services;
- Special Care High;
- Special Care Low; and,
- Clinically Complex.

In addition, along with the continued use of the RUG–IV nursing categories above, we also proposed to apply the administrative presumption using those other classifiers under the proposed PDPM that we identified as relating the most directly to identifying a patient's need for skilled care at the outset of the SNF stay. We proposed to designate such classifiers for this purpose based on their ability to fulfill the administrative presumption's role as described in the FY 2000 SNF PPS final rule (64 FR 41668 through 41669, July 30, 1999)—that is, to identify those situations that involve a high probability of the need for skilled care when taken in combination with the characteristic tendency for an SNF resident's condition to be at its most unstable and intensive state at the outset of the SNF stay.

Specifically, we additionally proposed to designate for this purpose proposed PT and OT case-mix groups TB, TC, TD, TF, and TG, the groups displayed in Table 21 of the proposed rule that collectively accounted for the five highest case-mix indexes for PT, as well as for OT and, thus, would consistently be associated with the most resource-intensive care across both of these therapy disciplines. We also proposed to designate the uppermost comorbidity group under the NTA component, in the belief that this particular classifier would serve to identify those cases that are the most likely to involve the kind of complex medication regimen (for example, a highly intensive drug requiring specialized expertise to administer, or an exceptionally large and diverse assortment of medications posing an increased risk of adverse drug interactions) that would require skilled oversight to manage safely and effectively. As discussed in section V.D.3.e of this final rule, the specific value assigned to the NTA component's uppermost comorbidity score (which was 11+ under the RCS–I model and is 12+ under PDPM) might change once again in the future if the NTA score bins are reconfigured to reflect changes in the resident population and care practices over time.

We further explained that under this proposed approach, those residents not classifying into a case-mix group in one of the designated nursing RUG categories under the proposed PDPM on the initial, 5-day Medicare-required assessment could nonetheless still qualify for the administrative presumption on that assessment by being placed in one of the designated case-mix groups for either the PT or OT components, or by receiving the uppermost comorbidity score under the NTA component. We indicated that these particular case-mix classifiers would appropriately serve to fulfill the administrative presumption's role of identifying those cases with the highest probability of requiring an SNF level of care throughout the initial portion of the SNF stay. We additionally noted that in order to help improve the accuracy of these newly-designated groups in serving this function, we would continue to review the new designations going forward and may make further adjustments to the proposed designations over time as we gain actual operating experience under the new classification model. As discussed above, this proposed administrative presumption mechanism would take effect October 1, 2019 in conjunction with the proposed PDPM itself. We invited comments on our proposed administrative presumption mechanism under the proposed PDPM.

Commenters submitted the following comments related to the proposed rule's discussion on our proposed administrative presumption mechanism under the proposed PDPM. A discussion of these comments, along with our responses, appears below.

Comment: One commenter mistakenly assumed that under the PDPM, the administrative presumption would change from its current use of the initial, 5-day Medicare-required assessment to using the initial MDS assessment (that is, the OBRA-required Admission assessment) instead, and expressed concern that the timeframes associated with the latter would be inappropriate for this purpose.

Response: We note that consistent with the discussion in the proposed rule (83 FR 21070–21072), the presumption's current use of the initial, 5-day Medicare-required assessment will, in fact, continue under the PDPM.

Comment: Several commenters urged us to designate other therapy groups, in addition to those set forth in the proposed rule, as appropriately serving to identify a level of acuity that would qualify for the presumption. They equated the omission of a given case-mix classifier from the presumption with a restriction on access and coverage, and characterized the individual level of care determinations that SNFs would routinely conduct absent the presumption as an added administrative burden. The commenters specifically cited as a concern the proposed rule's omission of any PT and OT groups for non-orthopedic conditions, as well as of any groups at all from the SLP component. One commenter took issue with the proposed rule's stated rationale for the omission of SLP (that is, that such services, unlike PT and OT, remain relatively constant over time and are not concentrated in the initial portion of the stay), noting that nursing services similarly do not taper off over the course of the stay and yet have been utilized under the presumption ever since its inception. The commenter pointed out that as with the other components, it is possible to identify individual groups within the SLP component that have relatively high service intensity. Along with the groups from the PT and OT components that were already proposed for designation under the presumption, the commenter recommended the designation of several additional PT and OT groups (that is, TA, TE, TJ, TK, TN, and TO), as well as a number of groups (that is, SC, SE, SF, SH, SI, SJ, SK, and SL) from the SLP component, and presented these particular groups as reflecting the most intensive therapy needs within their respective clinical categories. The commenter also suggested that the proposed designation of the NTA's uppermost comorbidity group might not actually be necessary, as anyone assigned to that group would likely qualify for the presumption already, based on their classification under the nursing component. Another commenter recommended that all of the PT and OT groups in the Other Orthopedic category should be

designated for use under the presumption, and pointed out that under PDPM, the NTA component's uppermost comorbidity score is actually 12+ rather than 11+ as indicated in the proposed rule.

Response: We agree with the commenters that the administrative presumption should encompass *all* of the groups that serve to fulfill the basic purpose of this provision—that is, readily identifying those beneficiaries with the greatest likelihood of meeting the level of care criteria. With one exception, we also concur with the commenters' analysis that the additional therapy groups recommended for designation under the presumption would appropriately serve to reflect the most intensive therapy needs within their respective clinical categories, as evidenced by the relatively high CMI that is associated with each of the recommended groups. However, regarding the recommendation to designate all PT and OT groups in the Other Orthopedic category, we note that one such group, TH, has a significantly lower CMI than all of the other recommended groups and, thus, is not being selected for designation under the presumption. Accordingly, we are adopting the remainder of the commenters' recommendations regarding the designation of additional groups from the PT and OT components, as well as all of the recommended groups from the SLP component. In addition, we are finalizing as proposed the use of the designated classifiers from the nursing component along with the uppermost comorbidity score of the NTA component. Regarding the latter, we appreciate the comment pointing out that the specific value assigned to the NTA component's uppermost comorbidity score under the PDPM is, in fact, 12+ and not 11+ as incorrectly indicated in the proposed rule's discussion of the presumption. We also appreciate another commenter's concern that the proposed NTA classifier might in some instances prove redundant in relation to the nursing groups; however, because we believe, as stated above, that the presumption should encompass *all* appropriate classifiers, we are finalizing the use of this particular classifier as we believe this particular classifier would serve to identify those cases that are the most likely to involve the kind of complex medication regimen that would require skilled oversight to manage safely and effectively. We also will evaluate the use of this classifier in actual operation and confirm whether there are instances in which it appropriately serves this function independently of the nursing groups. As we indicated in the proposed rule (83 FR 21072) regarding the NTA and other components, we will continue to review the new designations going forward and make further adjustments over time as we gain actual operating experience under the new classification model.

However, we would also note in this context that we do not share and cannot support the view that would essentially equate a given case-mix classifier's non-designation under the administrative presumption with a restriction on access or a denial of SNF coverage, or an increase in administrative burden. SNF coverage ultimately is based not on whether a beneficiary is assigned one of the designated classifiers, but on whether the SNF level of care criteria are met. As further explained in the proposed rule (83 FR 21071), the purpose of the administrative presumption is solely to afford a streamlined and simplified administrative procedure for readily identifying those beneficiaries with the *greatest likelihood* of meeting the level of care criteria, which in no way serves to disadvantage *other* beneficiaries who may *also* meet the level of care criteria. In fact, far from creating an overall increase in administrative burden from the non-designated classifiers, we expect that the presumption's framework of streamlined and simplified initial determinations for the designated classifiers will actually serve to *free up* staff resources, which can then be used for assessing coverage in the other cases.

Accordingly, for the reasons set forth in the proposed rule and in this final rule, we are finalizing our proposed classifiers for purposes of applying the administrative presumption under the PDPM with the following modifications. As discussed above, we are adding the following PT and OT classifiers to those we proposed: TA, TE, TJ, TK, TN and TO. We are also adding the following 8 SLP classifiers: SC, SE, SF, SH, SI, SJ, SK, and SL. Thus, effective October 1, 2019, we are designating the classifiers shown below for purposes of the administrative presumption under the PDPM:

- The case-mix classifiers in the following nursing categories: Extensive Services, Special Care High, Special Care Low, and Clinically Complex;
- The following PT and OT groups: TA, TB, TC, TD, TE, TF, TG, TJ, TK, TN, and TO;
- The following SLP groups: SC, SE, SF, SH, SI, SJ, SK, and SL; and
- The NTA component's uppermost comorbidity group (which, as finalized in this final rule, is 12+).

H. Effect of PDPM on Temporary AIDS Add-On Payment

As discussed in section V.I. of the proposed rule (83 FR 21072) and also in section III.E. of the ANPRM (82 FR 21007), section 511(a) of the MMA amended section 1888(e)(12) of the Act to provide for a temporary increase of 128 percent in the PPS per diem payment for any SNF residents with Acquired Immune Deficiency Syndrome (AIDS), effective with services furnished on or after October 1, 2004. This special add-on for SNF residents with AIDS was intended to be of limited duration, as the MMA legislation specified that it was to remain in effect only until the Secretary certifies that there is an appropriate adjustment in the case mix to compensate for the increased costs associated with such residents.

The temporary add-on for SNF residents with AIDS is also discussed in Program Transmittal #160 (Change Request #3291), issued on April 30, 2004, which is available online at *www.cms.gov/transmittals/downloads/r160cp.pdf*. In the SNF PPS final rule for FY 2010 (74 FR 40288, August 11, 2009), we did not address this certification in that final rule's implementation of the case-mix refinements for RUG–IV, thus allowing the add-on payment required by section 511 of the MMA to remain in effect for the time being.

In the House Ways and Means Committee Report that accompanied the MMA, the explanation of the MMA's temporary AIDS adjustment notes the following under *Reason for Change:* ''According to prior work by the Urban Institute, AIDS patients have much higher costs than other patients in the same resource utilization groups in skilled nursing facilities. The adjustment is based on that data analysis'' (H. Rep. No. 108–178, Part 2 at 221). The data analysis from that February 2001 Urban Institute study (entitled ''Medicare Payments for Patients with HIV/AIDS in Skilled Nursing Facilities''), in turn, had been conducted under a Report to Congress mandated under a predecessor provision, section 105 of the BBRA. This earlier BBRA provision, which ultimately was superseded by the temporary AIDS add-on provision required by the MMA, had amended section 1888(e)(12) of the Act to provide for special consideration for facilities serving specialized patient populations (that is, those who are ''immuno-compromised secondary to an infectious

disease, with specific diagnoses as specified by the Secretary'').

As we noted in the ANPRM and in the proposed rule, at that point over a decade and a half had elapsed since the Urban Institute conducted its study on AIDS patients in SNFs, a period that has seen major advances in the state of medical practice in treating this condition. We stated that these advances have notably included the introduction of powerful new drugs and innovative prescription regimens that have dramatically improved the ability to manage the viral load (the amount of human immunodeficiency virus (HIV) in the blood). We noted that the decrease in viral load secondary to medications has contributed to a shift from intensive nursing services for AIDS-related illnesses to an increase in antiretroviral therapy. We further stated that this phenomenon, in turn, is reflected in our recent analysis of differences in SNF resource utilization, which indicates that while the overall historical disparity in costs between AIDS and non-AIDS patients has not entirely disappeared, that disparity is now far greater with regard to drugs than it is for nursing. Specifically, as explained in the proposed rule, NTA costs per day for residents with AIDS were 151 percent higher than those for other residents while the difference in wage-weighted nursing staff time between the two groups was only 19 percent, as discussed in section 3.8.3. of the SNF PMR technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*), which the ANPRM referenced for further information on the underlying data analysis (82 FR 21007 through 21008). In the ANPRM, we also described how the RCS–I model would account for those NTA costs, including drugs, which specifically relate to residents with AIDS (82 FR 20997 through 20999). We additionally discussed in the ANPRM the possibility of making a specific 19 percent AIDS adjustment as part of the case-mix adjustment of the nursing component (82 FR 20995 through 20997). We further expressed our belief in the ANPRM (82 FR 21008) that when taken collectively, these adjustments would appropriately serve to justify issuing the certification prescribed under section 511(a) of the MMA, which would permit the MMA's existing, temporary AIDS add-on to be replaced by a permanent adjustment in the case mix that appropriately compensates for the increased costs associated with these residents.

As discussed in the proposed rule, in response to the ANPRM, we received comments expressing concerns that a projected 40 percent drop in overall payments for SNF residents with AIDS under the RCS–I model could adversely affect access to care for this patient population. Regarding those concerns, we noted in the proposed rule that the special add-on for SNF residents with AIDS itself was never meant to be permanent, and does not serve as a specific benchmark for use in establishing either the appropriate methodology or level of payment for this patient population. Rather, we stated that, as discussed in the ANPRM, it was designed to be only a temporary measure, representing a general approximation that reflected the current state of research and clinical practice at the time (82 FR 21007 through 21008). As such, we stated that the special add-on would not account for the significant changes in the care and treatment of this condition that have occurred over the intervening years. We further noted that as a simple across-the-board multiplier, the MMA adjustment by its very nature is not accurately targeted at those particular rate components that actually account for the disparity in cost between AIDS patients and others.

As discussed in section V.D.3.e. of the proposed rule (83 FR 21058), our updated investigations into the adequacy of payments under the proposed PDPM for residents with HIV/AIDS indicated that the four proposed ancillary payment components (PT, OT, SLP, and NTA) would adequately reimburse ancillary costs associated with HIV/AIDS residents (see section 3.8.2. of the SNF PDPM technical report, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*). Therefore, we stated that we believe it would be appropriate to issue the prescribed certification under section 511(a) of the MMA on the basis of the proposed PDPM's ancillary case-mix adjustment alone, as effectively providing the required appropriate adjustment in the case mix to compensate for the increased costs associated with such residents. However, to further ensure that the proposed PDPM would account as fully as possible for any remaining disparity with regard to nursing costs, as discussed in section V.D.3.d. of the proposed rule (83 FR 21055), we additionally proposed to include a specific AIDS adjustment as part of the case-mix adjustment of the nursing component. As discussed in section V.D.3.d. of the proposed rule, we used the STRIVE data to quantify the effects of HIV/AIDS diagnosis on nursing resource use. Regression analyses found that wage-weighted nursing staff time is 18 percent higher for residents with HIV/AIDS, controlling for the non-rehabilitation RUG of the resident. We noted that this figure is slightly lower than the 19 percent increase in wage-weighted nursing staff time reported in the ANPRM and the SNF PRM technical report because the updated investigation uses a FY 2017 study population and is based on the PDPM case-mix groups, while the earlier analysis was based on a FY 2014 study population and the RCS–I case-mix groups. More information on this analysis can be found in section 3.8.2. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*). Thus, we proposed an 18 percent increase in payment for the nursing component for residents with HIV/AIDS under the proposed PDPM to account for the increased nursing costs for such residents. We stated that similar to the proposed NTA adjustment for residents with HIV/AIDS, this adjustment would be identified by ICD–10–CM code B20 on the SNF claim and would be processed through the PRICER software used by CMS to set the appropriate payment rate for a resident's SNF stay. We also explained (83 FR 21073) that the 18 percent adjustment would be applied to the unadjusted base rate for the nursing component, and then this amount would be further case-mix adjusted per the resident's PDPM nursing classification.

In the proposed rule, we expressed the belief that when taken collectively, these adjustments under the proposed PDPM would appropriately serve to justify issuing the certification prescribed under section 511(a) of the MMA effective with the proposed conversion to the PDPM on October 1, 2019, thus permitting the MMA's existing, temporary AIDS add-on to be replaced by a permanent adjustment in the case mix (as proposed under the PDPM) that appropriately compensates for the increased costs associated with these residents, and we invited comments on this proposal. At the same time, we acknowledged that even with an accurately targeted model that compensates for the increased costs of SNF residents with AIDS, an abrupt conversion to an altogether different payment methodology might nevertheless be potentially disruptive for facilities, particularly those that serve a significant number of patients with AIDS and may have become accustomed to operating under the

existing payment methodology for those patients. Accordingly, we also invited comments on possible ways to help mitigate any potential disruption stemming from the proposed replacement of the special add-on payment with the permanent case-mix adjustments for SNF residents with AIDS under the proposed PDPM.

Commenters submitted the following comments related to the proposed rule's discussion on the Effect of the Proposed PDPM on Temporary AIDS Add-on Payment. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters expressed concern about the adequacy of payments under the PDPM for SNF residents with AIDS, once again citing the projected decrease in payments relative to the RUG–IV model (which currently includes the MMA's temporary 128 percent adjustment for such residents). One commenter specifically questioned the adequacy of the PDPM's NTA component in addressing the drug costs of AIDS patients, and cited a 2017 MedPAC report that characterized the SNF PPS's NTA payments as poorly targeted.

Response: We note that as with the previous comments on the corresponding aspect of the ANPRM, most of the commenters' concerns in this area stemmed from comparing the projected payment levels under the PDPM to those under the existing RUG–IV model's temporary 128 percent AIDS adjustment, and focused specifically on the contrast in payment levels between the two models. However, as noted above and explained in the proposed rule (83 FR 21073), it is not appropriate to use the MMA adjustment as a benchmark in assessing the accuracy of the PDPM's payment methodology, as the special add-on for SNF residents with AIDS itself was never meant to be permanent, and does not serve as a specific benchmark for use in establishing either the appropriate methodology or level of payment for this patient population. Rather, it was designed to be only a temporary measure, representing a general approximation that reflected the current state of research and clinical practice at the time. As such, the special add-on would not account for the significant changes in the care and treatment of this condition that have occurred over the intervening years. Moreover, as a simple across-the-board multiplier, the MMA adjustment by its very nature is not accurately targeted at those particular rate components that actually account for the disparity in cost between AIDS patients and others.

Regarding that final point about the imprecision of applying an across-the-board multiplier in this context, we further noted in the proposed rule (83 FR 20180) that our research found that HIV/AIDS was associated with a negative and statistically significant decrease in PT, OT and SLP costs per day. This means inherently that, to the extent that the existing add-on is applied against the full SNF PPS per diem payment, the magnitude of the add-on payment increases with increases in therapy payment, which conflicts with the data described above regarding the relationship between therapy costs and the presence of an AIDS diagnosis. As a result, maintaining the current add-on would create an inconsistency between how SNF payments would be made and the data regarding AIDS diagnoses and resident therapy costs.

Furthermore, to the extent that the RUG–IV model's case-mix classification system may have included inherent incentives toward the overprovision of therapy services, the MMA adjustment's operation as an across-the-board multiplier would actually serve to magnify the effects of any such incentives, by inflating the resulting payment levels even further beyond the patient's actual therapy care needs. In this context, we note that the specific standard prescribed for the Secretary's required certification under section 511(a) of the MMA is that ''. . . there is an appropriate adjustment in the case mix . . . to compensate for the increased costs'' associated with SNF residents with AIDS. As set forth in the proposed rule, we believe that the PDPM's payment methodology for patients with AIDS clearly meets this statutory standard of appropriately accounting for the actual costs incurred in caring for such patients. In fact, we believe it provides a far more accurate and current accounting of those costs than the temporary MMA adjustment that it would replace, which represents only a very broad approximation that was developed at a time when the treatment regimens for this condition differed dramatically from what they are currently. Finally, it is worth noting that the cited 2017 MedPAC report, which characterized the SNF PPS's NTA payments as poorly targeted, reflected that the SNF PPS has always included NTA costs within its nursing component rather than accounting for them separately, and the longstanding concerns about that approach were, in fact, the very impetus behind our development of a separate component for NTA costs under the PDPM.

Accordingly, for the reasons discussed in the proposed rule and in this final rule, the Secretary is certifying that there is an appropriate adjustment in the PDPM to compensate for the increased costs associated with residents with AIDS, and thus we are finalizing our proposal without modification to replace the temporary MMA add-on with the PDPM's permanent adjustment in the case mix that appropriately accounts for the increased costs of patients with AIDS, effective with the conversion to the PDPM on October 1, 2019.

I. Potential Impacts of Implementing the PDPM and Parity Adjustment

This section outlines the projected impacts of implementing the PDPM effective October 1, 2019 under the SNF PPS and the related policies finalized in sections V of this final rule that would be effective in conjunction with the PDPM. This impact analysis makes a series of assumptions, as described below (as were discussed in the proposed rule (83 FR 21073 through 21080)). First, the impacts presented here assume consistent provider behavior in terms of how care is provided under RUG–IV and how care might be provided under the PDPM, as we do not make any attempt to anticipate or predict provider reactions to the implementation of the PDPM. That being said, we acknowledge the possibility that implementing the PDPM could substantially affect resident care and coding behaviors. Most notably, based on the concerns raised during a number of TEPs, we acknowledge the possibility that, as therapy payments under the PDPM would not have the same connection to service provision as they do under RUG–IV, it is possible that some providers may choose to reduce their provision of therapy services to increase margins under the PDPM. However, we do not have any basis on which to assume the approximate nature or magnitude of these behavioral responses, nor have we received any sufficiently specific guidance on the likely nature or magnitude of behavioral responses from ANPRM commenters, TEP panelists, or other sources of feedback. As a result, lacking an appropriate basis to forecast behavioral responses, we do not adjust our analyses of resident and provider impacts discussed in this section for projected changes in provider behavior. However, we do intend to monitor behavior which may occur in response to the implementation of PDPM, and may consider proposing policies in the future to address such behaviors to the extent determined appropriate.

Additionally, we acknowledge that a number of states utilize some form of the RUG–IV case-mix classification system as part of their Medicaid programs and that any change in Medicare policy can have an impact on state programs. Again, we do not have any basis on which to assume the approximate nature or magnitude of these responses, for the same reasons cited above. Additionally, we do not expect impacts on state Medicaid programs resulting from PDPM implementation to have a notable impact on payments for Medicare-covered SNF stays, which are the basis for the impact analyses discussed in this section. Therefore, we do not consider possible changes to state Medicaid programs when conducting these analyses. We invited comments on our assumptions that behavior would remain unchanged under the proposed PDPM and that changes in state Medicaid programs resulting from PDPM implementation would not have a notable impact on payments for Medicare-covered SNF stays. We also invited comment on the impact of these policy proposals on state Medicaid programs. These comments are addressed among the general comments in section V.A. of this final rule.

As with prior system transitions, we proposed to implement the PDPM case-mix system, along with the other policy changes discussed throughout this section, in a budget neutral manner through application of a parity adjustment to the case-mix weights under the proposed PDPM, as further discussed below. We proposed to implement the PDPM in a budget neutral manner because, as with prior system transitions, in proposing changes to the case-mix methodology, we do not intend to change the aggregate amount of Medicare payments to SNFs. Rather, we aim to utilize a case-mix methodology to classify residents in such a manner as to best ensure that payments made for specific residents are an accurate reflection of resource utilization without introducing potential incentives which could encourage inappropriate care delivery, as we believe may exist under the current case-mix methodology. Therefore, the impact analysis presented here assumes implementation of these proposed changes in a budget neutral manner. We invited comments on the proposal, as further discussed below, to implement the PDPM in a budget neutral manner. In addition, we solicited comment on whether it would be appropriate to implement the proposed PDPM in a manner that is not budget neutral.

As discussed above, the impact analysis presented here assumes implementation of these changes in a budget neutral manner without a behavioral change. The prior sections describe how case-mix weights are set to reflect relative resource use for each case-mix group. We stated in the proposed rule that the proposed PDPM payment before application of a parity adjustment would be calculated using the unadjusted CMI for each component, the variable per diem payment adjustment schedule, the unadjusted urban and rural federal per diem rates shown in Tables 12 and 13, the labor-related share, and the geographic wage indexes. In applying a parity adjustment to the case-mix weights, we stated in the proposed rule that we would maintain the relative value of each CMI but would multiply every CMI by a ratio to achieve parity in overall SNF PPS payments under the PDPM and under the RUG–IV case-mix model. The parity adjustment multiplier was calculated through the following steps, as described in the proposed rule (83 FR 21074). First, we calculated RUG–IV total payment. Total RUG–IV payments were calculated by adding total allowed amounts across all FY 2017 SNF claims. The total allowed amount in the study population was the summation of Medicare and non-Medicare payments for Medicare-covered days. More specifically, it was the sum of Medicare claim payment amount, National Claim History (NCH) primary payer claim paid amount, NCH beneficiary inpatient deductible amount, NCH beneficiary Part A coinsurance liability amount, and NCH beneficiary blood deductible liability amount. Second, we calculated what total payment would have been under the proposed PDPM in FY 2017 before application of the parity adjustment. Total estimated payments under PDPM were calculated by summing the predicted payment for each case-mix component together for all FY 2017 SNF stays. This represented the total allowed amount if PDPM had been in place in FY 2017. Total estimated FY 2017 payments under the PDPM were calculated using resident information from FY 2017 SNF claims, the MDS assessment, and other Medicare claims, as well as the unadjusted CMI for each component, the variable per diem payment adjustment schedule, the unadjusted urban and rural federal per diem rates shown in Tables 12 and 13, the labor-related share, and the geographic wage indexes. After calculating total actual RUG–IV payments and total estimated case-mix-related PDPM payments, we subtracted non-case-mix component payments from total RUG–IV payments, as this component does not change across systems. This subtraction did not include the temporary add-on for residents with HIV/AIDS in the RUG–IV system, which PDPM replaces with additional payments for residents with HIV/AIDS through the NTA and nursing components (as discussed in section V.I. of the proposed rule and section V.H. of this final rule). By retaining the portion of non-case-mix component payments associated with the temporary HIV/AIDS add-on in total RUG–IV payments, all payments associated with the add-on under RUG–IV were re-allocated to the case-mix-adjusted components in PDPM. This was appropriate because, as discussed, under the PDPM, additional payments for residents with HIV/AIDS are made exclusively through the case-mix-adjusted components (that is, the nursing and NTA components). Lastly, in calculating budget neutrality, we set total estimated case-mix-related payment under PDPM such that it equals total allowable Medicare payments under RUG–IV. To do this, we divided the remaining total RUG–IV payments over the remaining total estimated PDPM payments prior to the parity adjustment. This division yielded a ratio (parity adjustment) of 1.46 by which the PDPM CMIs were multiplied so that total estimated payments under the PDPM would be equal to total actual payments under RUG–IV, assuming no changes in the population, provider behavior, and coding. We stated in the proposed rule that, if this parity adjustment had not been applied, total estimated payments under the PDPM would be 46 percent lower than total actual payments under RUG–IV, therefore the implementation of the PDPM would not be budget neutral. More details regarding this calculation and analysis are described in section 3.11.2. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*). The impact analysis presented in this section (and in the proposed rule) focuses on how payments under the PDPM would be re-allocated across different resident groups and among different facility types, assuming implementation in a budget neutral manner.

The projected resident-level impacts are presented in Table 37. The first column identifies different resident subpopulations and the second column

shows what percent of SNF stays in FY 2017 are represented by the given subpopulation. The third column shows the projected change in total payments for residents in a given subpopulation, represented as a percentage change in actual FY 2017 payments made for that subpopulation under RUG–IV versus estimated payments which would have been made to that subpopulation in FY 2017 had the PDPM been in place. Total RUG–IV payments are calculated by adding total allowed amounts across all FY 2017 SNF claims associated with a resident subpopulation. The total allowed amount in the study population is the summation of Medicare and non-Medicare payments for Medicare-covered days. More specifically, it is the summation of Medicare claim payment amount, NCH primary payer claim paid amount, NCH beneficiary inpatient deductible amount, NCH beneficiary Part A coinsurance liability amount, and NCH beneficiary blood deductible liability amount. Payments corresponding to the non-case-mix component are subtracted from the RUG–IV total payments, not including the portion of non-case-mix payments corresponding to the temporary add-on for residents with HIV/AIDS. Total estimated payments under PDPM are calculated by summing the predicted payment for each case-mix component together for all FY 2017 SNF stays associated with a resident subpopulation. Positive changes in this column represent a projected positive shift in payments for that subpopulation under the PDPM, while negative changes in this column represent projected negative shifts in payment for that subpopulation. More information on the construction of current payments under RUG–IV and payments under the PDPM for purposes of this impact analysis can be found in section 3.12. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*). Based on the data presented in Table 37, we observe that the most significant shift in payments created by implementation of the PDPM would be to redirect payments away from residents who are receiving very high amounts of therapy under the current SNF PPS, which strongly incentivizes the provision of therapy, to residents with more complex clinical needs. For example, we project that for residents whose most common therapy level is RU (ultra-high therapy)—the highest therapy level, there would be a reduction in associated payments of 8.4 percent, while payments for residents currently classified as non-rehabilitation would increase by 50.5 percent. Other resident types for which there may be higher relative payments under the PDPM are: Residents who have high NTA costs, receive extensive services, are dually enrolled in Medicare and Medicaid, use IV medication, have ESRD, diabetes, or a wound infection, receive amputation/prosthesis care, and/or have longer prior inpatient stays. Additionally, we received several comments in response to the 2017 ANPRM requesting that we estimate the impact of RCS–1 on the following potentially vulnerable subpopulations: Residents with addictions, bleeding disorders, behavioral issues, chronic neurological conditions, and bariatric care. In response to these comments, we added these subpopulations to our PDPM impact analysis. Table 37 shows that the PDPM is projected to increase the proportion of total payment associated with each of those subpopulations.

TABLE 37—PDPM IMPACT ANALYSIS, RESIDENT-LEVEL

Resident characteristics	Percent of stays	Percent change
All Stays	100.0	0.0
Sex:		
Female	60.3	−0.8
Male	39.7	1.2
Age:		
Below 65 years	10.3	7.2
65–74 years	24.1	3.1
75–84 years	32.5	−0.4
85–89 years	17.6	−3.1
Over 90 years	15.6	−4.3
Race/Ethnicity:		
White	83.8	−0.2
Black	11.2	0.8
Hispanic	1.7	0.9
Asian	1.3	−0.6
Native American	0.5	7.1
Other or Unknown	1.5	0.8
Medicare/Medicaid Dual Status:		
Dually Enrolled	34.7	3.3
Not Dually Enrolled	65.3	−2.1
Original Reason for Medicare Enrollment:		
Aged	74.6	−1.7
Disabled	24.5	4.8
ESRD	0.9	10.5
Utilization Days:		
1–15 days	35.4	13.7
16–30 days	33.8	0.0
31+ days	30.9	−2.5
Utilization Days = 100:		
No	98.4	0.1
Yes	1.6	−1.9
Length of Prior Inpatient Stay:		
0–2 days	2.2	1.3
3 days	22.5	−3.3
4–30 days	73.6	0.7

TABLE 37—PDPM IMPACT ANALYSIS, RESIDENT-LEVEL—Continued

Resident characteristics	Percent of stays	Percent change
31+ days	1.7	6.7
Most Common Therapy Level:		
RU	58.4	−8.4
RV	22.4	11.4
RH	6.8	27.4
RM	3.3	41.1
RL	0.1	67.5
Non-Rehab	9.1	50.5
Number of Therapy Disciplines Used:		
0	2.3	63.1
1	2.4	44.2
2	51.6	1.6
3	43.7	−3.1
Physical Therapy Utilization:		
No	3.7	50.9
Yes	96.3	−0.7
Occupational Therapy Utilization:		
No	4.5	47.7
Yes	95.5	−0.8
Speech Language Pathology Utilization:		
No	55.0	2.8
Yes	45.0	−2.5
Therapy Utilization:		
PT+OT+SLP	43.7	−3.1
PT+OT Only	50.8	1.3
PT+SLP Only	0.4	27.3
OT+SLP Only	0.4	30.1
PT Only	1.3	41.3
OT Only	0.6	47.9
SLP Only	0.5	46.8
Non-Therapy	2.3	63.1
NTA Costs ($):		
0–10	13.7	−3.5
10–50	44.5	−3.2
50–150	32.2	4.2
150+	9.6	18.7
NTA Comorbidity Score:		
0	23.5	−10.4
1–2	30.5	−4.7
3–5	31.0	4.0
6–8	9.9	15.0
9–11	3.6	24.4
12+	1.4	27.2
Extensive Services Level:		
Tracheostomy and Ventilator/Respirator	0.3	22.2
Tracheostomy or Ventilator/Respirator	0.6	7.3
Infection Isolation	1.1	9.1
Neither	98.0	−0.3
CFS Level:		
Cognitively Intact	58.5	−0.3
Mildly Impaired	20.7	−0.2
Moderately Impaired	16.8	−0.7
Severely Impaired	3.9	8.8
Clinical Category:		
Acute Infections	6.5	3.4
Acute Neurologic	6.4	−3.7
Cancer	4.6	−3.2
Cardiovascular and Coagulations	9.8	0.5
Major Joint Replacement or Spinal Surgery	8.6	−2.1
Medical Management	30.4	0.0
Non-Orthopedic Surgery	10.8	5.7
Non-Surgical Orthopedic/Musculoskeletal	5.9	−6.1
Orthopedic Surgery (Except Major Joint Replacement or Spinal Surgery)	8.9	−2.4
Pulmonary	8.1	5.4
Level of Complications in MS–DRG of Prior Inpatient Stay:		
No Complication	35.8	−3.1
CC/MCC	64.2	1.7
Stroke:		
No	90.9	0.0
Yes	9.1	0.3
HIV/AIDS:		

TABLE 37—PDPM IMPACT ANALYSIS, RESIDENT-LEVEL—Continued

Resident characteristics	Percent of stays	Percent change
No	99.7	0.3
Yes	0.3	−40.5
IV Medication:		
No	91.7	−2.1
Yes	8.3	23.5
Diabetes:		
No	64.0	−3.0
Yes	36.0	5.4
Wound Infection:		
No	98.9	−0.3
Yes	1.1	22.2
Amputation/Prosthesis Care:		
No	100.0	0.0
Yes	0.0	6.4
Presence of Dementia:		
No	70.9	0.5
Yes	29.1	−1.2
MDS Alzheimer's:		
No	95.2	0.0
Yes	4.8	−0.3
Unknown	0.0	5.0
Presence of Addictions:		
No	94.6	−0.1
Yes	5.4	1.8
Presence of Bleeding Disorders:		
No	90.9	−0.1
Yes	9.1	1.5
Presence of Behavioral Issues:		
No	53.1	−0.9
Yes	46.9	1.0
Presence of Chronic Neurological Conditions:		
No	74.4	−0.2
Yes	25.6	0.6
Presence of Bariatric Care:		
No	91.3	−0.6
Yes	8.7	6.5

The projected provider-level impacts are presented in Table 38. The first column identifies different facility subpopulations and the second column shows what percentage of SNFs in FY 2017 are represented by the given subpopulation. The third column shows the projected change in total payments for facilities in a given subpopulation, represented as a percentage change in actual FY 2017 payments made for that subpopulation under RUG–IV versus estimated payments which would have been made to that subpopulation in FY 2017 had the PDPM been in place. Total RUG–IV payments are calculated by adding total allowed amounts across all FY 2017 SNF claims associated with a facility subpopulation. The total allowed amount in the study population is the summation of Medicare and non-Medicare payments for Medicare-covered days. More specifically, it is the summation of Medicare claim payment amount, NCH primary payer claim paid amount, NCH beneficiary inpatient deductible amount, NCH beneficiary Part A coinsurance liability amount, and NCH beneficiary blood deductible liability amount. Payments corresponding to the non-case-mix component are subtracted from the RUG–IV total payments, not including the portion of non-case-mix payments corresponding to the temporary add-on for residents with HIV/AIDS. Total estimated payments under PDPM are calculated by summing the predicted payment for each case-mix component together for all FY 2017 SNF stays associated with a facility subpopulation. Positive changes in this column represent a projected positive shift in payments for that subpopulation under the PDPM, while negative changes in this column represent projected negative shifts in payment for that subpopulation. More information on the construction of current payments under RUG–IV and payments under the PDPM for purposes of this impact analysis can be found in section 3.12. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch.html*). Based on the data presented in Table 38, we observe that the most significant shift in Medicare payments created by implementation of the PDPM would be from facilities with a high proportion of rehabilitation residents (particularly facilities with high proportions of Ultra-High Rehabilitation residents) to facilities with high proportions of non-rehabilitation residents. We project that payments to facilities that bill 0 to 10 percent of utilization days as RU (ultra-high rehabilitation) would increase an estimated 27.6 percent under the PDPM while facilities that bill 90 to 100 percent of utilization days as RU would see an estimated decrease in payments of 9.8 percent. Other facility types that may see higher relative payments under the PDPM are small facilities, non-profit facilities, government-owned facilities, and hospital-based and swing-bed facilities.

TABLE 38—PDPM IMPACT ANALYSIS, FACILITY-LEVEL

Provider characteristics	Percent of providers	Percent change
All Stays	100.0	0.0
Ownership:		
For profit	72.0	−0.7
Non-profit	22.6	1.9
Government	5.4	4.2
Number of Certified SNF Beds:		
0–49	10.0	3.5
50–99	38.2	0.6
100–149	34.7	−0.2
150–199	11.1	−0.3
200+	5.9	−1.8
Location:		
Urban	72.7	−0.7
Rural	27.3	3.8
Facility Type:		
Freestanding	96.2	−0.3
Hospital-Based/Swing Bed	3.8	16.7
Location by Facility Type:		
Urban | Freestanding:	70.6	−1.0
Urban | Hospital-Based/Swing Bed	2.2	15.3
Rural | Freestanding	25.6	3.2
Rural | Hospital-Based/Swing Bed	1.6	21.1
Census Division:		
New England	5.9	2.0
Middle Atlantic	10.8	−2.6
East North Central	20.6	0.7
West North Central	12.5	6.7
South Atlantic	15.7	−0.4
East South Central	6.6	1.0
West South Central	13.1	−1.0
Mountain	4.7	1.1
Pacific	10.1	−0.8
Location by Region:		
Urban | New England	5.1	1.8
Urban | Middle Atlantic	9.5	−2.9
Urban | East North Central	14.4	−0.1
Urban | West North Central	6.0	4.6
Urban | South Atlantic	12.6	−1.1
Urban | East South Central	3.6	0.3
Urban | West South Central	8.7	−1.2
Urban | Mountain	3.4	0.1
Urban | Pacific	9.5	−0.9
Rural | New England	0.8	4.0
Rural | Middle Atlantic	1.3	2.7
Rural | East North Central	6.2	3.6
Rural | West North Central	6.5	10.5
Rural | South Atlantic	3.1	4.2
Rural | East South Central	3.0	2.1
Rural | West South Central	4.4	−0.1
Rural | Mountain	1.3	6.2
Rural | Pacific	0.6	2.2
% Stays with Maximum Utilization Days = 100:		
0–10	94.4	0.1
10–25	5.1	−2.8
25–100	0.4	−3.6
% Medicare/Medicaid Dual Enrollment:		
0–10	8.6	−1.3
10–25	17.5	−1.3
25–50	36.0	0.3
50–75	26.5	1.3
75–90	8.2	0.4
90–100	3.1	1.6
% Utilization Days Billed as RU:		
0–10	8.9	27.6
10–25	8.0	15.5
25–50	24.1	7.0
50–75	39.2	−0.4
75–90	17.2	−6.0
90–100	2.6	−9.8
% Utilization Days Billed as Non-Rehab:		
0–10	79.8	−1.5

TABLE 38—PDPM IMPACT ANALYSIS, FACILITY-LEVEL—Continued

Provider characteristics	Percent of providers	Percent change
10–25	16.6	8.6
25–50	2.7	23.1
50–75	0.4	35.8
75–90	0.2	41.8
90–100	0.4	33.6

We proposed to implement the PDPM effective beginning in FY 2020 (that is, October 1, 2019). This effective date would incorporate a 1-year period to allow time for provider education and training, internal system transitions, and to allow states to make any Medicaid program changes which may be necessary based on the changes related to PDPM.

With regard to the changes finalized in this rule, we provide our reasons for each change throughout the subsections above. Below in this section, we discuss alternatives we considered which relate generally to implementation of the PDPM.

When making major system changes, CMS often considers possible transition options for providers and other stakeholders between the former system and the new system. For example, when we updated OMB delineations used to establish a provider's wage index under the SNF PPS in FY 2015, we utilized a blended rate in the first year of implementation, whereby 50 percent of the provider's payment was derived from their former OMB delineation and 50 percent from their new OMB delineation (79 FR 45644–45646).

However, due to the fundamental nature of the change from the current RUG–IV case-mix model to the PDPM, which includes differences in resident assessment, payment algorithms, and other policies, as we stated in the proposed rule (83 FR 21079), we believe that proposing a blended rate for the whole system (that would require two full case-mix systems—RUG–IV and the PDPM—to run concurrently) is not advisable as part of any transition strategy for implementing the PDPM, due to the significant administrative and logistical issues that would be associated with such a transition strategy. Specifically, CMS and providers would be required to manage both the RUG–IV payment model and PDPM simultaneously, creating significant burden and undue complexity for all involved parties. Furthermore, providers would be required to follow both sets of MDS assessment rules, each of which carries with it its own level of complexity. CMS would also be required to process assessments and claims under each system, which would entail a significant amount of resources and burden for CMS, MACs, and providers. Finally, a blended rate option would also mitigate some of the burden reduction associated with implementing PDPM, estimated to save SNFs close to $200 million per year as compared to estimated burden under RUG–IV, given that the current assessment schedule would need to continue until full implementation of PDPM was achieved. As we stated in the proposed rule, we believe these issues also would be implicated in any alternative transition strategy which would require both case-mix systems to exist concurrently, such as giving providers a choice in the first year of implementation of operating under either the RUG–IV or PDPM. Therefore, we did not pursue any alternatives which required concurrent operation of both the RUG–IV and PDPM.

As discussed in the proposed rule (83 FR 21079), we then considered alternative effective dates for implementing the PDPM, and other associated policy changes. We considered implementing the new case-mix model effective beginning in FY 2019, but we believe that this would not permit sufficient time for providers and other stakeholders, including CMS, to make the necessary preparations for a change of this magnitude in the SNF PPS. We also believe that such a quick transition would not be in keeping with how similar types of SNF PPS changes have been implemented in the past. We also considered implementing PDPM more than one year after being finalized, such as implementing the PDPM effective beginning October 1, 2020 (FY 2021). However, we believe that setting the effective date of PDPM this far out is not necessary, based on our prior experience with similar SNF PPS changes. As is customary, we plan to continue to provide free software to providers which can be used to group residents under the PDPM, as well as providing data specifications for this grouper software as soon as is practicable, thereby mitigating potential concerns around software vendors having sufficient time to develop products for PDPM. Moreover, given the issues identified throughout the proposed rule and this final rule with the current RUG–IV model, notably the issues surrounding the burden and complexity of the current SNF PPS assessment schedule and concerns around the incentives for therapy overprovision under the RUG–IV system, we believe it appropriate to implement the PDPM as soon as is practicable.

Finally, we considered alternatives related to the proposal discussed in section V.I. of this final rule, specifically the proposed certification that we have met the requirements set forth in section 511(a) of the MMA, which would permit us to use the PDPM's permanent case-mix adjustments for SNF residents with AIDS to replace the temporary special add-on in the PPS per diem payment for such residents. As noted in section V.I. of this final rule, this special add-on for SNF residents with AIDS was intended to be of limited duration, as the MMA legislation specified that it was to remain in effect only until the Secretary certifies that there is an appropriate adjustment in the case mix to compensate for the increased costs associated with such residents. We considered maintaining this adjustment under the PDPM. However, given the adjustment incorporated into the NTA and nursing components under the PDPM to account for the increased costs of treating residents with AIDS, this would result in a substantial increase in payment for such residents beyond even the current add-on payment. Moreover, as discussed in section V.I. of this final rule, we believe that the PDPM provides a tailored case-mix adjustment that more accurately accounts for the additional costs and resource use of residents with AIDS, as compared to an undifferentiated add-on which simply applies an across-the-board multiplier to the full SNF PPS per diem. Finally, as stated in section 3.8.2. of the SNF PDPM technical report (available at *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/SNFPPS/therapyresearch.html*), HIV/AIDS was associated with a negative and

statistically significant decrease in PT, OT and SLP costs per day. This means inherently that, to the extent that the existing add-on is applied against the full SNF PPS per diem payment, the magnitude of the add-on payment increases with increases in therapy payment, which conflicts with the data described above regarding the relationship between therapy costs and the presence of an AIDS diagnosis. As a result, maintaining the current add-on would create an inconsistency between how SNF payments would be made and the data regarding AIDS diagnoses and resident therapy costs. Therefore, we proposed (and are finalizing in this rule) replacing this add-on payment with appropriate case-mix adjustments for the increased costs of care for this population of residents through the NTA and nursing components of the PDPM.

We invited comments on the projected impacts and on the proposals and alternatives discussed throughout this section.

Commenters submitted the following comments related to the proposed rule's discussion of the Potential Impacts of Implementing the Proposed PDPM and Proposed Parity Adjustment. A discussion of these comments, along with our responses, appears below.

Comment: Commenters agreed that PDPM should be implemented in a budget neutral manner. With regard to the impact analysis, several commenters suggest that CMS run the entire PDPM model on a second year of data (or partial 2018 data) to examine the impact on individual providers and beneficiaries. Commenters state that using only one year of data does not allow analysis of the impact of changing patient populations over time.

Response: We appreciate the support for our proposed budget neutral implementation. With regards to the comment that CMS should use more than one year of data for the impact analysis, we would note that while CMS did not specifically examine the impact of PDPM on individual providers and beneficiaries across multiple years, we did take several steps to ensure robustness of our results. First, to ensure that the classification would be relevant for the current SNF population, we used the latest complete year of data available, FY 2017, to construct the payment model. Second, based on comments received in response to the 2017 ANPRM, we used four years of data (FYs 2014–2017) to determine which comorbidities to include in the NTA component and the number of points to assign to each condition/service for purposes of resident classification and payment. Third, as discussed in section 1.3 of the SNF PDPM technical report, we conducted a series of investigations to test the robustness of our results across multiple years. We found that: The distribution of stays and resource utilization by each classifier used in the payment model (for example, clinical category, cognitive status, etc.), the case-mix groups generated by the CART algorithm, the costliest NTA comorbidities, and the distribution of stays across nursing RUGs was very similar across multiple years. Fourth, we examined changes in SNF resident characteristics over time in response to concerns raised by participants in technical expert panels, focusing on specific resident characteristics that TEP panelists identified as indicators of increasing acuity. These investigations generally found that resident characteristics changed little over time.

Finally, while we did not analyze the impact of PDPM on individual providers and beneficiaries across multiple years, we note that we also examined the impact of the RCS–I payment model, which has substantially similar classification criteria as PDPM, on various resident and provider subpopulations using FY 2014 data. The results of this analysis, shown in section 3.13 of the SNF PMR technical report and the 2017 ANPRM (82 FR 21008 through 21012), were consistent with the resident and provider subpopulation impact analysis conducted for PDPM (section 3.12 of the SNF PDPM technical report) in showing that a payment model based on the set of resident characteristics used to construct PDPM would be expected to increase payment associated with resident subpopulations with complex clinical needs, such as extensive services, high NTA utilization, IV medications, ESRD, diabetes, wound infections, amputation/prosthesis care, and longer inpatient stays. For all of the foregoing reasons, we expect PDPM to be robust and to have similar impacts on residents and providers across multiple years.

Comment: One commenter stated that there are several methodological issues that may affect the accuracy of PDPM impact calculations under budget neutrality. This includes:

(1) The use of hospital MS–DRGs in developing clinical categories will likely result in an inaccurate estimation of payment. Payment rates were set and impacts predicted based on using the MS–DRG assignment of the patient, whereas PDPM when implemented will rely on MDS responses. If SNFs report patients at a net lower acuity level in MDS data than the predicted clinical categorization, then the budget neutrality assumptions made by PDPM will be invalid.

(2) The conversion of charges to costs will likely result in an underestimation of payment. Because SNF charges have not driven payments under the SNF PPS before, it is possible SNFs will systematically re-evaluate their charges practices to bring them more in line with the cost information within their accounting systems. As a result, the use of SNF charges may need to be rapidly reevaluated once PDPM is implemented.

(3) The quality of FY 2017 section GG data is questionable due to the likely inaccuracies in newly implemented items. Thus, PDPM impacts may need to be re-run once more stable section GG data are available to ensure PDPM accurately accounts for patient functional characteristics.

Response: As stated in the proposed rule (83 FR 21074) and section 3.11.2 of the SNF PDPM technical report, the budget neutrality assumption refers to having total payments if PDPM had been in place be equal to total actual RUG–IV payments in FY 2017. It does not account for provider behavior change after the implementation of PDPM. We appreciate the concerns raised, and we will monitor the reporting of MDS clinical categories, charges, and section GG items under PDPM.

Comment: One commenter stated that PDPM does not adequately account for residents with behavioral health issues. The commenter stated that SNFs are treating younger patients with longer stays and complex behavioral needs. Further, the commenter said representatives of geriatric behavioral health services were not included in the TEPs that were convened during PDPM development. A few commenters requested that CMS study the impact of PDPM on beneficiaries with long stays, such as those exceeding 84 days in length to determine whether the payment model creates potential access issues for such beneficiaries.

Response: While our TEPs did not include a specific representative of geriatric behavioral health services, in response to the feedback received from TEP panelists, we investigated the impact of PDPM on residents with behavioral health issues. As discussed in section 3.12 of the SNF PDPM technical report, we found that PDPM is predicted to slightly increase payment associated with residents who have behavioral issues. Therefore, we believe the proposed payment model appropriately accounts for the resource needs of this subpopulation. Additionally, we found that PDPM is

expected to notably increase payment associated with younger residents (below 65 and 65–74 years of age). However, we also estimated that payment associated with very long stays (utilization = 100 days) would decline by 1.9 percent under PDPM. We do plan to monitor the impact of PDPM on many different subpopulations, including those with long SNF stays.

Comment: Another commenter raised concerns about the provider-specific impact analysis included in the supplementary materials that were designed to aid stakeholders in reviewing and commenting on the proposed rule. The commenter stated that there were large differences in the estimated payment impact on individual providers between the provider-level impact file that accompanied the 2017 ANPRM and the provider-level impact file that accompanied the FY 2019 proposed rule. Additionally, the commenter stated that some providers have impact estimates in the RCS–I provider-level impact file (which accompanied the 2017 ANPRM) but are missing estimates in the PDPM provider-level impact file (which accompanied the FY 2019 SNF PPS proposed rule). According to the commenter, these discrepancies raise concerns about the reliability, accuracy, and completeness of the data used to develop PDPM.

Response: The commenter that raised concerns about changes in the provider-level impacts between the RCS–I and the PDPM provider-level impact files correctly notes that the provider-level impacts changed across the two files. There are two main reasons for changes in provider-level impacts across these two files that do not raise concerns about the quality of the data used to conduct the provider-specific impact analysis or to develop PDPM. First, the year of analysis is different across the two files. The RCS–I analysis uses data from FY 2014, which was also the year of data used to develop RCS–I, while the PDPM analysis uses data from FY 2017. Changes in the resident population of specific providers could contribute to changes in the estimated provider-level impact of the payment models.

Second, the two provider-level files provide impacts for two different payment models: The first displays impacts for RCS–I, while the second displays impacts for PDPM. While the two payment models are similar, differences between the two models also contribute to changes in estimated provider-level impacts. For the foregoing reasons, we should not expect the estimated payment impact for each provider be the same across the two payment models and data years. We further note that at the population level, the estimated impact on specific types of providers and residents was similar under RCS–I and PDPM, reflecting the similarity of the payment models. Specifically, for both models we estimate that payment would shift from stays receiving high amounts of therapy and providers that provide high amounts of therapy to stays associated with medically complex beneficiaries and providers that serve these beneficiaries.

Regarding providers that were included in the RCS–I provider-specific file but not in the PDPM provider-specific file, this occurs for three reasons: (1) The provider had no stays in FY 2017, the year of analysis for the PDPM file, (2) after applying matching and validity restrictions, the provider had no stays remaining in the dataset, or had fewer than 11 stays (and therefore could not be included for confidentiality reasons), or (3) after excluding stays that did not have sufficient information to be classified into a case-mix group for each PDPM component, the provider had fewer than 11 stays. Of the roughly 1,100 providers that were included in the RCS–I file but not included in the PDPM file, about 60 percent were excluded for reason (3); of the remaining excluded providers, about half were excluded for reason (1) and half were excluded for reason (2). It should also be noted that in total, there are about 700 fewer providers in the PDPM file than there are in the RCS–I file. Because this number is less than the number of providers included in the RCS–I file but not included in the PDPM file, this indicates that there are also a number of providers that are included in the PDPM file but not in the RCS–I file. To confirm the representativeness of our PDPM study population, we compared resident characteristics for the study population and the Medicare Part A SNF population, as shown in section 3.1.5 of the SNF PDPM technical report. As noted in the technical report, the two populations are similar in most respects, although the study population contains a higher proportion of stays from for-profit and freestanding facilities and a lower proportion of stays from non-profit, government, hospital-based, and swing bed facilities. Given the similarity of the two populations, we do not believe our population restrictions compromised the representativeness of our study population or the reliability of our results.

Comment: One commenter stated that there are apparent errors in the PDPM provider-specific impact file. The commenter states that the total numbers of days and stays shown in the file do not match the sum of the values in the respective columns. Additionally, the commenter states that the percentages of stays shown in the case-mix group distribution does not sum to 500 percent (as they should because 100 percent of days are assigned to a case-mix group within each of the five components) for three specific facilities. The commenter notes that all other rows in this tab correctly sum to 500 percent. The commenter recommends CMS research these issues and publish a corrected file as necessary.

Response: The commenter that stated the total stays and days shown in provider-specific file do not match the sum of the values in the respective columns is correct. The reason for this apparent discrepancy is that, while the total stays and days shown in this file include providers with fewer than 11 stays, these providers are not shown separately in the file for confidentiality reasons. As a result, the displayed totals across all facilities do not match the totals calculated from summing across rows. Regarding the three instances the commenter cites in which the percentages for the case-mix group distribution do not sum to 500 percent, we were unable to replicate this issue. We verified that the case-mix group distribution shown in the provider-specific file for each of these three providers does in fact sum to 500 percent and further verified that the case-mix group distribution sums to 500 percent for all providers shown in the file. Therefore, we do not believe a correction is warranted.

Comment: Some commenters supported CMS' decision not to propose a blended rate transition between RUG–IV and PDPM, but rather to make a full transition from one system to the other. Some commenters expressed support for a transition, requesting that CMS conduct a feasibility study to examine the impact of PDPM, particularly the therapy components, on access to medically necessary therapy. One commenter requested that CMS phase-in any negative impacts on providers from implementing PDPM. One commenter stated that, given the similarities between the RCS–I model and the PDPM, CMS should move forward with implementing PDPM in FY 2019. One commenter requested clarification on how a patient's reimbursement would be affected if the stay began under RUG–IV and ended under PDPM.

Response: We appreciate the support for our decision not to implement a transition strategy such as a blended rate option. We do not believe that such

a transition, or one that would phase in negative impacts, would be beneficial for SNFs or their patients given the complexity of operating two systems simultaneously. With regard to the suggestion that CMS conduct a feasibility study to examine the impact of PDPM, we believe that the monitoring program we plan to undertake with implementation of PDPM will provide all of the necessary information in an efficient and expeditious manner that would negate the reasons for conducting a feasibility study. Finally, with regard to the comment that CMS implement PDPM in FY 2019, despite the similarities between RCS–I and PDPM, the education and training efforts necessary to ensure successful implementation of PDPM will likely require more time than such an implementation date would permit.

With regard to the comment about a patient that begins a stay under RUG–IV but ends under PDPM, given that there will be no transition period between RUG–IV and PDPM, providers would bill under RUG–IV for all days up to and including September 30, 2019 and then bill under PDPM for all days beginning October 1, 2019. Further, RUG–IV assessment scheduling and other RUG–IV payment-related policies would be in effect until September 30, 2019. Beginning on October 1, 2019, all PDPM related assessment scheduling and other PDPM payment-related policies would take effect.

Comment: One commenter stated that PDPM would require a minimum of 12 months for programming, testing, validating and deploying of software updates and tools. This commenter requested that CMS allow for our systems to report to providers RUG–IV payment data, such as associated HIPPS codes, up to 60 days after implementation of PDPM.

Response: We agree with the commenter regarding the timeframe for software development, which is part of the reason we are implementing PDPM on October 1, 2019, rather than in 2018. With regard to the comment that we report RUG–IV payment data after implementation of PDPM, we will consider this suggestion as part of transition planning.

Comment: Many commenters stressed the importance of provider education and training to support successful implementation of the PDPM. These commenters suggested that extensive education and training of all involved parties will be needed because PDPM is such a significant change from the existing system. These commenters recommend that CMS immediately begin work with stakeholders to identify and to plan for meeting these needs and to provide the necessary tools to implement the new system smoothly. Further, commenters suggested that, in Fall 2018, CMS should convene a PDPM Implementation Technical Expert Panel (TEP) comprised of SNF PPS stakeholders, representatives from states, referral sources, and payer representatives, and that the TEP Report should be made public and serve as the basis for a PDPM Transition Plan. Finally, several commenters urged CMS to release any technical specifications and manual revisions as soon as possible, to give providers and vendors as much time as possible to adapt to any PDPM-related changes.

Response: We agree with the comments regarding the importance of provider education and training and will be providing extensive opportunities and resources to accomplish this task. With regard to the suggestion for a TEP related to PDPM implementation, we appreciate this suggestion and will consider several methods to engage the stakeholder community in preparing for PDPM implementation. With regard to the comments on the need for transition planning and for CMS' timely release of any technical specifications and manual revisions, we agree with commenters and intend to release technical specifications and manual revisions as soon as possible, which will include specific instructions on operationalizing the transition from RUG–IV to PDPM.

Comment: A few commenters requested that CMS establish a formal and transparent process and timeline for refining the PDPM therapy components after implementation of PDPM.

Response: While we agree with using a transparent process for refining PDPM, as was used during its development, we believe it is premature at this time to provide such a timeframe for revisions to the model, until we are able to observe the impact of implementing this model.

Comment: One commenter requested that CMS consider providing additional funding during initial implementation of PDPM, given that providers will be under financial pressures associated with training, software purchases, as well as changes associated with other CMS initiatives.

Response: We do not believe that additional funding would be warranted for the activities described by the commenter. Given that CMS provides free grouper software, as well as a myriad of training and education resources, we believe that additional costs, such as software purchases, are private business decisions that exist outside the scope of SNF payments.

Accordingly, after considering the comments received, for the reasons discussed throughout section V of the FY 2019 SNF PPS proposed rule and for the reasons presented in this final rule, we are finalizing our proposals to implement the PDPM, as well as the other PDPM related changes discussed in this final rule, with the modifications previously discussed in this final rule, effective beginning October 1, 2019. Specifically, in section V.B of this final rule, we finalized our proposal, without modification, for updating the federal base payment rates and for adjusting the per diem rates for geographic differences under the PDPM. In section V.C.3.b of this final rule, we finalized the proposed PT and OT components under the PDPM and our proposals relating to the methodology for classifying residents under the PT and OT components, effective October 1, 2019, with the modifications discussed in that section. More specifically, in response to comments, rather than requiring providers to record the type of inpatient surgical procedure performed during the prior inpatient hospital stay by coding an ICD–10–PCS code in the second line of item I8000 as we proposed, we will instead require providers to select, as necessary, a surgical procedure category in a sub-item within Item J2000 which would identify the relevant surgical procedure that occurred during the patient's preceding hospital stay and which would augment the patient's PDPM clinical category. For purposes of calculating the function score, all missing values for section GG assessment items will receive zero points. Similarly, the function score will incorporate a new response ''10. Not attempted due to environmental limitations'' and we will assign it a point value of zero. Furthermore, consistent with a commenter's suggestion, we will adopt MDS item GG0170I1 (Walk 10 feet) as a substitute for retired item GG0170H1 (Does the resident walk), and we will use responses 07: ''resident refused,'' 09: ''not applicable,'' 10: ''not attempted due to environmental limitations,'' or 88: ''not attempted due to medical condition or safety concerns'' from MDS item GG0170I1 to identify residents who cannot walk. In section V.C.3.b of this final rule, we finalized, without modification, the proposed SLP component of PDPM and our proposals relating to the classification of residents under the SLP component. In section V.C.3.d of this final rule, we finalized,

without modification, our proposals relating to the methodology for classifying patients under the nursing component of PDPM. In section V.C.3.e of this final rule, we finalized, without modification, our proposed NTA component of the PDPM and the proposed classification methodology for the NTA component. In section V.C.4 of this final rule, we finalized, without modification, to apply a variable per diem adjustment as part of the PDPM, utilizing the adjustment factors and schedule for the PT and OT components found in Table 30 and the adjustment factors and schedule for the NTA component found in Table 31. In section V.D.1 of this final rule, we finalized our proposed changes to the MDS assessment schedule and related assessment policies as discussed in the proposed rule, with the following modifications. As discussed in that section, rather than making the IPA a required assessment as we proposed, this assessment will be optional, and providers may determine whether and when an IPA is completed. In addition, because the IPA is an optional assessment and providers can determine their own criteria for when an IPA is completed, we are revising the ARD criteria such that the ARD will be the date the facility chooses to complete the assessment relative to the triggering event that makes the facility complete the IPA. Payment based on the IPA would begin the same day as the ARD. In section V.D.2 of this final rule, we finalized, without modification, our proposed additions to the Swing Bed PPS Assessment found in Table 34 of this final rule. In section V.D.3 of this final rule, we finalized, without modification, the proposed additions to the PPS Discharge Assessment found in Table 35 of this final rule. In section V.E of this final rule, we finalized, without modification, our proposed application of a combined 25 percent limit on group and concurrent therapy, per therapy discipline, as well as our proposal to implement a non-fatal warning edit on a provider's validation report when the amount of group and concurrent therapy exceeds 25 percent within a given therapy discipline. In section V.F of this final rule, we finalized, without modification, our proposed interrupted stay policy. In section V.G of this final rule, we finalized our proposed classifiers for purposes of applying the administrative presumption, with the following modification. As discussed in that section, we added 6 PT and OT classifiers and 8 SLP classifiers. In section V.H of this final rule, we finalized our proposal to replace the existing MMA add-on for patients with AIDS with the PDPM permanent adjustment in the case-mix that appropriate accounts for the increased costs of patients with AIDS.

As we proposed and as discussed in section V.I of this final rule, we will implement the PDPM and the other PDPM-related changes finalized in this rule in a budget neutral manner.

VI. Other Issues

A. Other Revisions to the Regulation Text

Along with our revisions to the regulations as discussed elsewhere in this final rule, we also proposed (83 FR 21080) to make two other revisions in the regulation text. The first involves § 411.15(p)(3)(iv), which specifies that whenever a beneficiary is formally discharged (or otherwise departs) from the SNF, this event serves to end that beneficiary's status as a ''resident'' of the SNF for purposes of consolidated billing (the SNF ''bundling'' requirement), unless he or she is readmitted (or returns) to that or another SNF ''by midnight of the day of departure.'' In initially establishing this so-called ''midnight rule,'' the FY 2001 SNF PPS final rule (65 FR 46770, July 31, 2000) noted in this particular context that, as we explained in the proposed rule, a patient ''day'' begins at 12:01 a.m. and ends the following midnight, so that the phrase ''midnight of the day of departure'' refers to the midnight that immediately follows the actual moment of departure, rather than to the midnight that immediately precedes it (65 FR 46792).

However, the Medicare program's standard practice for counting inpatient days is actually one in which an inpatient day would begin at midnight (see, for example, § 20.1 in the Medicare Benefit Policy Manual, Chapter 3, which specifies that in counting inpatient days, ''. . . *a day begins at midnight* and ends 24 hours later'' (emphasis added)). Accordingly, in order to ensure consistency with that approach, we proposed to revise § 411.15(p)(3)(iv) to specify that for consolidated billing purposes, a beneficiary's ''resident'' status ends whenever he or she is formally discharged (or otherwise departs) from the SNF, unless he or she is readmitted (or returns) to that or another SNF ''before the following midnight.'' We further noted that this revision would not alter the underlying principle that a beneficiary's SNF ''resident'' status in this context ends upon departure from the SNF unless he or she returns to that or another SNF later on that same day; rather, it would simply serve to conform the actual wording of the applicable regulations text with the Medicare manual's standard definition of the starting point of a patient ''day.''

We also proposed a technical correction to § 424.20(a)(1)(i) (which describes the required content of the SNF level of care certification) in order to conform it more closely to that of the corresponding statutory requirements at section 1814(a)(2)(B) of the Act. This statutory provision defines the SNF level of care in terms of skilled services furnished on a daily basis which, as a practical matter, can only be provided on an inpatient basis in a SNF. In addition, it provides that the SNF-level care must be for either:

- An ongoing condition that was one of the conditions that the beneficiary had during the qualifying hospital stay; or
- A new condition that arose while the beneficiary was in the SNF for treatment of that ongoing condition.

In setting forth the SNF level of care definition itself, the implementing regulations at § 409.31 reflect both of the above two criteria (at paragraphs (b)(2)(i) and (b)(2)(ii), respectively); however, as we stated in the proposed rule (83 FR 21080), the regulations describing the content of the initial level of care certification at § 424.20(a)(1)(i) have inadvertently omitted the second criterion. Further, while that criterion admittedly might not be relevant in those instances where the initial certification is obtained promptly ''at the time of admission'' in accordance with the regulations at 42 CFR 424.20(b)(1), that same provision alternatively allows this requirement to be met ''as soon thereafter as is reasonable and practicable.'' Accordingly, in order to rectify this omission, we proposed to revise § 424.20(a)(1)(i) so that it more accurately tracks the language in the corresponding statutory authority at section 1814(a)(2)(B) of the Act.

We invited comments on our proposed revisions to § 411.15(p)(3)(iv) and § 424.20(a)(1)(i), but received no comments on either revision. Accordingly, in this final rule, we are finalizing both revisions as proposed, without further modification.

B. Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

1. Background

The Skilled Nursing Facility Quality Reporting Program (SNF QRP) is authorized by section 1888(e)(6) of the Act and it applies to freestanding SNFs, SNFs affiliated with acute care facilities,

and all non-CAH swing-bed rural hospitals. Under the SNF QRP, the Secretary reduces by 2 percentage points the annual market basket percentage update described in section 1888(e)(5)(B)(i) of the Act applicable to a SNF for a fiscal year, after application of section 1888(e)(5)(B)(ii) of the Act (the MFP adjustment) and section 1888(e)(5)(B)(iii) of the Act (the 1 percent market basket increase for FY 2018), in the case of a SNF that does not submit data in accordance with sections 1888(e)(6)(B)(i) of the Act for that fiscal year. For more information on the requirements we have adopted for the SNF QRP, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429), FY 2017 SNF PPS final rule (81 FR 52009 through 52010) and FY 2018 SNF PPS final rule (82 FR 36566).

Although we have historically used the preamble to the SNF PPS proposed and final rules each year to remind stakeholders of all previously finalized program requirements, we have concluded that repeating the same discussion each year is not necessary for every requirement, especially if we have codified it in our regulations. Accordingly, the following discussion is limited as much as possible to a discussion of our proposals, responses to comments submitted on those proposals, and policies we are finalizing for future years of the SNF QRP after consideration of the comments, and it represents the approach we intend to use in our rulemakings for this program going forward.

2. General Considerations Used for the Selection of Measures for the SNF QRP

a. Background

For a detailed discussion of the considerations we historically used for the selection of SNF QRP quality, resource use, and other measures, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46429 through 46431).

We received several comments generally related to the SNF QRP. The comments and our responses are discussed below.

Comment: Several commenters expressed general support for CMS's proposals related to the SNF QRP, acknowledging CMS's goal of improving the quality of health care for Medicare beneficiaries through improvements to patient assessments and quality reporting. One commenter highlighted the need for additional transparency from CMS through this ongoing process. Another commenter requested that CMS ensure that the SNF QRP efforts do not negatively impact specialty populations.

Response: We appreciate commenters' general support for the SNF QRP proposals. To foster transparency, we continue to seek stakeholder input and will take into consideration the impact of specialty populations in the ongoing measure development and maintenance efforts of the SNF QRP.

Comment: One commenter expressed support for the IMPACT Act's objectives. However, the commenter expressed concern over the rapid development and implementation of the standardized patient assessment data element (SPADE) work, suggesting that further evaluation is necessary.

Response: We understand the concerns raised by commenters pertaining to the development and implementation of the SPADEs. As discussed in the FY 2018 SNF PPS Final Rule, we agreed that further evaluation of the data elements was necessary. Specifically, we thought that more time was needed to develop, test, to think through the implementation, and to reflect on how to maximize the time SNFs have to prepare for the reporting of standardized resident assessment data in these categories. We have worked to be responsive to the concerns raised by stakeholders while meeting our obligation to require the reporting of standardized resident assessment data with respect to the categories described in section 1899B(b)(1)(B) of the Act. Therefore, as outlined in the FY 2018 SNF PPS final rule, we did not finalize the standardized 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 in that we felt this work needed more time for development and evaluation. Since the time of this proposal work, we have worked closely with stakeholders, solicited comments, reconvened our TEP, and are currently re-testing the SPADEs in a national field test (also known as the Alpha test). For more information on our prior proposal addressed in the FY 2018 SNF PPS final rule (82 FR 36568 through 36570, 36597 through 36605), we refer the reader to that detailed discussion. For more information on our national field test and associated work for SPADEs, please see: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/-IMPACT-Act-Standardized-Assessment-National-Testing-.html.*

b. Accounting for Social Risk Factors in the SNF QRP

In the FY 2018 SNF PPS final rule (82 FR 36567 through 36568), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex residents, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[3] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex residents, as well as those with social risk factors receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in our value-based purchasing programs.[4] As we noted in the FY 2018 SNF PPS final rule (82 FR 36567 through 36568), ASPE's report to Congress, which was required by the IMPACT Act, found that, in the context of value-based purchasing programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. ASPE is continuing to examine this issue in its second report required by the IMPACT Act, which is due to Congress in the fall of 2019. In addition, as we noted in the FY 2018 SNF PPS final rule (82 FR 36567), the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is

[3] See, for example, United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[4] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

appropriate for these measures.[5] The trial period ended in April 2017 and a final report is available at *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[6] allowing further examination of social risk factors in outcome measures.

In the FY 2018/CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging us to explore whether factors that could be used to stratify or risk adjust the measures (beyond dual eligibility); to consider the full range of differences in resident backgrounds that might affect outcomes; to explore risk adjustment approaches; and to offer careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by resident dual eligibility. In general, commenters noted that stratified measures could serve as tools for SNFs to identify gaps in outcomes for different groups of residents, improve the quality of health care for all residents, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned CMS to balance fair and equitable payment while avoiding payment penalties that mask health disparities or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, we are considering options to improve health disparities among patient-groups within and across hospitals by increasing the transparency of disparities as shown by quality measures. We also are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital Inpatient Quality Reporting (IQR) Program outcome measures. Furthermore, we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

Comment: Several commenters supported CMS' continuing evaluation of how social risk factors could impact SNF QRP measure rates and encouraged CMS to consider strategies and solutions in this area. Specific comments noted that lack of adjustment for social risk factors may negatively impact facility measure rates, and CMS should incorporate risk adjustment for sociodemographic and socioeconomic status into appropriate SNF QRP measures. We also received comments about the public display of measure information related to social risk factors, suggesting stratified measures be used and expressing concerns that publicly reported outcome measures could be misleading to consumers.

Response: We thank commenters for their comments and will take these comments into account as we further consider how to appropriately account for social risk factors in the SNF QRP. We also refer the reader to the FY 2018 SNF PPS final rule (82 FR 36567 through 36568) where we discussed in depth many of the issues raised by these commenters.

3. New Measure Removal Factor for Previously Adopted SNF QRP Measures

As a part of our Meaningful Measures Initiative discussed in section I.D. of this final rule, we strive to put patients first, ensuring that they, along with their clinicians, are empowered to make decisions about their own healthcare using data-driven information that is increasingly aligned with a parsimonious set of meaningful quality measures. We began reviewing the SNF QRP's measures in accordance with the Meaningful Measures Initiative, and we are working to identify how to move the SNF QRP forward in the least burdensome manner possible while continuing to incentivize improvement in the quality of care provided to patients.

Specifically, we believe the goals of the SNF QRP and the measures used in the program cover most of the Meaningful Measures Initiative priorities, including making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable.

We also evaluated the appropriateness and completeness of the SNF QRP's current measure removal factors. We have previously finalized that we would use notice and comment rulemaking to remove measures from the SNF QRP based on the following factors [7]

- *Factor 1.* Measure performance among SNFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.
- *Factor 2.* Performance or improvement on a measure does not result in better resident outcomes.
- *Factor 3.* A measure does not align with current clinical guidelines or practice.
- *Factor 4.* A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available.
- *Factor 5.* A measure that is more proximal in time to desired resident outcomes for the particular topic is available.
- *Factor 6.* A measure that is more strongly associated with desired resident outcomes for the particular topic is available.
- *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than resident harm.

We continue to believe that these measure removal factors are appropriate for use in the SNF QRP. However, even if one or more of the measure removal factors applies, we may nonetheless choose to retain the measure for certain specified reasons. Examples of such instances could include when a particular measure addresses a gap in quality that is so significant that removing the measure could in turn

[5] Available at *http://www.qualityforum.org/SES_Trial_Period.aspx*.

[6] Available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357*.

[7] We refer readers to the FY 2016 SNF PPS final rule (80 FR 46431 through 46432) for more information on the factors we consider for removing measures.

result in poor quality, or in the event that a given measure is statutorily required. We note further that, consistent with other quality reporting programs, we apply these factors on a case-by-case basis.

In the FY 2019 SNF PPS proposed rule (83 FR 21082), we proposed to adopt an additional factor to consider when evaluating potential measures for removal from the SNF QRP measure set:

- *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

As we discussed in section I.D. of this final rule, with respect to our new Meaningful Measures Initiative, we are engaging in efforts to ensure that the SNF QRP measure set continues to promote improved health outcomes for beneficiaries while minimizing the overall costs associated with the program. We believe these costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining the program. We have identified several different types of costs, including, but not limited to: (1) The provider and clinician information collection burden and burden associated with the submission/reporting of quality measures to CMS; (2) the provider and clinician cost associated with complying with other programmatic requirements; (3) the provider and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) the cost to CMS associated with the program oversight of the measure including measure maintenance and public display; and (5) the provider and clinician cost associated with compliance with other federal and/or state regulations (if applicable).

For example, it may be needlessly costly and/or of limited benefit to retain or maintain a measure which our analyses show no longer meaningfully supports program objectives (for example, informing beneficiary choice). It may also be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on a measure where we use the measure in more than one program. CMS may also have to expend unnecessary resources to maintain the specifications for the measure, as well as the tools we need to collect, validate, analyze, and publicly report the measure data. Furthermore, beneficiaries may find it confusing to see public reporting on the same measure in different programs.

When these costs outweigh the evidence supporting the continued use of a measure in the SNF QRP, we believe it may be appropriate to remove the measure from the program. Although we recognize that one of the main goals of the SNF QRP is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making data public related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data is of limited use because it cannot be easily interpreted by beneficiaries and used to influence their choice of providers. In these cases, removing the measure from the SNF QRP may better accommodate the costs of program administration and compliance without sacrificing improved health outcomes and beneficiary choice.

We proposed that we would remove measures based on this factor on a case-by-case basis. We might, for example, decide to retain a measure that is burdensome for health care providers to report if we conclude that the benefit to beneficiaries justifies the reporting burden. Our goal is to move the program forward in the least burdensome manner possible, while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients.

We invited public comment on our proposal to adopt an additional measure removal Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

We also proposed to add a new § 413.360(b)(3) that would codify the removal factors we have previously finalized for the SNF QRP, as well as the new measure removal factor that we proposed to adopt in the proposed rule.

We sought comments on these proposals. A discussion of these comments, along with our responses, appears below.

Comment: Several commenters expressed support for an additional factor to consider when evaluating potential measures for removal from the SNF QRP measure set: Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program. One commenter acknowledged that removal of a measure from the program may be appropriate when the costs outweigh the evidence supporting its continued use. Another commenter supported the addition of the new measure removal factor because it reduces unnecessary administrative burden.

Response: We appreciate the commenters' support.

Comment: One commenter supported CMS' proposal to codify the proposed measure removal factor in the regulatory text.

Response: We appreciate the commenter's support.

Comment: Some commenters expressed concerns related to the new measure removal factor. One commenter did not support the addition of the factor, suggesting that the costs and benefits considered under this factor are not equivalent, as costs are typically imposed on providers while benefits are rendered to beneficiaries. This commenter expressed the concern that providers may argue for removal of a measure that is costly to collect and report despite its benefits. Another commenter suggested that using administrative cost to CMS as a basis for removal may be problematic if clinicians or patients believe the measure is important. Another commenter added that the proposed measure removal factor is subjective and recommended clearer guidelines and criteria for determining the costs and benefits of a measure before it is removed.

Response: We agree that it is possible that providers may recommend removal of measures they do not support based on the argument that these measures are costly to report. However, input from providers is only one element of our case-by-case analysis of measures that we would take into account when weighing the costs associated with a measure against the benefit of retaining the measure in a program. We will weigh input we receive from all stakeholders with our own analysis of each measure to make our case-by-case determination of whether it would be appropriate to remove a measure based on its costs outweighing the benefit of its continued use in the program. We wish to clarify that it is not our intent to remove measures that continue to benefit residents or providers solely because these measures incur administrative costs to CMS; this is only one example of costs that would be weighed against the benefits when considering each measure on a case-by-case basis.

Regarding concern over the subjectivity of the new measure removal factor and the suggestion for clearer guidelines and criteria for determining the costs and benefits of a measure before it is removed, we intend to be transparent in our assessment of measures under this measure removal factor. As described above, there are various considerations of costs and

benefits, direct and indirect, financial and otherwise, that we will evaluate in applying removal Factor 8, and we will take into consideration the perspectives of multiple stakeholders. However, because we intend to evaluate each measure on a case-by-case basis, and each measure has been adopted to fill different needs in the SNF QRP, we do not believe it would be meaningful to identify a specific set of assessment criteria to apply to all measures. We believe costs include costs to stakeholders such as patients, caregivers, providers, CMS, and other entities. In addition, we note that the benefits we will consider center around benefits to residents and caregivers as the primary beneficiaries of our quality reporting program. When we propose through rulemaking to remove a measure under this measure removal factor, we will provide information on the costs and benefits we considered in evaluating the measure.

Comment: One commenter noted that the existing seven removal factors are sufficient for appropriate measure evaluation.

Response: While we acknowledge that there are seven factors currently adopted that may be used for considering measure removal from the SNF QRP, we believe the proposed new measure removal factor adds a new criterion that is not captured in the other seven factors. The proposed new measure removal factor will help advance the goals of the Meaningful Measures Initiative, which aims to improve outcomes for patients, their families, and health care providers while reducing burden and costs for clinicians and providers. We are also making minor grammatical edits to the SNF QRP measure removal factor language to align with the language of other CMS quality programs.

After considering the comments, we are finalizing our proposal to add an additional measure removal factor: Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program. We are also finalizing our proposal to the updates to the regulatory text and to codify the seven removal factors we have previously finalized for the SNF QRP, as well as the new measure removal factor, Factor 8 at new § 413.360(b)(3). We are also making minor grammatical edits to the SNF QRP measure removal factor language to align with the language of other CMS quality programs.

4. Quality Measures Currently Adopted for the FY 2020 SNF QRP

The SNF QRP currently has 12 measures for the FY 2020 program year, which are outlined in Table 39.

TABLE 39—QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2020 SNF QRP

Short name	Measure name and data source
Resident Assessment Instrument Minimum Data Set	
Pressure Ulcer	Percent of Residents or Patients With Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678).*
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment/Care Plan.	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Change in Mobility Score	Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634).
Discharge Mobility Score	Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).
Change in Self-Care Score	Application of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633).
Discharge Self-Care Score	Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
Claims-Based	
MSPB SNF	Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
DTC	Discharge to Community—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

*The measure will be replaced with the Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury measure, effective October 1, 2018.

Comment: While we did not solicit comment on currently adopted or future measures for the SNF QRP, we received multiple comments suggesting the removal or modification of measures finalized in previous rules as well as recommendations for future measure development.

Response: We thank commenters for their comments. We did not propose any changes to our previously finalized measures or to adopt any new measures for the SNF QRP. We will take these comments into consideration as we engage in future measure development and selection activities for the SNF QRP. The SNF QRP measures described in Table 39 were adopted in the FY 2016 SNF PPS final rule (80 FR 46432 through 46453), FY 2017 SNF PPS final rule (81 FR 52012 through 52039), or FY 2018 SNF PPS final rule (82 FR 36570 through 36594), and we refer the reader to those detailed discussions.

5. IMPACT Act Implementation Update

In the FY 2018 SNF PPS final rule (82 FR 36596 through 36597), we stated that we intended to specify two measures that would satisfy the domain of

accurately communicating the existence and provision of the transfer of health information and care preferences under section 1899B(c)(1)(E) of the Act no later than October 1, 2018, and intended to propose to adopt them for the FY 2021 SNF QRP, with data collection beginning on or about October 1, 2019.

As stated in the FY 2019 SNF PPS proposed rule (83 FR 21083), as a result of the input provided during a public comment period between November 10, 2016 and December 11, 2016, input provided by a technical expert panel (TEP), and pilot measure testing conducted in 2017, we are engaging in continued development work on these two measures, including supplementary measure testing and providing the public with an opportunity for comment in 2018. We stated that we would reconvene a TEP for these measures in mid-2018 which occurred in April 2018. We stated that we now intend to specify the measures under section 1899B(c)(1)(E) of the Act no later than October 1, 2019 and intend to propose to adopt the measures for the FY 2022 SNF QRP, with data collection beginning with residents admitted as well as discharged on or after October 1, 2020. For more information on the pilot testing, we refer readers to *https://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: A few commenters supported the delayed implementation of the measures. One commenter supported the continued evaluation and testing of the measures prior to adoption. The commenter believed that this delay is appropriate as it allows more time for thorough measure development, continued field testing of the measures, and public input on the draft measures. This commenter noted that continued development of the measures will help to ensure they are measuring the domain of interest and will have a meaningful impact on the quality of care.

Response: We appreciate the commenters support.

6. Form, Manner, and Timing of Data Submission Under the SNF QRP

Under our current policy, SNFs report data on SNF QRP assessment-based measures and standardized resident assessment data by reporting the designated data elements for each applicable resident on the Minimum Data Set (MDS) resident assessment instrument and then submitting completed instruments to CMS using the Quality Improvement Evaluation System Assessment Submission and Processing (QIES ASAP) system. We refer readers to the FY 2018 SNF PPS final rule (82 FR 36601 through 36603) for the data collection and submission time frames for assessment-based measures and standardized resident assessment data that we finalized for the SNF QRP.

7. Changes to the SNF QRP Reconsideration Requirements

Section 413.360(d)(1) of our regulations states, in part, that SNFs that do not meet the SNF QRP requirements for a program year will receive a letter of non-compliance through the QIES ASAP system, as well as through the United States Postal Service.

In the FY 2019 SNF PPS proposed rule (83 FR 21083), we proposed to revise § 413.360(d)(1) to expand the methods by which we would notify a SNF of non-compliance with the SNF QRP requirements for a program year. Revised § 413.360(d)(1) would state that we would notify SNFs of non-compliance with the SNF QRP requirements via a letter sent through at least one of the following notification methods: The QIES ASAP system; the United States Postal Service; or via an email from the Medicare Administrative Contractor (MAC). We believe that this change will address feedback from providers who requested additional methods for notification.

In addition, § 413.360(d)(4) currently states that we will make a decision on the request for reconsideration and provide notice of the decision to the SNF through the QIES ASAP system and via letter sent through the United States Postal Service.

We proposed to revise § 413.360(d)(4) to state that we will notify SNFs, in writing, of our final decision regarding any reconsideration request via a letter sent through at least one of the following notification methods: The QIES ASAP system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC).

We invited public comments on these proposals.

Comment: Several commenters expressed support for CMS' efforts to expand the methods for notifying providers of non-compliance and decisions on reconsideration requests. One commenter acknowledged that the addition of email notifications from the Medicare Administrative Contractor (MAC) as a third notification method may help reduce burden, adding that providers should be notified via at least two of the three methods and that letters should require return receipt to ensure notifications are not lost in the mail. Another commenter recommended that CMS either specify a notification method that will always be used, allow providers to select a preferred method, or consistently use all three methods to ensure that notifications are received by appropriate organization leaders. Several commenters suggested that CMS provide additional information regarding how to specify appropriate recipients of email notifications from the Medicare Administrative Contractor (MAC). Another commenter recommended selecting a consistent notification process, using the same methods for all SNFs, noting that consistent and predictable notification will reduce provider burden and lower the risk of missing a notification.

Response: We thank commenters for their support. We will use at least one method of notification, and providers will be notified regarding the specific method of communication that CMS will use via the SNF QRP Reconsideration and Exception and Extension website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-QR-Reconsideration-and-Exception-and-Extension.html* and announcements via the PAC listserv. The announcements will be posted annually following the May 15th data submission deadline—prior to the distribution of the initial notices of non-compliance determination in late spring/early summer. Messaging will include the method of communication for the notices, instructions for sending a reconsideration request, and the final deadline for submitting the request. This policy would be effective October 1, 2018.

With regard to the comment about specifying the recipient of notification for a facility, our notifications are sent to the point of contact on file in the QIES database. This information is populated via ASPEN. It is the responsibility of the facility to ensure that this information is up-to-date. For information regarding how to update provider information in QIES, we refer providers to contact their Medicare Administrative Contractor or CMS Regional Office at *https://www.cms.gov/About-CMS/Agency-Information/RegionalOffices/index.html*. Downloads of contact information for each Regional Office are available at the bottom of the web page.

We disagree with the recommendation that CMS notify all

SNFs using the same method in order to account for circumstances that are beyond our control, such as technical issues that may impede the delivery of electronic notifications. As discussed, providers will be notified in advance of the specific method of communication that CMS will use.

We are finalizing our proposal to revise § 413.360(d)(1) to state that we will notify a SNF of non-compliance with the SNF QRP requirements for a program year via a letter sent through at least one of the following notification methods: The QIES ASAP system; the United States Postal Service; or via an email from the Medicare Administrative Contractor (MAC).

We are also finalizing our proposal, to revise § 413.360(d)(4) to state that we will notify SNFs, in writing, of our final decision regarding any reconsideration request via a letter sent through at least one of the following notification methods: The QIES ASAP system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC).

8. Policies Regarding Public Display for the SNF QRP

Section 1899B(g) of the Act requires the Secretary to establish procedures for the public reporting of SNFs' performance on measures under sections 1899B(c)(1) and 1899B(d)(1) of the Act. SNF QRP measure data will be displayed on the Nursing Home Compare website, an interactive web tool that assists individuals by providing information on SNF quality of care to those who need to select a SNF.

In the FY 2018 SNF PPS final rule (82 FR 36606 through 36607), we finalized that we would publicly display the Medicare Spending Per Beneficiary-PAC SNF QRP and Discharge to Community-PAC SNF QRP measures in calendar year 2018 based on discharges from October 1, 2016 through September 30, 2017. In the FY 2019 SNF PPS proposed rule (83 FR 21084), we proposed to increase the number of years of data used to calculate the Medicare Spending Per Beneficiary-PAC SNF QRP and Discharge to Community-PAC SNF QRP measures for purposes of display from 1 year to 2 years. Under this proposal, data on these measures would be publicly reported in CY 2019, or as soon thereafter as operationally feasible, based on discharges from October 1, 2016 through September 30, 2018.

Increasing the measure calculation and public display periods from 1 to 2 years of data increases the number of SNFs with enough data adequate for public reporting for the Medicare Spending Per Beneficiary-PAC SNF QRP measure from 86 percent (based on 2016 Medicare FFS claims data) to 95 percent (based on 2015 through 2016 Medicare FFS claims data), and for the Discharge to Community-PAC SNF QRP measure from 83 percent (based on 2016 Medicare FFS claims data) to 94 percent (based on 2015 through 2016 Medicare FFS claims data). Increasing measure public display periods to 2 years also aligns with the public display periods of these measures in the IRF QRP and LTCH QRP.

We also proposed to begin publicly displaying data in CY 2020, or as soon thereafter as is operationally feasible, on the following four assessment-based measures: (1) Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633) (Change in Self-Care Score); (2) Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634) (Change in Mobility Score); (3) Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635) (Discharge Self-Care Score); and (4) Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636) (Discharge Mobility Score). SNFs are required to submit data on these four assessment-based measures with respect to admissions as well as discharges occurring on or after October 1, 2018. We proposed to display data for these assessment-based measures based on 4 rolling quarters of data, initially using 4 quarters of discharges from January 1, 2019 through December 31, 2019. To ensure the statistical reliability of the measure rates for these four assessment-based measures, we also proposed that if a SNF has fewer than 20 eligible cases during any 4 consecutive rolling quarters of data that we are displaying for any of these measures, then we would note in our public display of that measure that with respect to that SNF, the number of cases/resident stays is too small to publicly report.

Comment: One commenter supported the proposal to publicly display the four SNF functional outcome measures on the SNF Compare website in CY 2020.

Response: We thank the commenter for the support.

Comment: Several commenters, including MedPAC, supported increasing the number of years of data used to calculate the Medicare Spending per Beneficiary-PAC SNF QRP and Discharge to Community-PAC SNF QRP measures from 1 year to 2 years to increase the number of providers that can be included in public reporting and also to align the measurement period with that used in other PAC settings. One commenter was concerned that increasing the measurement period to 2 years would penalize facilities that showed improvement in a one-year period, as the data would be aggregated across 2 years. Two commenters agreed with increasing the measurement period from 1 to 2 years but questioned the usefulness of a measure that they stated required a significant adjustment in collection methods to acquire data necessary to calculate a rate.

Response: We thank MedPAC and the other commenters for their support to increase the number of years of data used to calculate the Medicare Spending per Beneficiary-PAC SNF QRP measure and Discharge to Community-PAC SNF QRP measure from 1 to 2 years. We appreciate the commenter's concern about the impact of aggregating data across 2 years on the ability to demonstrate improvement in a 1-year period; however, we believe that the benefit of increasing the number of SNFs in public reporting outweighs the expressed concern associated with increasing the measurement period to 2 years because it would provide more information to consumers who may have a limited number of SNFs in their area. Further, improvements in 1-year period will be included in the 2-year data, so providers' efforts to improve can still be reflected in their measure scores. The proposed change will also align with the measurement period of the three claims-based measures (Medicare Spending per Beneficiary, Discharge to Community, and Potentially Preventable Readmissions) across the IRF, LTCH, and SNF QRPs.

Comment: MedPAC suggested that if CMS increases the measurement period for the Medicare Spending per Beneficiary PAC SNF QRP measure and Discharge to Community PAC SNF QRP measure to 2 years, CMS could consider giving more weight to the most recent performance year. MedPAC also suggested that CMS reconsider the approach to establishing minimum counts of episodes for public reporting of the Medicare Spending per Beneficiary-PAC SNF QRP measure to ensure accurate representation of a provider's performance.

Response: We thank MedPAC for its suggestion to consider greater weighting of the most recent year of data and to reconsider the approach to establishing minimum counts of episodes for public reporting. We will consider testing these suggestions in the future.

Comment: A commenter noted the importance of understanding the

relationship between the Medicare Spending per Beneficiary-PAC SNF QRP measure, quality, and beneficiary out-of-pocket expenses. The commenter also noted the importance of educating consumers on this measure. The commenter suggested that CMS analyze these relationships further and define a strategy for interpreting the results before making the measure results public. Another commenter noted that facilities should not be penalized for decisions made by physicians that are beyond providers' control.

Response: We thank the commenters for the suggestions for additional analyses on the relationship between the Medicare Spending per Beneficiary-PAC SNF QRP measure, quality, and out-of-pocket spending. We will consider analyses on these topics in the future. Regarding beneficiary education for interpreting results, we will continue to work to develop language to support beneficiary understanding of the measures in public reporting. Regarding the comment on facility penalty for physician decision-making, the measure is intended to promote care coordination and improve efficiency by creating a continuum of accountability between Medicare providers.

Comment: Some commenters suggested that the public reporting of the SNF functional outcome measures: (1) Change in Self-Care Score; (2) Change in Mobility Score; (3) Discharge Self-Care Score; and (4) Discharge Mobility Score, on the SNF Compare website be delayed beyond CY 2020. One commenter suggested that the reporting be delayed until additional measures that address the maintenance of functional abilities are also developed and reported alongside the functional improvement measures and also encouraged the development of measures related to other nursing goals. Other commenters suggested that CMS reconsider publicly reporting the SNF functional quality measures in CY 2020 if these measures do not receive NQF endorsement prior to public display.

Response: We thank the commenters for their suggestions. We addressed the importance of measuring functional maintenance for SNF residents in the FY 2018 SNF PPS final rule (82 FR 36588). We interpret the commenter's recommendation of ''at least one nursing goals measure'' to refer to the development of new measures relating to functional status for SNF residents. We support future quality measurement work that will address the development of other measures that focus on maintaining function and the slowing of functional decline. We agree that the NQF endorsement process is an important part of measure development. The four functional outcome quality measures that we proposed to publicly report are NQF-endorsed for the IRF setting, and we plan to submit these four assessment-based measures to NQF for endorsement consideration in the SNF setting as soon as feasible.

After consideration of public comments we received, we are finalizing our proposal, to increase the number of years of data used to calculate the Medicare Spending per Beneficiary-PAC SNF QRP measure and Discharge to Community-PAC SNF QRP measure for purposes of public display from 1 to 2 years, starting in CY 2019 or as soon thereafter as operationally feasible. We are also finalizing our proposal to begin publicly displaying data in CY 2020, or as soon thereafter as is operationally feasible, on the following four assessment-based measures: (1) Application of IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633); (2) Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634); (3) Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635); and (4) Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).

C. Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP)

1. Background

Section 215(b) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) authorized the SNF VBP Program (the ''Program'') by adding section 1888(h) to the Act. As a prerequisite to implementing the SNF VBP Program, in the FY 2016 SNF PPS final rule (80 FR 46409 through 46426), we adopted an all-cause, all-condition hospital readmission measure, as required by section 1888(g)(1) of the Act. In the FY 2017 SNF PPS final rule (81 FR 51986 through 52009), we adopted an all-condition, risk-adjusted potentially preventable hospital readmission measure for SNFs, as required by section 1888(g)(2) of the Act. In the FY 2018 SNF PPS final rule (82 FR 36608 through 36623), we adopted additional policies for the Program, including an exchange function methodology for disbursing value-based incentive payments.

Section 1888(h)(1)(B) of the Act requires that the SNF VBP Program apply to payments for services furnished on or after October 1, 2018. The SNF VBP Program applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. We believe the implementation of the SNF VBP Program is an important step towards transforming how care is paid for, moving increasingly towards rewarding better value, outcomes, and innovations instead of merely rewarding volume.

For additional background information on the SNF VBP Program, including an overview of the SNF VBP Report to Congress and a summary of the Program's statutory requirements, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46409 through 46410). We also refer readers to the FY 2017 SNF PPS final rule (81 FR 51986 through 52009) for discussion of the policies that we adopted related to the potentially preventable hospital readmission measure, scoring, and other topics. Finally, we refer readers to the FY 2018 SNF PPS final rule (82 FR 36608 through 36623) for discussions of the policies that we adopted related to value-based incentive payments, the exchange function, and other topics.

We proposed additional requirements for the FY 2021 SNF VBP Program in the FY 2019 SNF PPS proposed rule (83 FR 21084 through 21089). We received several general comments on the SNF VBP Program.

Comment: One commenter supported our goal of reducing preventable hospital readmissions, noting that those readmissions increase costs for the Medicare program, significantly affect beneficiaries, and increase the likelihood of medical errors related to care coordination.

Response: We thank the commenter for this support.

Comment: A commenter suggested that we consider developing an integrated approach that provides incentives to SNFs to accept more medically complex patients and promotes readmission prevention. The commenter suggested that, while the PDPM and SNF VBP Programs are authorized separately, integrating them might be helpful to that end, and could include payments for telemedicine, post-discharge care coordination, and training on readmission prevention protocols and refinements to Interrupted Stay policies. The commenter stated that readmissions prevention strategies can be very effective at saving Medicare spending and improving the patient experience, but can also require initial investments in technology and staff training.

Response: We agree that readmission prevention strategies can be effective at

saving Medicare spending and improving the patient experience. At this time, we do not believe it is possible to integrate the PDPM and SNF VBP Program given their separate authorities and purposes. However, we will continue to monitor the effects of the SNF VBP Program and the case-mix classification methodology in the SNF prospective payment system, including the PDPM.

Comment: One commenter encouraged us to make public as much SNF VBP data as possible on Nursing Home Compare and *data.medicare.gov*, including individual facilities' baseline and performance period readmissions rates, achievement and improvement points, performance scores, rankings, and value-based incentive payment percentages. The commenter noted that CMS has provided most of this type of information for other programs, and that the public should expect the same level of transparency from SNF VBP.

Response: We agree with the comment and intend to be as transparent as possible in order to inform consumer decision-making, quality improvement initiatives, and high quality patient care. As required by section 1888(h)(9) of the Act, we will publish facility performance information, including SNF performance scores and rankings, the range of SNF performance scores, the number of SNFs receiving value-based incentive payments, and the range and total amounts of those payments, on the *Nursing Home Compare* website.

Comment: One commenter requested that we ensure that specialty populations such as children, patients with HIV/AIDS, ventilator-dependent patients, and those with Huntington's disease or other neurodegenerative disorders, do not experience unintended negative results based on the SNF VBP Program's incentives.

Response: We monitor numerous aspects of the SNF VBP Program, including trends in measure rates, SNF performance scores, and starting with FY 2019, value-based incentive payment percentages and their effects on SNFs' care quality and on beneficiaries' access to care. We understand the commenter's concerns about specialty patient populations, and we will continue working to ensure that such populations do not experience unintended consequences because of the SNF VBP Program.

2. Measures

For background on the measures we have adopted for the SNF VBP Program, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46419), where we finalized the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) that we are currently using for the SNF VBP Program. We also refer readers to the FY 2017 SNF PPS final rule (81 FR 51987 through 51995), where we finalized the Skilled Nursing Facility 30-Day Potentially Preventable Readmission Measure (SNFPPR) that we will use for the SNF VBP Program instead of the SNFRM as soon as practicable, as required by statute.

We did not propose any changes to the Program's measures. However, we received several comments on the Program's measures.

Comment: One commenter requested that we announce when we will transition the SNF VBP Program to a measure of potentially preventable readmissions rather than the current all-cause readmissions measure. One commenter recommended that we not replace the SNFRM with the SNFPPR before FY 2021 to allow SNFs time to adjust to the SNFRM and other measures of readmissions. Another commenter encouraged us to transition the Program to the measure of potentially preventable readmissions, stating that the PPR will exclude planned readmissions that are not considered a negative outcome, and therefore, should not be counted against SNFs. Other commenters urged us to seek NQF endorsement and input from the Measure Applications Partnership as soon as possible on the SNFPPR, and requested that we provide a timeline for when we will replace the all-cause measure with the SNFPPR. Another commenter requested that we consider standardizing and consolidating various SNF hospitalization measures used in Medicare to focus SNFs' quality improvement efforts. The commenter noted that state initiatives may also have similar measures based on different data, and that the multitude of hospitalization measures may be confusing for consumers and may dilute provider improvement efforts.

Response: We sought input from the MAP on the SNFPPR prior to proposing it for adoption in the SNF VBP. The MAP published its views in a February 2016 report, as we described in the FY 2017 SNF PPS final rule (81 FR 51989 through 51990). In that report,[8] MAP noted the statutory requirement that we specify a measure of potentially preventable readmissions for the SNF VBP Program, and explained support for the importance of the measure and its acknowledgement that ''readmission for the SNF setting is not an occasional occurrence.'' MAP's report also noted public commenters' input, including general support for the recommendation to ''encourage continued development'' of the SNFPPR and some concerns about the measure's specifications and MAP's making a recommendation on a measure that is not fully tested. Regarding submission of the SNFPPR for consensus endorsement, we currently plan to submit the measure for NQF endorsement in 2019 upon completion of additional testing. We plan to propose transitioning to this measure after the completion of the endorsement process.

We also acknowledge the commenter's concern about the number of hospitalization measures in Medicare and in other quality programs, including those used by the states. We will consider how we might further streamline our quality programs, particularly under the Meaningful Measures Initiative. However, we note that all rehospitalization measures share the same underlying care focus—that is, avoiding rehospitalizations—even if they vary somewhat in the specifics of which hospitalizations they measure. We continue to believe that SNFs working to improve care quality and minimize rehospitalizations for their patients will perform well on hospitalization measures.

We continue to determine when it is practicable to transition the Program to the measure of potentially preventable readmissions, and we will propose that transition in future rulemaking, which we believe will provide sufficient notice to SNFs about the quality measure that will form the basis for the SNF VBP Program. We intend to take all of the views expressed by public commenters into account when we make that decision, as well as the operational necessities of the Program (such as the time needed to calculate measure rates on the SNFPPR and how that time interacts with the Program's performance and baseline periods). However, we would like to clarify that the SNFRM currently excludes certain planned readmissions.

Comment: One commenter stated that the SNF VBP Program should consist of more than just one hospital readmissions measure, and encouraged us to work with Congress to include additional measures in the Program, potentially including those currently displayed on *Nursing Home Compare,* were part of the SNF VBP demonstration, or are part of the SNF QRP. The commenter also specifically

[8] Available at *http://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_PAC-LTC.aspx.*

suggested measures including turnover as a percentage of nursing staff, total CNA hours per patient day, and total licensed nursing hours per patient day, noting that higher staffing levels are correlated with higher quality of care outcomes.

Response: We thank the commenter for these suggestions. As the commenter noted, any changes to expand the SNF VBP Program's measure set would require Congressional action.

Comment: One commenter expressed concern about the data elements that SNFs must document to track their performance on the SNFRM, noting that they are different than those used for the CMS Star Ratings. The commenter also urged us to better align the measures between the SNF QRP and SNF VBP Programs, stating that SNFs want harmonization in what they are required to collect, document, and extract for performance tracking and improvement purposes.

Response: SNFs may choose to track readmissions to the hospitals as part of their quality improvement efforts, and we note that the measures that we have specified for the SNF VBP program impose no data collection requirements on SNFs. Additionally, while we understand the potential benefits of quality measure alignment between the SNF QRP and SNF VBP Programs, we do not believe that this type of alignment meets the SNF VBP Program's needs at this time. While we generally agree that aligning measures across programs is ideal, we hesitate to do so when it is inappropriate to the programs and does not align with statutory direction. In this case, aligning with the SNF QRP readmission measure would require the SNF VBP Program to ignore readmissions that occur during the SNF stay, and we believe this is inappropriate to a value-based purchasing program intended to reduce readmissions among SNF patients in accordance with the statute. Likewise, the SNF QRP readmission measure must follow a statutory requirement to align with readmission measures in other post-acute QRPs that are not compatible with the needs of the SNF VBP program.

We thank the commenters for their feedback on SNF VBP measures.

a. Accounting for Social Risk Factors in the SNF VBP Program

In the FY 2018 SNF PPS final rule (82 FR 36611 through 36613), we discussed the importance of improving beneficiary outcomes including reducing health disparities. We also discussed our commitment to ensuring that medically complex patients, as well as those with social risk factors, receive excellent care. We discussed how studies show that social risk factors, such as being near or below the poverty level as determined by HHS, belonging to a racial or ethnic minority group, or living with a disability, can be associated with poor health outcomes and how some of this disparity is related to the quality of health care.[9] Among our core objectives, we aim to improve health outcomes, attain health equity for all beneficiaries, and ensure that complex patients, as well as those with social risk factors, receive excellent care. Within this context, reports by the Office of the Assistant Secretary for Planning and Evaluation (ASPE) and the National Academy of Medicine have examined the influence of social risk factors in our value-based purchasing programs.[10] As we noted in the FY 2018 SNF PPS final rule (82 FR 36611), ASPE's report to Congress found that, in the context of value-based purchasing programs, dual eligibility for Medicare and Medicaid was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as noted in the FY 2018 SNF PPS final rule, the National Quality Forum (NQF) undertook a 2-year trial period in which certain new measures and measures undergoing maintenance review have been assessed to determine if risk adjustment for social risk factors is appropriate for these measures.[11] The trial period ended in April 2017 and a final report is available at *http://www.qualityforum.org/SES_Trial_Period.aspx*. The trial concluded that ''measures with a conceptual basis for adjustment generally did not demonstrate an empirical relationship'' between social risk factors and the outcomes measured. This discrepancy may be explained in part by the methods used for adjustment and the limited availability of robust data on social risk factors. NQF has extended the socioeconomic status (SES) trial,[12] allowing further examination of social risk factors in outcome measures.

In the FY 2018/CY 2018 proposed rules for our quality reporting and value-based purchasing programs, we solicited feedback on which social risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a provider that would also allow for a comparison of those differences, or disparities, across providers. Feedback we received across our quality reporting programs included encouraging CMS to explore whether factors could be used to stratify or risk adjust the measures (beyond dual eligibility); to consider the full range of differences in patient backgrounds that might affect outcomes; to explore risk adjustment approaches; and to offer careful consideration of what type of information display would be most useful to the public.

We also sought public comment on confidential reporting and future public reporting of some of our measures stratified by patient dual eligibility. In general, commenters noted that stratified measures could serve as tools for hospitals to identify gaps in outcomes for different groups of patients, improve the quality of health care for all patients, and empower consumers to make informed decisions about health care. Commenters encouraged us to stratify measures by other social risk factors such as age, income, and educational attainment. With regard to value-based purchasing programs, commenters also cautioned CMS to balance fair and equitable payment while avoiding payment penalties that mask health disparities, or discouraging the provision of care to more medically complex patients. Commenters also noted that value-based payment program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

We stated in the FY 2019 SNF VBP PPS proposed rule that as a next step, we are considering options to improve health disparities among patient groups within and across hospitals, SNFs, and other health care providers by increasing the transparency of disparities as shown by quality measures. We also stated that we are considering how this work applies to other CMS quality programs in the future. We refer readers to the FY 2018

[9] See, for example United States Department of Health and Human Services. ''Healthy People 2020: Disparities. 2014.'' Available at *http://www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*; or National Academies of Sciences, Engineering, and Medicine. Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors. Washington, DC: National Academies of Sciences, Engineering, and Medicine 2016.

[10] Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE), ''Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs.'' December 2016. Available at *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[11] Available at *http://www.qualityforum.org/SES_Trial_Period.aspx.*

[12] Available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357.*

IPPS/LTCH PPS final rule (82 FR 38403 through 38409) for more details, where we discuss the potential stratification of certain Hospital Inpatient Quality Reporting Program outcome measures. Furthermore, we stated that we continue to consider options to address equity and disparities in our value-based purchasing programs.

We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences.

We received several comments on our discussion of social risk factors.

Comment: One commenter suggested that we consider adjusting for social risk factors through peer grouping to avoid masking disparities in clinical performance. The commenter also suggested that we target technical assistance resources to low-performing providers and support research to reduce measurement bias. Another commenter was concerned that we had not yet adjusted the SNF Readmission Measure based on socioeconomic factors. The commenter expressed concern that we would score SNFs unfairly due to more challenging case mixes, and stated that we must adjust readmission scores to avoid unfair payment penalties for those SNFs serving patient populations with lower socioeconomic status. One commenter acknowledged that we are required by statute to adopt a measure of all-cause readmissions, but expressed concerns about the SNFRM due to its lack of risk adjustment for socioeconomic status, its lacking focus on preventable readmissions, and some design elements. The commenter encouraged us to create a socioeconomic status risk adjustment for this measure, noting that SNFs in underserved areas predominantly caring for low-income, dual-eligible residents may be penalized by measures of all-cause readmissions. Another commenter urged us to include risk adjustment for socioeconomic status for any readmission measures adopted under the SNF VBP Program. The commenter concurred with the December 2016 Report to Congress on Social Risk Factors' conclusion that social risk factors are essential determinants of health and stated that the IMPACT Act provides CMS with a wealth of patient-specific data that it can use to develop additional risk adjustment policies. The commenter encouraged us to use those data to adjust SNF VBP measures and provide incentives to SNFs caring for patients with social risk factors.

Response: We thank the commenters for these suggestions and will take them into account as we develop additional policies on social risk factors in the future. However, in response to the commenter who expressed concern about the current SNF Readmission Measure, we note that the SNF Readmission Measure includes the following case-mix adjustments that we believe promote fairness in the application of financial penalties: Demographic characteristics (age and sex), principal diagnosis from the Medicare claim corresponding to the prior proximal hospitalization as categorized by AHRQ's Clinical Classification Software (CCS) groupings, length of stay during the patient's prior proximal hospitalization, length of stay in the intensive care unit (ICU), end-stage renal disease (ESRD) status, the patient's disability status, the number of prior hospitalizations in the previous 365 days, system-specific surgical indicators, individual comorbidities as grouped by Hierarchical Condition Categories (HCCs) or other comorbidity indices, and a variable counting the number of comorbidities if the patient had more than two HCCs. We refer readers to the FY 2016 SNF PPS final rule (80 FR 46411 through 46419) for additional technical details on the SNFRM.

Comment: One commenter encouraged us to continue using findings from the NQF Sociodemographic Status trial to inform our efforts to address equity and disparities in our VBP Programs, but recommended that we not add SES covariates to the SNFRM risk adjustment model as that action may create biases in reporting, undermine system-based approaches to providing high quality care, and create access to care problems.

Response: We remain concerned about the possibility that additional risk adjustment may mask important performance differences for providers and suppliers that treat patients with additional comorbidities or complications, and we will continue studying the issue. We intend to monitor NQF's ongoing work on this topic carefully.

Comment: One commenter agreed with recommendations to incorporate social risk factors in risk adjustment, but was not sure about which risk characteristics are available in the Medicare eligibility files and whether those characteristics have been evaluated independently. The commenter also suggested that we coordinate research efforts with states that may already be conducting work in this area. One commenter urged us to incorporate risk adjustment for sociodemographic and socioeconomic status into SNF VBP measures, but expressed support for the continued use of unadjusted data for measures related to items that are within the SNF's control. The commenter urged us to make unadjusted performance measure data available to the public to ensure that analysis of health care disparities can continue, and until risk-adjusted measures are available, to report stratified measure rates to the public. The commenter also expressed support for alternative payment mechanisms that account for the complexities of extremely disadvantaged patients, and called on us to monitor the effects of our quality improvement programs carefully. Another commenter supported our continued evaluation of social determinants of health, including providers' commitments to caring for the Medicaid population, and their impact on our payment systems. The commenter encouraged us to ensure that our payment methodologies are updated consistently to account for these factors and maintain equitable access to care.

Response: We intend to continue working with states and other stakeholders to the greatest extent possible to understand the challenges associated with additional risk adjustment for socioeconomic and sociodemographic status in quality measurement programs, including assessing the appropriateness of incorporating specific risk factors in the risk adjustment models. That work includes identifying appropriate data sources for social risk factors, and we will consider the commenter's point about the Medicare eligibility files as a potential data source.

We agree with the commenters that studying health care disparities is critically important for the health care system, and we will continue to do so. We will also take that point under consideration as we consider social risk factors adjustment policies for the SNF VBP Program in the future. We will continue monitoring the SNF VBP Program to ensure that Medicare beneficiaries maintain access to needed SNF care.

We thank the commenters for this feedback, and will take it account as we consider the appropriateness of accounting for social risk factors in the SNF VBP Program.

3. Performance Standards

a. FY 2021 Performance Standards

We refer readers to the FY 2017 SNF PPS final rule (81 FR 51995 through

51998) for a summary of the statutory provisions governing performance standards under the SNF VBP Program and our finalized performance standards policy, as well as the numerical values for the achievement threshold and benchmark for the FY 2019 program year. We also responded to public comments on these policies in that final rule.

We published the final numerical values for the FY 2020 performance standards in the FY 2018 SNF PPS final rule (82 FR 36613), and for reference, we are displaying those values again in Table 40.

TABLE 40—FINAL FY 2020 SNF VBP PROGRAM PERFORMANCE STANDARDS

Measure ID	Measure description	Achievement threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.80218	0.83721

We will continue to use the achievement threshold and benchmark as previously finalized in the FY 2018 SNF PPS final rule. However, due to timing constraints associated with the compilation of the FY 2017 MedPAR file to include 3 months of data following the last discharge date, we were unable to provide estimated numerical values for the FY 2021 Program year's performance standards in the proposed rule. As discussed further below, we proposed to adopt FY 2017 as the baseline period for the FY 2021 program year. While we did not expect either the achievement threshold or benchmark to change significantly from what was finalized for the FY 2020 Program year, we stated our intent to publish the final numerical values for the performance standards based on the FY 2017 baseline period in the FY 2019 SNF PPS final rule.

We welcomed public comment on this approach.

Comment: One commenter urged us to score SNFs on achievement only, stating that Medicare's quality programs should reward providers based on clear, absolute, and prospectively set performance targets.

Response: While we appreciate this suggestion, we note that we are required by section 1888(h)(3)(B) of the Act to establish performance standards that include levels of achievement and improvement, and to use to the higher of either improvement or achievement when calculating the SNF performance score.

Comment: One commenter stated its understanding of the timing constraints that we discussed with respect to the MedPAR file for performance standards calculations, and reiterated its prior support for the Program's switch to fiscal year instead of calendar year performance periods.

Response: We appreciate the continued support for the policy we finalized in the FY 2018 SNF PPS final rule (82 FR 36613 through 36614) to change the SNF VBP Program's performance and baseline periods from calendar years to fiscal years. Additionally, as we note further below, we are finalizing FY 2019 (October 1, 2018 through September 30, 2019) as the performance period for the FY 2021 SNF VBP Program year.

Comment: One commenter supported our efforts to measure improvement and encouraged us to reward providers that consistently achieve high performance under the SNF VBP Program.

Response: We believe that the performance standards that we are adopting, which include levels of achievement and improvement as required by the SNF VBP Program's statute, continue to offer opportunities for us to recognize both SNFs that achieve high performance and those SNFs that improve over time.

After consideration of the public comments, we are finalizing the numerical values for the FY 2021 SNF VBP Program based on the FY 2017 baseline period. Those values follow below in Table 41.

TABLE 41—FINAL FY 2021 SNF VBP PROGRAM PERFORMANCE STANDARDS

Measure ID	Measure description	Achievement threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.79476	0.83212

b. Correction of Performance Standard Numerical Values in Cases of Errors

As noted previously, section 1888(h)(3)(C) of the Act requires that we establish and announce the performance standards for a fiscal year not later than 60 days prior to the performance period for the fiscal year involved. However, we currently do not have a policy that would address the situation where, subsequent to publishing the numerical values for the finalized performance standards for a program year, we discover an error that affects those numerical values. Examples of the types of errors that we could subsequently discover are inaccurate variables on Medicare claims, programming errors, excluding data should have been included in the performance standards calculations, and other technical errors that resulted in inaccurate achievement threshold and benchmark calculations. While we do not have reason to believe that the SNF VBP Program has previously published inaccurate numerical values for performance standards, in the FY 2019 SNF PPS proposed rule (83 FR 21086), we stated our concern about the possibility that we would discover an error in the future and have no ability to correct the numerical values.

We are aware that SNFs rely on the performance standards that we publicly display in order to target quality improvement efforts, and we do not believe that it would be fair to SNFs to repeatedly update our finalized performance standards if we were to identify multiple errors. In order to balance the need of SNFs to know what performance standards they will be held accountable to for a SNF VBP program year with our obligation to provide SNFs with the most accurate performance standards that we can based on the data available at the time, we proposed that if we discover an error in the calculations subsequent to having published the numerical values for the performance standards for a program year, we would update the numerical values to correct the error. We also

proposed that we would only update the numerical values one time, even if we subsequently identified a second error, because we believe that a one-time correction would allow us to incorporate new information into the calculations without subjecting SNFs to multiple updates. Any update we would make to the numerical values based on a calculation error would be announced via the CMS website, listservs, and other available channels to ensure that SNFs are made fully aware of the update.

We welcomed public comments on this proposal.

Comment: One commenter supported our proposal to adopt correction authority for performance standards and agreed that making multiple changes to the performance standards in a given program year would be difficult for SNFs' quality improvement efforts. The commenter also urged us to be transparent if we find additional technical errors.

Response: We thank the commenter for the support, and we intend to be as transparent as possible if we identify any errors in the calculation of the numerical values of the SNF VBP Program's performance standards.

After consideration of the public comments we have received, we are finalizing our policy to correct performance standard numerical values in cases of errors as proposed.

4. FY 2021 Performance Period and Baseline Period and for Subsequent Years

a. Background

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422) for a discussion of our considerations for determining performance periods under the SNF VBP Program. Based on those considerations, as well as public comment, we adopted CY 2017 as the performance period for the FY 2019 SNF VBP Program, with a corresponding baseline period of CY 2015.

Additionally, in the FY 2018 SNF PPS final rule (82 FR 36613 through 36614), we adopted FY 2018 as the performance period for the FY 2020 SNF VBP Program, with a corresponding baseline period of FY 2016. We refer readers to that rule for a discussion of the need to shift the Program's measurement periods from the calendar year to the fiscal year.

b. FY 2021 Performance and Baseline Periods

As we discussed with respect to the FY 2019 and FY 2020 SNF VBP Program years, we continue to believe that a 12-month duration for the performance and baseline period is the most appropriate for the SNF VBP Program. Therefore, we proposed to adopt FY 2019 (October 1, 2018 through September 30, 2019) as the performance period for the FY 2021 SNF VBP Program year. We also proposed to adopt FY 2017 (October 1, 2016 through September 30, 2017) hospital discharges as the baseline period for the FY 2021 SNF VBP Program year.

We welcomed public comment on these proposals.

Comment: One commenter expressed concern about our proposal to use FY 2019 as the performance period for the FY 2021 SNF VBP Program year, stating that SNFs need more time to improve their data collection, reporting, and evaluation efforts. The commenter requested that we align our measures with the SNF QRP and other quality programs, which will allow SNFs additional time for performance tracking and improvement activities. The commenter also requested that we provide SNFs with more timely performance feedback to help them identify areas for improvement efforts. One commenter expressed concern about the proposed performance period, stating that SNFs do not believe they are ready for FY 2019 to be used as the performance period and indicated that the collection and reporting of quality measures is a significant administrative burden. The commenter urged us to move to an automated system to reduce the reporting burden on SNFs and requested that we provide SNFs with timely performance feedback that they can use to identify areas where they need to focus their improvement efforts.

Response: We would like to clarify for the commenter that the SNF VBP Program's measure is calculated based on hospital claims, and therefore, does not require data collection or impose any reporting burden on SNFs, though SNFs may choose to track readmissions to the hospital for their patients as part of their care coordination and quality improvement efforts. We do not believe that SNFs need additional time to track readmissions to the hospital for their patients or to undertake quality improvement efforts to minimize those readmissions because SNFs have had ample notice about the SNF VBP Program's operations and its focus on measures of hospital readmissions. We will, however, strive to provide as much timely information to SNFs as possible on their measured performance, but we note that the measure that we have specified for the Program includes significant calculations, including detailed risk adjustment, that complicates our intention to provide feedback more promptly than on a quarterly basis to SNFs.

Comment: One commenter supported our performance and baseline period proposals and agreed that 12-month periods are appropriate for both the SNFRM and the SNFPPR.

Response: We thank the commenter for the support.

After consideration of the public comments that we received, we are finalizing the performance period and baseline period for FY 2021 as proposed.

c. Performance Periods and Baseline Periods for Subsequent Program Years

As we have described in previous rules (see, for example, the FY 2016 SNF PPS final rule, 80 FR 46422), we strive to link performance furnished by SNFs as closely as possible to the program year to ensure clear connections between quality measurement and value-based payment. We also strive to measure performance using a sufficiently reliable population of patients that broadly represent the total care provided by SNFs.

Therefore, we proposed that beginning with the FY 2022 program year and for subsequent program years, we would adopt for each program year, a performance period that is the 1-year period following the performance period for the previous program year. We also proposed that beginning with the FY 2022 program year and for subsequent program years, we would adopt for each program year a baseline period that is the 1-year period following the baseline period for the previous year. Under this policy, the performance period for the FY 2022 program year would be FY 2020 (the 1-year period following the proposed FY 2021 performance period of FY 2019), and the baseline period for the FY 2022 program year would be FY 2018 (the 1-year period following the proposed FY 2021 baseline period of FY 2017). We believe adopting this policy will provide SNFs with certainty about the performance and baseline periods during which their performance will be assessed for future program years.

We welcomed public comments on this proposal.

Comment: One commenter supported our proposal to adopt performance and baseline periods automatically for subsequent program years.

Response: We thank the commenter for the support.

After consideration of the public comments that we have received, we are finalizing our policy to adopt performance periods and baseline

periods for subsequent program years as proposed.

5. SNF VBP Performance Scoring

a. Background

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52000 through 52005) for a detailed discussion of the scoring methodology that we have finalized for the Program, along with responses to public comments on our policies and examples of scoring calculations. We also refer readers to the FY 2018 SNF PPS final rule (82 FR 36614 through 36616) for discussion of the rounding policy we adopted, our request for comments on SNFs with zero readmissions, and our request for comments on a potential extraordinary circumstances exception policy.

b. Scoring Policy for SNFs Without Sufficient Baseline Period Data

In some cases, a SNF will not have sufficient baseline period data available for scoring for a Program year, whether due to the SNF not being open during the baseline period, only being open for a small portion of the baseline period, or other reasons (such as receiving an extraordinary circumstance exception, which we finalize below). The availability of baseline data for each SNF is an integral component of our scoring methodology, and we are concerned that the absence of sufficient baseline data for a SNF will preclude us from being able to score that SNF on improvement for a program year. As discussed further below, with respect to the proposed scoring adjustment for a SNF without sufficient data in the performance period to create a reliable SNF performance score, we are concerned that measuring SNFs with fewer than 25 eligible stays (or index SNF stays that would be included in the calculation of the SNF readmission measure) during the baseline period may result in unreliable improvement scores, and as a result, unreliable SNF performance scores. We considered policy options to address this issue.

We continue to believe it is important to compare SNF performance during the same periods to control for factors that may not be attributable to the SNF, such as increased patient case-mix acuity during colder weather periods when influenza, pneumonia, and other seasonal conditions and illnesses are historically more prevalent in the beneficiary population. Using a 12-month performance and baseline period for all SNFs ensures that, to the greatest extent possible, differences in performance can be attributed to the SNF's care quality rather than to exogenous factors.

Additionally, because we have proposed that for FY 2021 and future Program years, the start of the performance period for a Program year would begin exactly 12-months after the end of the baseline period for that Program year and there would not be sufficient time to compute risk-standardized readmission rates from another 12-month baseline period before the performance period if a SNF had insufficient data during the baseline period. For the FY 2021 Program, for example, the proposed baseline period would conclude at the end of FY 2017 (September 30, 2017) and the proposed performance period would begin on the first day of FY 2019 (October 1, 2018). We also do not believe it would be equitable to score SNFs without sufficient baseline period data using data from a different period. Doing so would, in our view, impede our ability to compare SNFs' performance on the Program's quality measure fairly, as additional factors that may affect SNFs' care could arise when comparing performance during different time periods. Therefore, we have concluded that it is not operationally feasible or equitable to use different baseline periods for purposes of awarding improvement scores to SNFs for a Program year.

We believe that SNFs without sufficient data from a single baseline period, which we would define for this purpose as SNFs with fewer than 25 eligible stays during the baseline period for a fiscal year based on an analysis of Pearson correlation coefficients at various denominator counts, should not be measured on improvement for that Program year. Accordingly, we are proposing to score these SNFs based only on their achievement during the performance period for any Program year for which they do not have sufficient baseline period data. The analysis of Pearson correlation coefficients at various denominator counts used in developing this proposal is available on our website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNFRM-Reliability-Testing-Memo.pdf.*

We proposed to codify this proposal by adding § 413.338(d)(1)(iv). We welcomed public comment on this proposal.

Comment: One commenter agreed with our proposal to not score SNFs on improvement when they do not have sufficient data during the baseline period for appropriate year-over-year comparisons. However, the commenter expressed concern that this approach is different for this group of low-volume SNFs compared to SNFs that are consistently low-volume. The commenter expressed continued concerns with the readmission rates awarded to SNFs when they have low case volume.

Response: We note that the policies that we have proposed for SNFs without sufficient baseline period data and for low-volume adjustment are intended to address separate permutations of the SNFRM reliability issue. In the first case, our intent is to ensure that we compare sufficiently-reliable SNFRM rates when assessing SNFs' improvement over time. That assessment relies on SNFRM rates being sufficiently reliable in both the baseline period and performance period to make the comparison that we use to award improvement points. In contrast, the low-volume scoring adjustment proposal focuses on the SNFRM's reliability during the performance period, which is necessary for both achievement and improvement scoring. We believe that these proposals ensure that SNFRM rates are sufficiently reliable for purposes of SNF VBP scoring, and as the commenter requested, ensure that SNFs are not scored on the SNFRM when the measure's case count is too low to produce sufficiently reliable scores.

Comment: One commenter supported our proposal to score SNFs without sufficient baseline period data on achievement only, agreeing with our view that measure results in those cases are susceptible to random variation and may not reliably represent quality in that facility.

Response: We thank the commenter for the support.

After consideration of the public comments that we received, we are finalizing our scoring policy for SNFs without sufficient baseline period data as proposed. We are also finalizing our regulation text on this policy as proposed.

c. SNF VBP Scoring Adjustment for Low-Volume SNFs

In previous rules, we have discussed and sought comment on policies related to SNFs with zero readmissions during the performance period. For example, in the FY 2018 SNF PPS rule (82 FR 36615 through 36616), we sought comment on policies we should consider for SNFs with zero readmissions during the performance period because under the risk adjustment and the statistical approach used to calculate the SNFRM, outlier values are shifted towards the

mean, especially for smaller SNFs. As a result, SNFs with observed readmission rates of zero may receive risk-standardized readmission rates that are greater than zero. We continue to be concerned about the effects of the SNFRM's risk adjustment and statistical approach on the scores that we award to SNFs under the Program. We are specifically concerned that as a result of this approach, the SNFRM is not sufficiently reliable to generate accurate performance scores for SNFs with a low number of eligible stays during the performance period. We would like to ensure that the Program's scoring methodology results in fair and reliable SNF performance scores because those scores are linked to a SNF's ranking and payment.

Therefore, we considered whether we should make changes to our methodology for assessing the total performance of SNFs for a Program year that better accounts for SNFs with zero or low numbers of eligible stays during the performance period. Because the number of eligible SNF stays makes up the denominator of the SNFRM, we have concluded that the reliability of a SNF's measure rate and resulting performance score is adversely impacted if the SNF has less than 25 eligible stays during the performance period, as the Pearson correlation coefficient is lower at denominator counts of 5, 10, 15, and 20 eligible stays in comparison to 25 eligible stays. The analysis of Pearson correlation coefficients at various denominator counts used in developing this proposal is available on our website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNFRM-Reliability-Testing-Memo.pdf.*

We believe that the most appropriate way to ensure that low-volume SNFs (which we define for purposes of the SNF VBP Program as SNFs with fewer than 25 eligible stays during the performance period) receive sufficiently reliable SNF performance scores is to adopt an adjustment to the scoring methodology we use for the SNF VBP Program. We proposed that if a SNF has less than 25 eligible stays during a performance period for a Program year, we would assign a performance score to the SNF for that Program year. That assigned performance score would, when used to calculate the value-based incentive payment amount for the SNF, result in a value-based incentive payment amount that is equal to the adjusted Federal per diem rate that the SNF would have received for the fiscal year in the absence of the Program. The actual performance score that we would assign to an individual low-volume SNF for a Program year would be identified based on the distribution of all SNFs' performance scores for that Program year after calculating the exchange function. We would then assign that score to an individual low-volume SNF, and we would notify the low-volume SNF that it would be receiving an assigned performance score for the Program year in the SNF Performance Score Report that we provide not later than 60 days prior to the fiscal year involved.

We believe this scoring adjustment policy would appropriately ensure that our SNF performance score methodology is fair and reliable for SNFs with fewer than 25 eligible stays during the performance period for a Program year.

In section X.A.6. of the proposed rule, we estimated that $527.4 million would be withheld from SNFs' payments for the FY 2019 Program year based on the most recently available data. Additionally, the 60 percent payback percentage would result in an estimated $316.4 million being paid to SNFs in the form of value-based incentive payments with respect to FY 2019 services. Of the $316.4 amount, we estimated that $8.6 million will be paid to low-volume SNFs. However, if our proposal to adopt a scoring adjustment for low-volume SNFs were finalized, we estimated that we would redistribute an additional $6.7 million in value-based incentive payments to low-volume SNFs with respect to FY 2019 services, for a total of $15.3 million of the estimated $527.4 million available for value-based incentive payments for that Program year. The additional $6.7 million in value-based incentive payments that would result from finalizing this proposal would increase the 60 percent payback percentage for FY 2019 by approximately 1.28 percent, which would result in a payback percentage 61.28 percent of withheld funds. The payback percentage would similarly increase for all other Program years, however the actual amount of the increase for a particular Program year would vary based on the number of low-volume SNFs that we identify for that Program year and the distribution of all SNFs' performance scores for that Program year.

As an alternative, we considered assigning a performance score to SNFs with fewer than 25 eligible stays during the performance period that would result in a value-based incentive payment percentage of 1.2 percent, or 60 percent of the 2 percent withhold. This amount would match low-volume SNFs' incentive payment percentages with the finalized SNF VBP Program payback percentage of 60 percent, and would represent a smaller adjustment to low-volume SNFs' incentive payment percentages than the proposed policy described above. We estimated that this alternative would redistribute an additional $1 million with respect to FY 2019 services to low-volume SNFs. We also estimated that this alternative would increase the 60 percent payback percentage for FY 2019 by approximately 0.18 percent of the approximately $527.4 million of the total withheld from SNFs' payments, which would result in a payback percentage of 60.18 percent of the estimated $527.4 million in withheld funds for that Program year. However, as with the proposal above, we stated that the specific amount by which the payback percentage would increase for each Program year would vary based on the number of low-volume SNFs that we identify for each Program year and the distribution of all SNFs' performance scores for that Program year.

We welcomed public comments on this proposal and on the alternative that we considered. We also proposed to codify the definition of low-volume SNF at § 413.338(a)(16), and the definition of eligible stay at § 413.338(a)(17). We proposed to codify the low-volume scoring adjustment proposal at § 413.338(d)(3). We also proposed a conforming edit to the payback percentage policy at § 413.338(c)(2)(i).

Comment: One commenter expressed support for our proposed low-volume adjustment that would provide SNFs with a neutral value-based incentive payment percentage.

Response: We thank the commenter and appreciate the support.

Comment: One commenter requested clarification on how the SNF VBP will affect newly certified facilities that have no data from either the performance period or baseline period for the FY 2019 SNF VBP Program year.

Response: SNFs with zero eligible stays during both the baseline and performance periods are not covered by the low-volume adjustment policy. For the purposes of the SNF readmission measure, an eligible stay is an index SNF admission that would be included in the denominator of the measure. We will notify all SNFs of their incentive multipliers for the Program year, including SNFs with zero eligible stays during the baseline and performance periods. These SNFs will receive an incentive multiplier that results in the adjusted Federal per diem rate under the Medicare SNF PPS that they would

otherwise have received absent the Program.

Comment: Commenter suggested as an alternative to our low-volume adjustment proposal that we consider adopting a 2-year performance period for low-volume SNFs only and weight the most recent year more highly.

Response: We thank the commenter for this feedback and will consider this in future rulemaking.

Comment: One commenter suggested that we consider assigning a 2 percent payment penalty to low-volume SNFs instead of adopting the low-volume scoring adjustment as proposed. The commenter suggested that this policy would encourage low-volume SNFs to increase their Medicare cases sizes, which would enable Medicare to adequately measure their care quality and hold all SNFs accountable for their care.

Response: We do not believe the intent of the SNF VBP was to incentivize SNFs to increase their Medicare case volume. We wish to avoid increasing possible healthcare disparities for smaller facilities when payment differences are driven solely by smaller measure denominators, and not quality of care as reflected in measure performance. Finally, we are concerned about the possibility of gaming this kind of policy, as SNFs might seek out Medicare cases to avoid the 2 percent penalty the commenter suggests.

Comment: One commenter expressed support for our proposed low-volume adjustment and opposition to the alternative that we presented, stating that performance scores under the Program can be skewed by a single readmission and that the alternative would reduce Medicare rates for low-volume SNFs regardless of their performance and with no opportunity to earn additional incentive payments. Another commenter supported our proposal to adopt a low-volume scoring adjustment, noting that the evidence shows that the SNFRM is not a reliable quality indicator when facilities have fewer than 25 qualifying admissions. The commenter also agreed with our proposal to adjust the Program's payback percentage to account for this policy.

Response: We thank the commenters for the support.

Comment: One commenter stated that low-volume SNFs should be excluded from the SNF VBP Program since they have no realistic opportunity to earn value-based incentive payments.

Response: We believe that the low-volume scoring adjustment policy ensures that these SNFs are adequately protected from being scored on insufficiently-reliable SNFRM rates.

Comment: One commenter appreciated our efforts to address low-volume SNFs and SNFs without baseline period data. However, the commenter was concerned that CMS had not provided enough information on these topics and requested additional clarity.

Response: We believe we have provided as much clarity as possible on the effects of the low-volume scoring adjustment policy in both the preamble of the proposed rule and the Regulatory Impact Analysis that was included in the proposed rule. We have also provided additional clarity in this final rule and in the Regulatory Impact Analysis that is included in this final rule. We will also ensure that affected SNFs are made fully aware when their SNF performance scores were assigned as a result of the policy and notify them of their value-based incentive payment percentage for the fiscal year, as required by section 1888(h)(7) of the Act. We believe that notification will ensure that SNFs are aware of the effects that this policy has on their SNF performance scores and incentive payments.

After consideration of the public comments that we have received, we are finalizing our scoring adjustment for low-volume SNFs as proposed. We are also finalizing our regulation text on this policy as proposed.

d. Extraordinary Circumstances Exception Policy for the SNF VBP Program

In the FY 2018 SNF PPS final rule (82 FR 36616), we summarized public comments that we received on the topic of a possible extraordinary circumstances exception policy for the SNF VBP Program. As we stated in that rule, in other value-based purchasing and quality reporting programs, we have adopted Extraordinary Circumstances Exceptions (ECE) policies intended to allow facilities to receive relief from program requirements due to natural disasters or other circumstances beyond the facility's control that may affect the facility's ability to provide high-quality health care.

In other programs, we have defined 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 or otherwise affect the facility's ability to continue normal operations. 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, flood caused by man-made actions, civil disorders, and explosions. A disaster may be widespread and impact multiple structures or be isolated and affect a single site only. As a result of either a natural or man-made disaster, we are concerned that SNFs' care quality and subsequent impact on measure performance in the SNF VBP Program may suffer, and as a result, SNFs might be penalized under the Program's quality measurement and scoring methodology. However, we do not wish to penalize SNFs in these circumstances. For example, we recognize that SNFs might receive patients involuntarily discharged from hospitals facing mandatory evacuation due to probable flooding, and these patients might be readmitted to inpatient acute care hospitals and result in poorer readmission measure performance in the SNF VBP Program. We therefore proposed to adopt an ECE policy for the SNF VBP Program to provide relief to SNFs affected by natural disasters or other circumstances beyond the facility's control that affect the care provided to the facility's patients. We proposed that if a SNF can demonstrate that an extraordinary circumstance affected the care that it provided to its patients and subsequent measure performance, we would exclude from the calculation of the measure rate for the applicable baseline and performance periods the calendar months during which the SNF was affected by the extraordinary circumstance. Under this proposal, a SNF requesting an ECE would indicate the dates and duration of the extraordinary circumstance in its request, along with any available evidence of the extraordinary circumstance, and if approved, we would exclude the corresponding calendar months from that SNF's measure rate for the applicable measurement period and by extension, its SNF performance score.

We further proposed that SNFs must submit this ECE request to CMS by filling out the ECE request form that we will place on the QualityNet website to the *SNFVBPinquiries@cms.hhs.gov* mailbox within 90 days following the extraordinary circumstance.

To accompany an ECE request, SNFs must provide any available evidence showing the effects of the extraordinary circumstance on the care they provided to their patients, including, but not limited to, photographs, newspaper and other media articles, and any other

materials that would aid CMS in making its decision. We stated that we will review exception requests, and at our discretion based on our evaluation of the impact of the extraordinary circumstances on the SNF's care, provide a response to the SNF as quickly as feasible.

We stated our intent for this policy to offer relief to SNFs whose care provided to patients suffered as a result of the disaster or other extraordinary circumstance, and we believe that excluding calendar months affected by extraordinary circumstances from SNFs' measure performance under the Program appropriately ensures that such circumstances do not unduly affect SNFs' performance rates or performance scores. We developed this process to align with the ECE process adopted by the SNF Quality Reporting Program to the greatest extent possible and to minimize burden on SNFs. This policy is not intended to preclude us from granting exceptions to SNFs 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 made the determination to grant an exception to all SNFs in a region or locale, we proposed to communicate this decision through routine communication channels to SNFs and vendors, including but not limited to, issuing memos, emails, and notices on our SNF VBP website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Other-VBPs/SNF-VBP.html*.

We noted that if we finalize this policy, we would score any SNFs receiving ECEs on achievement and improvement for any remaining months during the performance period, provided the SNF had at least 25 eligible stays during both of those periods. If a SNF should receive an approved ECE for 6 months of the performance period, for example, we would score the SNF on its achievement during the remaining 6 months on the Program's measure as long as the SNF met the proposed 25 eligible stay threshold during the performance period. We would also score the SNF on improvement as long as it met the proposed 25 eligible stay threshold during the applicable baseline period.

We welcomed public comments on this proposal. We also proposed to codify this proposal at § 413.338(d)(4).

Comment: Two commenters expressed appreciation and support for our proposal to adopt an ECE policy for the SNF VBP Program. The commenters acknowledged that these exceptions are provided in other programs and agreed that we should align our ECE policy with the Hospital VBP Program as much as possible. A third commenter reiterated its previous support for an ECE policy in the SNF VBP Program.

Response: We thank the commenters for the support.

After consideration of the public comments that we received, we are finalizing our Extraordinary Circumstances Exception policy as proposed. We are also finalizing our regulation text on this policy as proposed.

6. SNF Value-Based Incentive Payments

We refer readers to the FY 2018 SNF PPS final rule (82 FR 36616 through 36621) for discussion of the exchange function methodology that we have adopted for the Program, as well as the specific form of the exchange function (logistic, or S-shaped curve) that we finalized, and the payback percentage of 60 percent. We adopted these policies for FY 2019 and subsequent fiscal years.

As required by section 1888(h)(7) of the Act, we will inform each SNF of the adjustments to its Medicare payments as a result of the SNF VBP Program that we will make not later than 60 days prior to the fiscal year involved. We will fulfill that requirement via SNF Performance Score Reports that we will circulate to SNFs using the QIES–CASPER system, which is also how we distribute the quarterly confidential feedback reports that we are required to provide to SNFs under section 1888(g)(5) of the Act. The SNF Performance Score Reports will contain the SNF's performance score, ranking, and value-based incentive payment adjustment factor that will be applied to claims submitted for the applicable fiscal year. Additionally, as we finalized in the FY 2018 SNF PPS final rule (82 FR 36622 through 36623), the provision of the SNF Performance Score Report will trigger the Phase Two Review and Corrections Process, and SNFs will have 30 days from the date we post the report on the QIES–CASPER system to submit corrections to their SNF performance score and ranking to the *SNFVBPinquiries@cms.hhs.gov* mailbox.

Finally, as we discussed in the FY 2018 SNF PPS final rule (82 FR 36618), beginning with FY 2019 (October 1, 2018) payments, we intend to make the 2 percent reduction and the SNF-specific value-based incentive payment adjustment to SNF claims simultaneously. Beginning with FY 2019, we will identify the adjusted federal per diem rate for each SNF for claims under the SNF PPS. We will then reduce that amount by 2 percent by multiplying the per diem amount by 0.98, in accordance with the requirements in section 1888(h)(6) of the Act. We will then multiply the result of that calculation by each SNF's specific value-based incentive payment adjustment factor, which will be based on each SNF's performance score for the program year and will be calculated by the exchange function, to generate the value-based incentive payment amount that applies to the SNF for the fiscal year. Finally, we will add the value-based incentive payment amount to the reduced rate, resulting in a new adjusted federal per diem rate that applies to the SNF for the fiscal year.

At the time of the publication of the proposed rule, we had not completed SNF performance score calculations for the FY 2019 program year. However, we stated our intent to provide the range of value-based incentive payment adjustment factors applicable to the FY 2019 program year in this final rule. For the FY 2019 SNF VBP Program Year, and incorporating the 2 percent reduction to SNFs' payments, we estimate the value-based incentive payment adjustment factors that we will award to SNFs range from 0.9802915381 to 1.02326809. That is, we estimate that SNFs may receive incentive payment percentages ranging from approximately −1.97 percent to approximately +2.33 percent, on a net basis.

We proposed to codify the SNF VBP Program's payment adjustments at § 413.337(f).

Comment: Two commenters urged us to revisit the payback percentage policy that we adopted in the FY 2018 SNF PPS final rule (82 FR 36619 through 36621), stating that we should distribute 70 percent of the funds withheld from SNFs' Medicare payments through the SNF VBP Program, the maximum amount allowable under the statute. One commenter requested that we return the remaining 30 percent of funds for SNF quality improvement initiatives, including programs to improve SNFs' performance when they have high readmission rates, while the other commenter stated that we should remit 100 percent of the Program's funds as is done in the Hospital Value-Based Purchasing Program.

Response: As we discussed in the FY 2018 SNF PPS final rule (82 FR 36621), we are not authorized to distribute the 30 percent of SNFs' Medicare payments that would remain after the payment withhold is determined for any purposes. Those funds are retained in the Medicare Trust Fund and used for other Medicare Program purposes authorized by statute. We are not allowed under current law to distribute

100 percent of the withheld funds for SNF VBP purposes.

Further, we do not believe it is appropriate to revisit the payback percentage policy at this time, with the exception of the low-volume policy, which we view as a narrow exception to the 60 percent payback percentage that would have no effect on the majority of facilities. At the time of the publication of this final rule, the SNF VBP Program will not yet have delivered its first incentive payments based on measured performance, and we do not believe we should consider whether to change the payback percentage further until we are able to more fully assess the effects that it has on the quality of care provided in SNFs. We refer readers to the FY 2018 SNF PPS final rule (82 FR 36619 through 36621) for our full discussion of the payback percentage policy that we have adopted for the SNF VBP Program.

We thank the commenters for their feedback. As noted in section III.B.5. of this final rule, we are finalizing the codification of the SNF VBP program payment adjustment as proposed.

D. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange Through Possible Revisions to the CMS Patient Health and Safety Requirements for Skilled Nursing Facility Providers and Suppliers

In the FY 2019 SNF PPS proposed rule, we included a Request for Information (RFI) related to promoting interoperability and electronic healthcare information exchange (83 FR 21089). We received 22 comments on this RFI, and appreciate the input provided by commenters.

VII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to publish a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval.

To fairly evaluate whether an information collection should be approved by OMB, PRA section 3506(c)(2)(A) 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 burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

In our May 8, 2018 proposed rule (83 FR 21018), we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements (ICRs).We did not receive any comments on the ICR section of the proposed rule.

A. Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (as compared to the FY 2019 SNF PPS proposed rule when we used May 2016 estimates) (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 42 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. We are using the adjusted wages to derive our cost estimates.

TABLE 42—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Health Information Technician	29–2071	20.59	20.59	41.18
Registered Nurse	29–1141	35.36	35.36	70.72

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Information Collection Requirements (ICRs)

1. ICRs Regarding the SNF PPS Assessment Schedule Under the PDPM

The following sets out the requirements and burden associated with the MDS assessment schedule that will be effective October 1, 2019 under the SNF PPS in conjunction with implementation of the PDPM. The requirements and burden will be submitted to OMB for approval under control number 0938–1140 (CMS–10387).

Section V.D. of this final rule finalizes revisions to the current SNF PPS assessment schedule to require only two scheduled assessments (as opposed to the current requirement for five scheduled assessments) for each SNF stay: A 5-day scheduled PPS assessment and a discharge assessment.

The current 5-day scheduled PPS assessment will be used as the admission assessment under this rule's finalized PDPM and set the resident's case-mix classification for the resident's SNF stay. The PPS discharge assessment (which is already required for all SNF Part A residents) will serve as the discharge assessment and be used for monitoring purposes. In section V.D. of this final rule, we discuss that while we proposed to require SNFs to reclassify residents under the PDPM using the Interim Payment Assessment (IPA) if certain criteria are met, we have decided in this final rule to make this assessment optional, thereby leaving completion of this assessment at the discretion of the individual provider. Thus, the 5-day SNF PPS scheduled assessment will be the only PPS assessment required to classify a resident under the PDPM for payment purposes, while the IPA may also be completed, as discussed in section V.D. of this final rule. This eliminates the requirement for the following assessments under the SNF PPS: 14-day scheduled PPS assessment, 30-day scheduled PPS assessment, 60-day scheduled PPS assessment, 90-day scheduled PPS assessment, Start of Therapy Other Medicare Required

Assessment (OMRA), End of Therapy OMRA, and Change of Therapy OMRA.

In estimating the amount of time to complete a PPS assessment, we utilize the OMRA assessment, or the NO/SO item set (this is consistent with the current information collection request as approved by OMB on July 28, 2017; see *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201703-0938-018*) as a proxy for all assessments. In section V.D. of this final rule, we finalized the addition of 18 items to the PPS discharge assessment in order to calculate and monitor the total amount of therapy provided during a SNF stay. These items are listed in Table 35 under section V.D. of this final rule. Given that the PPS OMRA assessment has 272 items (as compared to 125 items currently on the PPS discharge assessment) we believe the items that we are adding to the PPS discharge assessment, while increasing burden for each of the respective assessments, is accounted for by using the longer PPS OMRA assessment as a proxy for the time required to complete all assessments.

When calculating the burden for each assessment, we estimated that it will take 40 minutes (0.6667 hours) at $70.72/hr for an RN to collect the information necessary for preparing the assessment, 10 minutes (0.1667 hours) at $55.95/hr (the average hourly wage for RN ($70.72/hr) and health information technician ($41.18/hr)) for staff to code the responses, and 1 minute (0.0167 hours) at $41.18/hr for a health information technician to transmit the results. In total, we estimate that it would take 51 minutes (0.85 hours) to complete a single PPS assessment. Based on the adjusted hourly wages for the noted staff, we estimate that it would cost $57.17 [($70.72/hr × 0.6667 hr) + ($55.95/hr × 0.1667 hr) + ($41.18/hr × 0.0167 hr)] to prepare, code, and transmit each PPS assessment.

The ongoing burden associated with the revisions to the SNF PPS assessment schedule is the time and effort it would take each Medicare Part A SNF to complete the 5-day PPS and discharge assessments. Based on our most current data, there are 15,471 Medicare Part A SNFs (as opposed to the 15,455 discussed in the proposed rule). Based on FY 2017 data, we estimate that 2,406,401 5-day PPS assessments will be completed and submitted by Part A SNFs each year under the PDPM. We used the same number of assessments (2,406,401) as a proxy for the number of PPS discharge assessments that would be completed and submitted each year, since all residents who require a 5-day PPS assessment will also require a discharge assessment under the SNF PDPM.

As compared to the FY 2019 SNF PPS proposed rule, in which we used the Significant Change in Status Assessment (SCSA) as a proxy to estimate the number of IPAs (83 FR 21093), we have eliminated this portion of our burden estimate as this assessment would not be required, per the discussion in section V.D. of this final rule. Therefore, we estimate that the total number of 5-day scheduled PPS assessments, and PPS discharge assessments that would be completed across all facilities is 4,812,802 assessments (2,406,401 + 2,406,401, respectively) instead of 4,905,042 assessments (2,406,401 + 92,240 + 2,406,401) that was set out in the proposed rule. For all assessments under the PDPM, we estimated a burden of 4,090,882 hours (4,812,802 assessments × 0.85 hr/assessment) at a cost of $275,147,890 (4,812,802 assessments × $57.17/assessment).

Based on the same FY 2017 data, there were 5,833,476 non-discharge related assessments (scheduled and unscheduled PPS assessments) completed under the RUG- IV payment system. To this number we add the same proxy as above for the number of discharge assessments (2,406,401), since every resident under RUG–IV who required a 5-day scheduled PPS assessment would also require a discharge assessment. This brings the total number of estimated assessments under RUG–IV to 8,239,877. Using the same wage and time figures (per assessment), we estimated a burden of 7,003,895 hours (8,239,877 assessments × 0.85 hr/assessment) at a cost of $471,073,768 (8,239,877 assessments × $57.17/assessment).

When comparing the currently approved RUG–IV burden with the PDPM burden, we estimate a savings of 2,913,013 administrative hours (7,003,895 RUG–IV hours − 4,090,882 PDPM hours) or approximately 188 hours per provider per year (2,913,013 hours/15,471 providers). As depicted in Table 43, we also estimate a cost savings of $195,925,878 ($471,073,768 RUG–IV costs − $275,147,890 PDPM costs) or $12,664 per provider per year ($195,925,878/15,471 providers). This represents a significant decrease in administrative burden to providers under PDPM.

TABLE 43—PDPM SAVINGS

Burden reconciliation	Respondents *	Responses (assessments)	Burden per response (hours)	Total annual burden (hours)	Cost ($)
RUG–IV	15,455	8,239,877	0.85	7,003,895	471,073,768
PDPM	15,471	4,812,802	0.85	4,090,882	275,147,890
SAVINGS	(16)	(3,427,075)	No change	(2,913,013)	(195,925,878)

* The RUG–IV number of respondents is based on the last approved PRA package in 2017. Numbers of respondents changes from year to year.

Finally, in section V.D. of this final rule, we finalized the addition of 3 items, as listed in Table 34 of this final rule), to the MDS 3.0 for Nursing Homes and Swing Bed Providers. Based on the small number of items being added and the small percentage of assessments that Swing Bed providers make up, we do not believe this action will cause any measurable adjustments to our currently approved burden estimates. Consequently, we are not revising any of those estimates.

2. ICRs Regarding the SNF VBP Program

In section VI.C.5.d. of this final rule, we are adopting an Extraordinary Circumstances Exception (ECE) process for the SNF VBP. Because the same CMS Extraordinary Circumstances Exceptions (ECE) Request Form would be used across ten quality programs: Hospital IQR Program, Hospital Outpatient Reporting Program, Inpatient Psychiatric Facility Quality Reporting Program, PPS-Exempt Cancer Hospital Quality Reporting Program, Ambulatory Surgical Center Quality Reporting Program, Hospital VBP Program, Hospital-Acquired Condition Reduction Program, Hospital Readmissions Reduction Program, End Stage Renal Disease Quality Incentive Program, and

Skilled Nursing Facility Value-Based Purchasing Program—the form and its associated requirements/burden will be submitted to OMB for approval under one information collection request (CMS–10210, OMB control number: 0938–1022) and in association with our IPPS final rule (CMS–1694–F; RIN 0938–AT27). To avoid double counting we are not setting out the form's SNF-related burden in this final rule. Separately, we are not removing or adding any new or revised SNF VBP measure-related requirements or burden in this rule. Consequently, this final rule does not set out any new VBP-related collections of information that would be subject to OMB approval under the authority of the PRA.

3. ICRs for the SNF Quality Reporting Program (QRP)

We are not removing or adding any new or revised SNF QRP measure-related requirements or burden in this rule. Consequently, this final rule does not set out any new QRP-related collections of information that would be subject to OMB approval under the authority of the PRA.

C. Summary of Requirements and Annual Burden Estimates

TABLE 44—INFORMATION COLLECTION REQUIREMENTS AND BURDEN ESTIMATES

Requirement	OMB control No.	Respondents	Responses (per respondent)	Total responses	Time per response (hr)	Total time (hr)	Labor cost per hour ($/hr)	Annualized cost ($)
SNF PPS Assessment Schedule.	0938–1140	15,471	(311)	(4,812,802)	0.85	(4,090,882)	Varies	(275,147,890)

VIII. Economic Analyses

A. Regulatory Impact Analysis

1. Statement of Need

This final rule will update the FY 2018 SNF prospective payment rates as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each FY, the unadjusted federal per diem rates, the case-mix classification system, and the factors to be applied in making the area wage adjustment. As these statutory provisions prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, we do not have the discretion to adopt an alternative approach on these issues. We did not include the impacts of the proposed PDPM and related policies in the sections that follow, as we have included this discussion in section V.I. of this final rule.

2. Introduction

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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an economically significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis (RIA) as further discussed below. Also, the rule has been reviewed by OMB.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. OMB's implementation guidance, issued on April 5, 2017, explains that ''Federal spending regulatory actions that cause only income transfers between taxpayers and program beneficiaries (for example, regulations associated with . . . Medicare spending) are considered 'transfer rules' and are not covered by E.O. 13771. . . . However . . . such regulatory actions may impose requirements apart from transfers . . . In those cases, the actions would need to be offset to the extent they impose more than de minimis costs. Examples of ancillary requirements that may require offsets include new reporting or recordkeeping requirements.'' As discussed in section VII. of this final rule, we estimate that this final rule will lead to paperwork cost savings of approximately $196 million per year, or $171 million per year on an ongoing basis discounted at 7 percent relative to year 2016, over a perpetual time horizon. This final rule is considered an E.O. 13771 deregulatory action.

3. Overall Impacts

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2018 (82 FR 36530). We estimate that the aggregate impact will be an increase of approximately $820 million in payments to SNFs in FY 2019, resulting from the SNF market basket update to the payment rates, as required by section 53111 of the BBA 2018. Absent the application of section 53111 of the BBA 2018, as discussed in section III.A.2. of this final rule, the aggregate impact from the 2.0 percentage point market basket increase factor would have been approximately $680 million. We note that these impact numbers do not incorporate the SNF VBP reductions that we estimate will total $527.4 million for FY 2019.

We would note that events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented, and thus, very susceptible to forecasting errors due to events that may occur within the assessed impact time period. In accordance with sections 1888(e)(4)(E) and 1888(e)(5) of the Act, we update the FY 2018 payment rates by a factor equal to the market basket index percentage change adjusted by the MFP adjustment to determine the payment rates for FY 2019. As discussed previously, section 53111 of the BBA 2018 stipulates a market basket increase factor of 2.4 percent. The impact to Medicare is included in the total column of Table 45. In updating the SNF PPS rates for FY 2019, we made a number of standard annual revisions and clarifications

mentioned elsewhere in this final rule (for example, the update to the wage and market basket indexes used for adjusting the federal rates).

The annual update set forth in this final rule applies to SNF PPS payments in FY 2019. Accordingly, the analysis of the impact of the annual update that follows only describes the impact of this single year. Furthermore, in accordance with the requirements of the Act, we will publish a rule or notice for each subsequent FY that will provide for an update to the payment rates and include an associated impact analysis.

4. Detailed Economic Analysis

The FY 2019 SNF PPS payment impacts appear in Table 45. Using the most recently available data, in this case FY 2017, we apply the current FY 2018 wage index and labor-related share value to the number of payment days to simulate FY 2018 payments. Then, using the same FY 2017 data, we apply the proposed FY 2019 wage index and labor-related share value to simulate FY 2019 payments. We tabulate the resulting payments according to the classifications in Table 45 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2018 payments to the simulated FY 2019 payments to determine the overall impact. The breakdown of the various categories of data Table 45 follows:

- The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, census region, and ownership.
- The first row of figures describes the estimated effects of the various changes on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next nineteen rows show the effects on facilities by urban versus rural status by census region. The last three rows show the effects on facilities by ownership (that is, government, profit, and non-profit status).
- The second column shows the number of facilities in the impact database.
- The third column shows the effect of the annual update to the wage index. This represents the effect of using the most recent wage data available. The total impact of this change is 0 percent; however, there are distributional effects of the change.
- The fourth column shows the effect of all of the changes on the FY 2019 payments. The update of 2.4 percent is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments will increase by 2.4 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 45, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes in this rule, providers in the urban Pacific region will experience a 3.4 percent increase in FY 2019 total payments.

TABLE 45—IMPACT TO THE SNF PPS FOR FY 2019

	Number of facilities FY 2019 (%)	Update wage data (%)	Total change (%)
Group:			
Total	15,471	0.0	2.4
Urban	11,042	0.0	2.4
Rural	4,429	0.1	2.5
Hospital-based urban	498	0.0	2.4
Freestanding urban	10,544	0.0	2.4
Hospital-based rural	555	0.0	2.4
Freestanding rural	3,874	0.2	2.6
Urban by region:			
New England	790	−0.7	1.7
Middle Atlantic	1,481	0.0	2.4
South Atlantic	1,869	−0.1	2.3
East North Central	2,127	−0.4	2.0
East South Central	555	−0.2	2.2
West North Central	920	−0.4	2.0
West South Central	1,346	0.3	2.7
Mountain	527	−0.8	1.6
Pacific	1,421	1.0	3.4
Outlying	6	−0.5	1.9
Rural by region:			
New England	134	−0.7	1.6
Middle Atlantic	215	0.1	2.5
South Atlantic	494	0.1	2.5
East North Central	931	0.1	2.5
East South Central	523	−0.3	2.1
West North Central	1,074	0.3	2.7
West South Central	734	1.0	3.5
Mountain	229	0.2	2.6
Pacific	95	−0.5	1.9
Ownership:			
Government	10,887	0.0	2.4
Profit	3,570	−0.1	2.3
Non-Profit	1,014	0.0	2.4

Note: The Total column includes the 2.4 percent market basket increase required by section 53111 of the BBA 2018. Additionally, we found no SNFs in rural outlying areas.

5. Impacts for the SNF QRP

We did not propose to add, remove, or revise any measures in the SNF QRP. Consequently, this final rule does not set out any new QRP-related impacts associated with the SNF QRP.

6. Impacts for the SNF VBP Program

In Table 44 of the FY 2019 SNF PPS proposed rule (83 FR 21096 through 20197), we estimated the impacts of the FY 2019 SNF VBP Program without taking into account our low-volume scoring adjustment proposal. We modeled SNFs' performance in the Program using SNFRM data from CY 2014 as the baseline period and FY 2016 as the performance period. Additionally, we modeled a logistic exchange function with a payback percentage of 60 percent, as we finalized in the FY 2018 SNF PPS final rule (82 FR 36619 through 36621), and based the following analyses on payments to SNFs in FY 2016. We estimated the total reductions to payments required by section 1888(h)(6) of the Act, to be $527.4 million for FY 2019. Based on the 60 percent payback percentage, we estimated that we would disburse approximately $316.4 million in value-based incentive payments to SNFs in FY 2019, which we estimated would result in approximately $211 million in savings to the Medicare program in FY 2019.

In Table 45 of the FY 2019 SNF PPS proposed rule (83 FR 21097), we also modeled the estimated impacts of the FY 2019 SNF VBP Program and included in that model the impacts of our proposed scoring adjustment for low-volume SNFs. We estimated that the scoring adjustment policy proposal would redistribute an additional $6.7 million to the group of low volume SNFs. As we discuss further in section II.E.3.e. of this final rule, we are finalizing our low-volume scoring adjustment policy, and our estimated FY 2019 SNF VBP impacts, which we described in Table 45 of the proposed rule, are reproduced as Table 46 below.

We continue to estimate that this policy will result in increasing low-volume SNFs' value-based incentive payment percentages by approximately 0.99 percent, on average, from the value-based incentive payment percentage that they would receive in the absence of the low-volume adjustment. An increase in value-based incentive payment percentages by 0.99 percent is needed to bring low-volume SNFs back to the 2.0 percent that was withheld from their payments. We also continue to estimate that we will pay an additional $6.7 million in incentive payments to low-volume SNFs, which would increase the 60 percent payback percentage for FY 2019 by approximately 1.28 percent, making the new payback percentage for FY 2019 equal to 61.28 percent of the estimated $527.4 million in withheld funds for that fiscal year.

Our detailed analysis of the impacts of the FY 2019 SNF VBP Program, including the finalized low-volume scoring adjustment policy, follows in Table 46.

TABLE 46—ESTIMATED SNF VBP PROGRAM IMPACTS INCLUDING EFFECTS OF THE FINALIZED LOW-VOLUME SCORING ADJUSTMENT

Category	Criterion	Number of facilities	RSRR (mean)	Mean SNF performance score	Mean incentive multiplier (60% payback)	Percent of proposed payback
Group	Total	12,845	0.18912	41.371	1.192	99.9*
	Urban	9,604	0.18957	40.956	1.177	84.4
	Rural	3,241	0.18779	41.011	1.181	15.4
Urban by Region	Total	9,604				
	01=Boston	713	0.19089	37.26777	1.059	4.9
	02=New York	836	0.19029	40.90383	1.165	11.8
	03=Philadelphia	1,040	0.18601	45.31896	1.325	10.1
	04=Atlanta	1,767	0.19332	37.28735	1.052	13.3
	05=Chicago	1,961	0.18784	43.06368	1.246	16.0
	06=Dallas	1,134	0.19416	34.53275	0.949	6.1
	07=Kansas City	510	0.19057	39.26278	1.132	2.6
	08=Denver	241	0.17832	57.62596	1.790	2.9
	09=San Francisco	1,098	0.18908	40.80722	1.176	12.5
	10=Seattle	304	0.17808	56.67839	1.713	4.2
Rural by Region	Total	3,241				
	01=Boston	115	0.18133	51.89294	1.568	0.9
	02=New York	77	0.18366	50.48193	1.569	0.5
	03=Philadelphia	240	0.18789	42.12621	1.218	1.3
	04=Atlanta	764	0.19283	36.51452	1.032	3.3
	05=Chicago	818	0.18397	47.85089	1.399	4.5
	06=Dallas	557	0.19355	34.00868	0.952	1.7
	07=Kansas City	421	0.18634	42.64769	1.236	1.2
	08=Denver	132	0.18000	52.38900	1.544	0.7
	09=San Francisco	48	0.17780	61.50419	1.931	0.6
	10=Seattle	69	0.17628	60.70084	1.836	0.7
Ownership Type	Total	12,847				
	Government	688	0.18529	46.450	1.380	5.2
	Profit	9,250	0.19039	39.526	1.127	72.0
	Non-Profit	2,909	0.18597	46.038	1.353	22.9
Number of Beds	Total	12,847				
	1st Quartile:	3,222	0.18760	42.466	1.226	24.6
	2nd Quartile:	3,221	0.18878	40.971	1.175	24.4
	3rd Quartile:	3,197	0.19048	40.242	1.153	23.3
	4th Quartile:	3,207	0.18963	41.800	1.212	27.7

*This category does not add to 100% because a small number of SNFs did not have urban/rural designations in our data.

7. Alternatives Considered

As described in this section, we estimated that the aggregate impact for FY 2019 under the SNF PPS will be an increase of approximately $820 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, as required by section 53111 of the BBA 2018. Absent application of section 53111 of the BBA 2018, as discussed in section III.A.2. of this final rule, the market basket increase factor of 2.0 percent would have resulted in an aggregate increase in payments to SNFs of approximately $680 million.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating base payment rates under the SNF PPS, and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register**, and to do so before the August 1 that precedes the start of the new FY; accordingly, we are not pursuing alternatives for this process.

As discussed in section VI.C. of this final rule, we also considered an alternative SNF VBP low-volume scoring policy. This alternative scoring assignment would result in a value-based incentive payment percentage of 1.2 percent, or 60 percent of the 2 percent withhold. This amount would match low-volume SNFs' incentive payment percentages with the finalized SNF VBP Program payback percentage of 60 percent, and would represent a smaller adjustment to low-volume SNFs' incentive payment percentages than the proposed policy described above. We estimated that this alternative would redistribute an additional $1 million with respect to FY 2019 services to low-volume SNFs. We also estimated that this alternative would increase the 60 percent payback percentage for FY 2019 by approximately 0.18 percent of the approximately $527.4 million of the total withheld from SNFs' payments, which would result in a payback percentage of 60.18 percent of the estimated $527.4 million in withheld funds for that Program year. We estimated that this alternative would pay back SNFs about $5.7 million less than the proposed low-volume scoring methodology adjustment in total estimated payments on an annual basis. However, under this alternative, like the policy we are finalizing, the specific amount by which the payback percentage would increase for each Program year would vary based on the number of low-volume SNFs that we identify for each Program year and the distribution of all SNFs' performance scores for that Program year.

We discussed the comments that we received on this alternative and our responses to those comments in section II.E.3.e. of this final rule in our discussion of the low-volume scoring adjustment policy.

8. Accounting Statement

As required by OMB Circular A–4 (available online at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Tables 48 and 49, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule for FY 2019. Tables 45 and 48 provides our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this final rule, based on the data for 15,471 SNFs in our database. Tables 46 and 49 provide our best estimate of the possible changes in Medicare payments under the SNF VBP as a result of the policies in this final rule.

TABLE 47—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2018 SNF PPS FISCAL YEAR TO THE 2019 SNF PPS FISCAL YEAR

Category	Transfers
Annualized Monetized Transfers	$820 million.*
From Whom To Whom?	Federal Government to SNF Medicare Providers.

*The net increase of $820 million in transfer payments is a result of the market basket increase of $820 million.

TABLE 48—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR THE FY 2019 SNF VBP PROGRAM

Category	Transfers
Annualized Monetized Transfers	$316.4 million.*
From Whom To Whom?	Federal Government to SNF Medicare Providers.

*This estimate does not include the two percent reduction to SNFs' Medicare payments (estimated to be $527.4 million) required by statute.

9. Conclusion

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2018 (82 FR 36530). Based on the above, we estimate the overall estimated payments for SNFs in FY 2019 are projected to increase by approximately $820 million, or 2.4 percent, compared with those in FY 2018. We estimate that in FY 2019 under RUG–IV, SNFs in urban and rural areas will experience, on average, a 2.4 percent increase and 2.5 percent increase, respectively, in estimated payments compared with FY 2018. Providers in the urban rural West South Central region will experience the largest estimated increase in payments of approximately 3.5 percent. Providers in the urban Mountain and rural New England regions will experience the smallest estimated increase in payments of 1.6 percent.

B. Regulatory Flexibility Act Analysis

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, non-

profit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers are small entities, either by reason of their non-profit status or by having revenues of $27.5 million or less in any 1 year. We utilized the revenues of individual SNF providers (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, for the purposes of the RFA, we estimate that almost all SNFs are small entities as that term is used in the RFA, according to the Small Business Administration's latest size standards (NAICS 623110), with total revenues of $27.5 million or less in any 1 year. (For details, see the Small Business Administration's website at *http://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards*). In addition, approximately 20 percent of SNFs classified as small entities are non-profit organizations. Finally, individuals and states are not included in the definition of a small entity.

This final rule sets forth updates of the SNF PPS rates contained in the SNF PPS final rule for FY 2018 (82 FR 36530). Based on the above, we estimate that the aggregate impact for FY 2019 will be an increase of $820 million in payments to SNFs, resulting from the SNF market basket update to the payment rates. While it is projected in Table 45 that providers will experience a net increase in payments, we note that some individual providers within the same region or group may experience different impacts on payments than others due to the distributional impact of the FY 2019 wage indexes and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings, utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. In their March 2017 Report to Congress (available at *http://medpac.gov/docs/default-source/reports/mar17_medpac_ch8.pdf*), MedPAC states that Medicare covers approximately 11 percent of total patient days in freestanding facilities and 21 percent of facility revenue (March 2017 MedPAC Report to Congress, 202). As a result, for most facilities, when all payers are included in the revenue stream, the overall impact on total revenues should be substantially less than those impacts presented in Table 45. As indicated in Table 45, the effect on facilities is projected to be an aggregate positive impact of 2.4 percent for FY 2019. As the overall impact on the industry as a whole, and thus on small entities specifically, is less than the 3 to 5 percent threshold discussed previously, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small entities for FY 2019.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. This final rule will affect small rural hospitals that (1) furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals will be similar to the impact on SNF providers overall. Moreover, as noted in previous SNF PPS final rules (most recently, the one for FY 2018 (82 FR 36530)), the category of small rural hospitals is included within the analysis of the impact of this final rule on small entities in general. As indicated in Table 45, the effect on facilities for FY 2019 is projected to be an aggregate positive impact of 2.4 percent. As the overall impact on the industry as a whole is less than the 3 to 5 percent threshold discussed above, the Secretary has determined that this final rule will not have a significant impact on a substantial number of small rural hospitals for FY 2019.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 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 2018, that threshold is approximately $150 million. This final rule will impose no mandates on state, local, or tribal governments or on the private sector.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This final rule will have no substantial direct effect on state and local governments, preempt state law, or otherwise have federalism implications.

E. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

F. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last 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 thought that the number of past commenters is a fair estimate of the number of reviewers of this rule. In the FY 2019 SNF PPS proposed rule (83 FR 21099), we welcomed any comments on the approach in estimating the number of entities which will review the proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption in the FY 2019 SNF PPS proposed rule (83 FR 21099).

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 4 hours for the staff to review half of the proposed rule. For each SNF that reviews the rule, the estimated cost is $429.52 (4 hours × $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $124,561 ($429.52 × 247 reviewers).

In accordance with the provisions of Executive Order 12866, this final rule

was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 413

Health facilities, Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, 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 chapter IV as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

§ 411.15 [Amended]

■ 2. Section 411.15 is amended in paragraph (p)(3)(iv) by removing the phrase ''by midnight of the day of departure'' and adding in its place the phrase ''before the following midnight''.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 3. The authority citation for part 413 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww; and sec. 124 of Public Law 106–113, 113 Stat. 1501A–332; sec. 3201 of Public Law 112–96, 126 Stat. 156; sec. 632 of Public Law 112–240, 126 Stat. 2354; sec. 217 of Public Law 113–93, 129 Stat. 1040; and sec. 204 of Public Law 113–295, 128 Stat. 4010; and sec. 808 of Public Law 114–27, 129 Stat. 362.

■ 4. Section 413.337 is amended by revising paragraph (d)(1)(v) and adding paragraphs (d)(1)(vi) and (vii) and (f) to read as follows:

§ 413.337 Methodology for calculating the prospective payment rates.

* * * * *

(d) * * *

(1) * * *

(v) For each subsequent fiscal year, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a factor equal to the SNF market basket index percentage change for the fiscal year involved, except as provided in paragraphs (d)(1)(vi) and (vii) of this section.

(vi) For fiscal year 2018, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a SNF market basket index percentage change of 1 percent (after application of paragraphs (d)(2) and (3) of this section).

(vii) For fiscal year 2019, the unadjusted Federal payment rate is equal to the rate computed for the previous fiscal year increased by a SNF market basket index percentage change of 2.4 percent (after application of paragraphs (d)(2) and (3) of this section).

* * * * *

(f) *Adjustments to payment rates under the SNF Value-Based Purchasing Program.* Beginning with payment for services furnished on October 1, 2018, the adjusted Federal per diem rate (as defined in § 413.338(a)(2)) otherwise applicable to a SNF for the fiscal year is reduced by the applicable percent (as defined in § 413.338(a)(3)). The resulting amount is then adjusted by the value-based incentive payment amount (as defined in § 413.338(a)(14)) based on the SNF's performance score for that fiscal year under the SNF Value-Based Purchasing Program, as calculated under § 413.338.

■ 5. Section 413.338 is amended by—

■ a. Revising the section heading;

■ b. Adding paragraphs (a)(16) and (17);

■ c. Revising paragraph (c)(2)(i); and

■ d. Adding paragraphs (d)(1)(iv) and (d)(3) and (4).

The additions and revision read as follows:

§ 413.338 Skilled nursing facility value-based purchasing program.

(a) * * *

(16) *Low-volume SNF* means a SNF with fewer than 25 eligible stays included in the SNF readmission measure denominator during the performance period for a fiscal year.

(17) *Eligible stay* means, for purposes of the SNF readmission measure, an index SNF admission that would be included in the denominator of that measure.

* * * * *

(c) * * *

(2) * * *

(i) *Total amount available for a fiscal year.* The total amount available for value-based incentive payments for a fiscal year is at least 60 percent of the total amount of the reduction to the adjusted SNF PPS payments for that fiscal year, as estimated by CMS, and will be increased as appropriate for each fiscal year to account for the assignment of a performance score to low-volume SNFs under paragraph (d)(3) of this section.

(d) * * *

(1) * * *

(iv) CMS will not award points for improvement to a SNF that has fewer than 25 eligible stays during the baseline period.

* * * * *

(3) If CMS determines that a SNF is a low-volume SNF with respect to a fiscal year, CMS will assign a performance score to the SNF for the fiscal year that, when used to calculate the value-based incentive payment amount (as defined in paragraph (a)(14) of this section), results in a value-based incentive payment amount that is equal to the adjusted Federal per diem rate (as defined in paragraph (a)(2) of this section) that would apply to the SNF for the fiscal year without application of § 413.337(f).

(4)(i) A SNF may request and CMS may grant exceptions to the SNF Value-Based Purchasing Program's requirements under this section for one or more calendar months when there are certain extraordinary circumstances beyond the control of the SNF.

(ii) A SNF may request an exception within 90 days of the date that the extraordinary circumstances occurred by sending an email to *SNFVBPinquiries@cms.hhs.gov* that includes a completed Extraordinary Circumstances Request form (available on the SNF VBP section of QualityNet at *https://www.qualitynet.org/*) and any available evidence of the impact of the extraordinary circumstances on the care that the SNF furnished to patients, including, but not limited to, photographs, newspaper, and other media articles.

(iii) Except as provided in paragraph (d)(4)(iv) of this section, CMS will not consider an exception request unless the SNF requesting such exception has complied fully with the requirements in this paragraph (d).

(iv) CMS may grant exceptions to SNFs without a request if it determines that an extraordinary circumstance affects an entire region or locale.

(v) CMS will calculate a SNF performance score for a fiscal year for a SNF for which it has granted an exception request that does not include its performance on the SNF readmission

measure during the calendar months affected by the extraordinary circumstance.

* * * * *

■ 6. Section 413.360 is amended by adding paragraph (b)(3) and revising paragraphs (d)(1) and (4) to read as follows:

§ 413.360 Requirements under the Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

* * * * *

(b) * * *

(3) CMS may remove a quality measure from the SNF QRP based on one or more of the following factors:

(i) Measure performance among SNFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

(ii) Performance or improvement on a measure does not result in better resident outcomes.

(iii) A measure does not align with current clinical guidelines or practice.

(iv) The availability of a more broadly applicable (across settings, populations, or conditions) measure for the particular topic.

(v) The availability of a measure that is more proximal in time to desired resident outcomes for the particular topic.

(vi) The availability of a measure that is more strongly associated with desired resident outcomes for the particular topic.

(vii) Collection or public reporting of a measure leads to negative unintended consequences other than resident harm.

(viii) The costs associated with a measure outweigh the benefit of its continued use in the program.

* * * * *

(d) * * *

(1) SNFs that do not meet the requirements in paragraph (b) of this section for a program year will receive a written notification of non-compliance through at least one of the following methods: Quality Improvement Evaluation System (QIES) Assessment Submission and Processing (ASAP) system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC). A SNF may request reconsideration no later than 30 calendar days after the date identified on the letter of non-compliance.

* * * * *

(4) CMS will notify SNFs, in writing, of its final decision regarding any reconsideration request through at least one of the following notification methods: QIES ASAP system, the United States Postal Service, or via email from the Medicare Administrative Contractor (MAC).

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 7. The authority citation for part 424 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 8. Section 424.20 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 424.20 Requirements for posthospital SNF care.

* * * * *

(a) * * *

(1) * * *

(i) The individual needs or needed on a daily basis skilled nursing care (furnished directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in an SNF or a swing-bed hospital on an inpatient basis, and the SNF care is or was needed for a condition for which the individual received inpatient care in a participating hospital or a qualified hospital, as defined in § 409.3 of this chapter, or for a new condition that arose while the individual was receiving care in the SNF or swing-bed hospital for a condition for which he or she received inpatient care in a participating or qualified hospital; or.

* * * * *

Dated: July 26, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: July 26, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–16570 Filed 7–31–18; 4:15 pm]

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Part III

Department of the Treasury

Internal Revenue Service

26 CFR Part 1
Additional First Year Depreciation Deduction; Proposed Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–104397–18]

RIN 1545–BO74

Additional First Year Depreciation Deduction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that provide guidance regarding the additional first year depreciation deduction under section 168(k) of the Internal Revenue Code (Code). These proposed regulations reflect changes made by the Tax Cuts and Jobs Act. These proposed regulations affect taxpayers who deduct depreciation for qualified property acquired and placed in service after September 27, 2017.

DATES: Written or electronic comments and requests for a public hearing must be received by October 9, 2018.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–104397–18), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–104397–18), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–104397–18).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Elizabeth R. Binder, (202) 317–7005; concerning submissions of comments or requests for a public hearing, Regina L. Johnson, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains proposed amendments to 26 CFR part 1 under section 168(k). Section 168(k) was added to the Code by section 101 of the Job Creation and Worker Assistance Act of 2002, Public Law 107–147 (116 Stat. 21). Section 168(k) allows an additional first year depreciation deduction in the placed-in-service year of qualified property. Subsequent amendments to section 168(k) increased the percentage of the additional first year depreciation deduction from 30 percent to 50 percent (to 100 percent for property acquired and placed in service after September 8, 2010, and generally before January 1, 2012), extended the placed-in-service date generally through December 31, 2019, and made other changes. See section 201 of the Jobs and Growth Tax Relief Reconciliation Act of 2003, Public Law 108–27 (117 Stat. 752), sections 403 and 408 of the Working Families Tax Relief Act of 2004, Public Law 108–311 (118 Stat. 1166), sections 336 and 337 of the American Jobs Creation Act of 2004, Public Law 108–357 (118 Stat. 1418), sections 403 and 405 of the Gulf Opportunity Zone Act of 2005, Public Law 109–135 (119 Stat. 2577), section 103 of the Economic Stimulus Act of 2008, Public Law 110–185 (122 Stat. 613), section 3081 of the Housing Assistance Tax Act of 2008, Public Law 110–289 (122 Stat. 2654), section 1201 of the American Recovery and Reinvestment Tax Act of 2009, Public Law 111–5 (123 Stat. 115), section 2022 of the Small Business Jobs Act of 2010, Public Law 111–240 (124 Stat. 2504), section 401 of the Tax Relief, Unemployment Insurance Reauthorization, and Job Creation Act of 2010, Public Law 111–312 (124 Stat. 3296), section 331 of the American Taxpayer Relief Act of 2012, Public Law 112–240 (126 Stat. 2313), sections 125, 202, 210, 212, and 214 of the Tax Increase Prevention Act of 2014, Public Law 113–295 (128 Stat. 4010), and section 143 of the Protecting Americans from Tax Hikes Act of 2015, enacted as Division Q of the Consolidated Appropriations Act, 2016, Public Law 114–113 (129 Stat. 2242).

On December 22, 2017, section 168(k) and related provisions were amended by sections 12001(b)(13), 13201, and 13204 of the Tax Cuts and Jobs Act, Public Law 115–97 (131 Stat. 2054) (the ''Act'') to provide further changes to the additional first year depreciation deduction. Unless otherwise indicated, all references to section 168(k) hereinafter are references to section 168(k) as amended.

Section 167(a) allows as a depreciation deduction a reasonable allowance for the exhaustion, wear and tear, and obsolescence of property used in a trade or business or of property held for the production of income. The depreciation deduction allowable for tangible depreciable property placed in service after 1986 generally is determined under the Modified Accelerated Cost Recovery System provided by section 168 (MACRS property). The depreciation deduction allowable for computer software that is placed in service after August 10, 1993, and is not an amortizable section 197 intangible, is determined under section 167(f)(1).

Section 168(k), prior to amendment by the Act, allowed an additional first year depreciation deduction for the placed-in-service year equal to 50 percent of the adjusted basis of qualified property. Qualified property was defined in part as property the original use of which begins with the taxpayer.

Section 13201 of the Act made several amendments to the allowance for additional first year depreciation deduction in section 168(k). For example, the additional first year depreciation deduction percentage is increased from 50 to 100 percent; the property eligible for the additional first year depreciation deduction is expanded to include certain used depreciable property and certain film, television, or live theatrical productions; the placed-in-service date is extended from before January 1, 2020, to before January 1, 2027 (from before January 1, 2021, to before January 1, 2028, for longer production period property or certain aircraft property described in section 168(k)(2)(B) or (C)); and the date on which a specified plant is planted or grafted by the taxpayer is extended from before January 1, 2020, to before January 1, 2027.

Section 168(k) allows a 100-percent additional first year depreciation deduction for qualified property acquired and placed in service after September 27, 2017, and placed in service before January 1, 2023 (before January 1, 2024, for longer production period property or certain aircraft property described in section 168(k)(2)(B) or (C)). If a taxpayer elects to apply section 168(k)(5), the 100-percent additional first year depreciation deduction also is allowed for a specified plant planted or grafted after September 27, 2017, and before January 1, 2023. The 100-percent additional first year depreciation deduction is decreased by 20 percent annually for qualified property placed in service, or a specified plant planted or grafted, after December 31, 2022 (after December 31, 2023, for longer production period property or certain aircraft property described in section 168(k)(2)(B) or (C)).

Section 168(k)(2)(A), as amended by the Act, defines ''qualified property'' as meaning, in general, property (1) to which section 168 applies that has a recovery period of 20 years or less, which is computer software as defined in section 167(f)(1)(B) for which a deduction is allowable under section 167(a) without regard to section 168(k), which is water utility property, which is

a qualified film or television production as defined in section 181(d) for which a deduction would have been allowable without regard to section 181(a)(2) or (g) or section 168(k), or which is a qualified live theatrical production as defined in section 181(e) for which a deduction would have been allowable without regard to section 181(a)(2) or (g) or section 168(k); (2) the original use of which begins with the taxpayer or the acquisition of which by the taxpayer meets the requirements of section 168(k)(2)(E)(ii); and (3) which is placed in service by the taxpayer before January 1, 2027. Section 168(k)(2)(E)(ii) requires that the acquired property was not used by the taxpayer at any time prior to such acquisition and the acquisition of such property meets the requirements of section 179(d)(2)(A), (B), and (C) and section 179(d)(3).

However, section 168(k)(2)(D) provides that qualified property does not include any property to which the alternative depreciation system under section 168(g) applies, determined without regard to section 168(g)(7) (relating to election to have the alternative depreciation system apply), and after application of section 280F(b) (relating to listed property with limited business use).

Section 13201(h) of the Act provides the effective dates of the amendments to section 168(k) made by section 13201 of the Act. Except as provided in section 13201(h)(2) of the Act, section 13201(h)(1) of the Act provides that these amendments apply to property acquired and placed in service after September 27, 2017. However, property is not treated as acquired after the date on which a written binding contract is entered into for such acquisition. Section 13201(h)(2) provides that the amendments apply to specified plants planted or grafted after September 27, 2017.

Additionally, section 12001(b)(13) of the Act repealed section 168(k)(4) (relating to the election to accelerate alternative minimum tax credits in lieu of the additional first year depreciation deduction) for taxable years beginning after December 31, 2017. Further, section 13204(a)(4)(B)(ii) repealed section 168(k)(3) (relating to qualified improvement property) for property placed in service after December 31, 2017.

Explanation of Provisions

The proposed regulations describe and clarify the statutory requirements that must be met for depreciable property to qualify for the additional first year depreciation deduction provided by section 168(k). Further, the proposed regulations instruct taxpayers how to determine the additional first year depreciation deduction and the amount of depreciation otherwise allowable for this property. Because the Act made substantial amendments to section 168(k), the proposed regulations update existing regulations in § 1.168(k)–1 by providing a new section at § 1.168(k)–2 for property acquired and placed in service after September 27, 2017, and make conforming amendments to the existing regulations.

1. Eligibility Requirements for Additional First Year Depreciation Deduction

The proposed regulations follow section 168(k)(2), as amended by the Act, and section 13201(h) of the Act to provide that depreciable property must meet four requirements to be qualified property. These requirements are (1) the depreciable property must be of a specified type; (2) the original use of the depreciable property must commence with the taxpayer or used depreciable property must meet the acquisition requirements of section 168(k)(2)(E)(ii); (3) the depreciable property must be placed in service by the taxpayer within a specified time period or must be planted or grafted by the taxpayer before a specified date; and (4) the depreciable property must be acquired by the taxpayer after September 27, 2017.

2. Property of a Specified Type

A. Property Eligible for the Additional First Year Depreciation Deduction

The proposed regulations follow the definition of qualified property in section 168(k)(2)(A)(i) and (k)(5) and provide that qualified property must be one of the following: (1) MACRS property that has a recovery period of 20 years or less; (2) computer software as defined in, and depreciated under, section 167(f)(1); (3) water utility property as defined in section 168(e)(5) and depreciated under section 168; (4) a qualified film or television production as defined in section 181(d) and for which a deduction would have been allowable under section 181 without regard to section 181(a)(2) and (g) or section 168(k); (5) a qualified live theatrical production as defined in section 181(e) and for which a deduction would have been allowable under section 181 without regard to section 181(a)(2) and (g) or section 168(k); or (6) a specified plant as defined in section 168(k)(5)(B) and for which the taxpayer has made an election to apply section 168(k)(5). Qualified improvement property acquired after September 27, 2017, and placed in service after September 27, 2017, and before January 1, 2018, also is qualified property.

For property placed in service after December 31, 2017, section 13204 of the Act amended section 168(e) to eliminate the 15-year MACRS property classification for qualified leasehold improvement property, qualified restaurant property, and qualified retail improvement property, and amended section 168(k) to eliminate qualified improvement property as a specific category of qualified property. Because of the effective date of section 13204 of the Act (property placed in service after December 31, 2017), the proposed regulations provide that MACRS property with a recovery period of 20 years or less includes the following MACRS property that is acquired by the taxpayer after September 27, 2017, and placed in service by the taxpayer after September 27, 2017, and before January 1, 2018: (1) Qualified leasehold improvement property; (2) qualified restaurant property that is qualified improvement property; and (3) qualified retail improvement property. For the same reason, the proposed regulations provide that qualified property includes qualified improvement property that is acquired by the taxpayer after September 27, 2017, and placed in service by the taxpayer after September 27, 2017, and before January 1, 2018. Further, to account for the statutory amendments to the definition of qualified improvement property made by the Act, the proposed regulations define qualified improvement property for purposes of section 168(k)(3) (before amendment by section 13204 of the Act) and section 168(e)(6) (as amended by section 13204 of the Act).

For purposes of determining the eligibility of MACRS property as qualified property, the proposed regulations retain the rule in § 1.168(k)–1(b)(2)(i)(A) that the recovery period applicable for the MACRS property under section 168(c) of the general depreciation system (GDS) is used, regardless of any election made by the taxpayer to depreciate the class of property under the alternative depreciation system of section 168(g) (ADS).

B. Property Not Eligible for the Additional First Year Depreciation Deduction

The proposed regulations provide that qualified property does not include (1) property excluded from the application of section 168 as a result of section 168(f); (2) property that is required to be depreciated under the ADS (as described below); (3) any class of

property for which the taxpayer elects not to deduct the additional first year depreciation under section 168(k)(7); (4) a specified plant placed in service by the taxpayer in the taxable year and for which the taxpayer made an election to apply section 168(k)(5) for a prior year under section 168(k)(5)(D); (5) any class of property for which the taxpayer elects to apply section 168(k)(4) (this exclusion applies to property placed in service in any taxable year beginning before January 1, 2018, because section 12001(b)(13) of the Act repealed section 168(k)(4) for taxable years beginning after December 31, 2017); or (6) property described in section 168(k)(9)(A) or (B). Section 168(k)(9) provides that qualified property does not include (A) any property that is primarily used in a trade or business described in section 163(j)(7)(A)(iv), or (B) any property used in a trade or business that has had floor plan financing indebtedness (as defined in section 163(j)(9)) if the floor plan financing interest related to such indebtedness was taken into account under section 163(j)(1)(C). Section 163(j) applies to taxable years beginning after December 31, 2017. Accordingly, the exclusion of property described in section 168(k)(9) from the additional first year depreciation deduction applies to property placed in service in any taxable year beginning after December 31, 2017.

Property is required to be depreciated under the ADS if the property is described under section 168(g)(1)(A), (B), (C), (D), (F), or (G) or if other provisions of the Code require depreciation for the property to be determined under the ADS. Accordingly, MACRS property that is nonresidential real property, residential rental property, and qualified improvement property held by an electing real property trade or business (as defined in section 163(j)(7)(B)), and property with a recovery period of 10 years or more that is held by an electing farming business (as defined in section 163(j)(7)(C)), are not eligible for the additional first year depreciation deduction for taxable years beginning after December 31, 2017. Pursuant to section 168(k)(2)(D), MACRS property for which the taxpayer makes an election under section 168(g)(7) to depreciate the property under the ADS is eligible for the additional first year depreciation deduction (assuming all other requirements are met).

C. Elections

The proposed regulations provide rules for making the election out of the additional first year depreciation deduction pursuant to section 168(k)(7) and for making the election to apply section 168(k)(5) to a specified plant. Additionally, the proposed regulations provide rules for making the election under section 168(k)(10) to deduct 50 percent, instead of 100 percent, additional first year depreciation for qualified property acquired after September 27, 2017, by the taxpayer and placed in service or planted or grafted, as applicable, by the taxpayer during its taxable year that includes September 28, 2017. Because section 168(k)(10) does not state that the election may be made ''with respect to any class of property'' as stated in section 168(k)(7) for making the election out of the additional first year depreciation deduction, the proposed regulations provide that the election under section 168(k)(10) applies to all qualified property.

3. New and Used Property

A. New Property

The proposed regulations generally retain the original use rules in § 1.168(k)–1(b)(3). Pursuant to section 168(k)(2)(A)(ii), the proposed regulations do not provide any date by which the original use of the property must commence with the taxpayer. Because section 13201 of the Act removed the rules regarding sale-leaseback transactions, the proposed regulations also do not retain the original use rules in § 1.168(k)–1(b)(3)(iii)(A) and (C) regarding such transactions, including a sale-leaseback transaction followed by a syndication transaction. The rule in the proposed regulations for syndication transactions involving new or used property is explained later in the preamble.

B. Used Property

Pursuant to section 168(k)(2)(A)(ii) and (k)(2)(E)(ii), the proposed regulations provide that the acquisition of used property is eligible for the additional first year depreciation deduction if such acquisition meets the following requirements: (1) The property was not used by the taxpayer or a predecessor at any time prior to the acquisition; (2) the acquisition of the property meets the related party and carryover basis requirements of section 179(d)(2)(A), (B), and (C) and § 1.179–4(c)(1)(ii), (iii), and (iv), or (c)(2); and (3) the acquisition of the property meets the cost requirements of section 179(d)(3) and § 1.179–4(d).

i. Section 336(e) Election

A section 338 election and a section 336(e) election share many of the same characteristics. Therefore, the proposed regulations modify § 1.179–4(c)(2), which addresses the treatment of a section 338 election, to include property deemed to have been acquired by a new target corporation as a result of a section 336(e) election. Section 1.336–1(a)(1) provides that to the extent not inconsistent with section 336(e) or the regulations under section 336(e), the principles of section 338 and the regulations under section 338 apply for purposes of the regulations under section 336. To the extent that property is deemed to have been acquired by a ''new target corporation,'' the Treasury Department and the IRS read § 1.179–4(c)(2), without modification, as applying to the deemed acquisition of property by a new target corporation as a result of a section 336(e) election, just as it applies as the result of a section 338 election. However, to remove any doubt, the proposed regulations modify § 1.179–4(c)(2) to provide that property deemed to have been acquired by a new target corporation as a result of a section 338 or a section 336(e) election will be considered acquired by purchase for purposes of section 179.

ii. Property Not Previously Used by the Taxpayer

The proposed regulations provide that the property is treated as used by the taxpayer or a predecessor at any time before its acquisition of the property only if the taxpayer or the predecessor had a depreciable interest in the property at any time before the acquisition, whether or not the taxpayer or the predecessor claimed depreciation deductions for the property. If a lessee has a depreciable interest in the improvements made to leased property and subsequently the lessee acquires the leased property of which the improvements are a part, the proposed regulations provide that the unadjusted depreciable basis, as defined in § 1.168(b)–1(a)(3), of the acquired property that is eligible for the additional first year depreciation deduction, assuming all other requirements are met, does not include the unadjusted depreciable basis attributable to the improvements.

Further, if a taxpayer initially acquires a depreciable interest in a portion of the property and subsequently acquires an additional depreciable interest in the same property, the proposed regulations also provide that such additional depreciable interest is not treated as being previously used by the taxpayer. However, if a taxpayer holds a depreciable interest in a portion of the property, sells that portion or a part of that portion, and subsequently acquires a depreciable interest in another portion

of the same property, the proposed regulations provide that the taxpayer will be treated as previously having a depreciable interest in the property up to the amount of the portion for which the taxpayer held a depreciable interest in the property before the sale.

The Treasury Department and the IRS request comments on whether a safe harbor should be provided on how many taxable years a taxpayer or a predecessor should look back to determine if the taxpayer or the predecessor previously had a depreciable interest in the property. Such comments should provide the number of taxable years recommended for the look-back period and the reasoning for such number.

iii. Rules Applying to Consolidated Groups

Members of a consolidated group generally are treated as separate taxpayers. See *Woolford Realty Co.* v. *Rose,* 286 U.S. 319, 328 (1932) (''[a] corporation does not cease to be [a taxpayer] by affiliating with another''). However, the Treasury Department and the IRS believe that the additional first year depreciation deduction should not be permitted to members of a consolidated group when property is disposed of by one member of a consolidated group outside the group and subsequently acquired by another member of the same group because permitting such a deduction would not clearly reflect the group's income tax liability. See section 1502 (permitting consolidated group regulations different from the rules of chapter 1 of subtitle A of the Code otherwise applicable to separate corporations to clearly reflect the income tax liability of a consolidated group or each member of the group). To implement this position, these proposed regulations treat a member of a consolidated group as previously having a depreciable interest in all property in which the consolidated group is treated as previously having a depreciable interest. For purposes of this rule, a consolidated group will be treated as having a depreciable interest in property if any current or previous member of the group had a depreciable interest in the property while a member of the group.

The Treasury Department and the IRS also believe that the additional first year depreciation deduction should not be allowed when, as part of a series of related transactions, one or more members of a consolidated group acquire both the stock of a corporation that previously had a depreciable interest in the property and the property itself. Assume a corporation (the selling corporation) has a depreciable interest in property and sells it to an unrelated party. Subsequently, as part of a series of related transactions, a member of a consolidated group, unrelated to the selling corporation, acquires the property and either that member or a different member of the group acquires the stock of the selling corporation. In substance, the series of transactions is the same as if the selling corporation reacquired the property and then transferred it to another member of the group, in which case the additional first year depreciation deduction would not be allowed. Accordingly, these proposed regulations deny the deduction in such circumstances.

Additionally, if the acquisition of property is part of a series of related transactions that also includes one or more transactions in which the transferee of the property ceases to be a member of a consolidated group, then whether the taxpayer is a member of a consolidated group is tested immediately after the last transaction in the series.

iv. Series of Related Transactions

In determining whether property meets the requirements of section 168(k)(2)(E)(ii), the Treasury Department and the IRS believe that the ordering of steps, or the use of an unrelated intermediary, in a series of related transactions should not control. For example, if a father buys and places equipment in service for use in the father's trade or business and subsequently the father sells the equipment to his daughter for use in her trade or business, the father and daughter are related parties under section 179(d)(2)(A) and § 1.179–4(c)(1)(ii) and therefore, the daughter's acquisition of the equipment is not eligible for the additional first year depreciation deduction. However, if in a series of related transactions, the father sells the equipment to an unrelated party and then the unrelated party sells the equipment to the father's daughter, the daughter's acquisition of the equipment from the unrelated party, absent the rule in the proposed regulations, is eligible for the additional first year depreciation deduction (assuming all other requirements are met). Thus, the proposed regulations provide that in the case of a series of related transactions, the transfer of the property will be treated as directly transferred from the original transferor to the ultimate transferee, and the relation between the original transferor and the ultimate transferee is tested immediately after the last transaction in the series.

C. Application to Partnerships

On September 8, 2003, the Treasury Department and the IRS published temporary regulations (T.D. 9091, 2003–2 C.B. 939) in the **Federal Register** (68 FR 52986) relating to the additional first year depreciation deduction provisions of sections 168(k) and 1400L(b) (before amendment by sections 403 and 408 of the Working Families Tax Relief Act of 2004). Those regulations provided that any increase in the basis of qualified property due to a section 754 election generally is not eligible for the additional first year depreciation deduction. The preamble to those regulations explained that any increase in basis due to a section 754 election does not satisfy the original use requirement. The final regulations (T.D. 9283, 2006–2 C.B. 633, 642–43) published in the **Federal Register** on August 31, 2006 (71 FR 51738) retained the rule for increases in basis due to section 754 elections at § 1.168(k)–1(f)(9). Because the Act amended section 168(k) to allow the additional first year depreciation deduction for certain used property in addition to new property, the Treasury Department and the IRS have reconsidered whether basis adjustments under sections 734(b) and 743(b) now qualify for the additional first year depreciation deduction. The Treasury Department and the IRS also have considered whether certain section 704(c) adjustments as well as the basis of distributed property determined under section 732 should qualify for the additional first year depreciation deduction.

i. Section 704(c) Remedial Allocations

Section 1.704–3(d)(2) provides, in part, that under the remedial allocation method, the portion of a partnership's book basis in contributed property that exceeds its adjusted tax basis is recovered using any recovery period and depreciation (or other cost recovery) method available to the partnership for newly purchased property (of the same type as the contributed property) that is placed in service at the time of contribution. The proposed regulations provide that remedial allocations under section 704(c) do not qualify for the additional first year depreciation deduction under section 168(k).

Notwithstanding the language of § 1.704–3(d)(2) that any method available to the partnership for newly purchased property may be used to recover the portion of the partnership's book basis in contributed property that exceeds its adjusted tax basis, remedial allocations do not meet the requirements of section 168(k)(2)(E)(ii).

Because the underlying property is contributed to the partnership in a section 721 transaction, the partnership's basis in the property is determined by reference to the contributing partner's basis in the property, which violates sections 179(d)(2)(C) and 168(k)(2)(E)(ii)(II). In addition, the partnership has already had a depreciable interest in the contributed property at the time the remedial allocation is made, which is in violation of section 168(k)(2)(E)(ii)(I) as well as the original use requirement.

The same rule applies in the case of revaluations of partnership property (reverse section 704(c) allocations).

ii. Zero Basis Property

Section 1.704–1(b)(2)(iv)(*g*)(*3*) provides that, if partnership property has a zero adjusted tax basis, any reasonable method may be used to determine the book depreciation, depletion, or amortization of the property. The proposed regulations provide that the additional first year depreciation deduction under section 168(k) will not be allowed on property contributed to the partnership with a zero adjusted tax basis because, with the additional first year depreciation deduction, the partners have the potential to shift built-in gain among partners.

iii. Basis Determined Under Section 732

Section 732(a)(1) provides that the basis of property (other than money) distributed by a partnership to a partner other than in liquidation of the partner's interest is its adjusted basis to the partnership immediately before the distribution. Section 732(a)(2) provides that the basis determined under section 732(a)(1) shall not exceed the adjusted basis of the partner's interest in the partnership reduced by any money distributed in the same transaction. Section 732(b) provides that the basis of property (other than money) distributed by a partnership to a partner in liquidation of the partner's interest is equal to the adjusted basis of the partner's interest in the partnership reduced by any money distributed in the same transaction.

Property distributed by a partnership to a partner fails to satisfy the original use requirement because the partnership used the property prior to the distribution. Distributed property also fails to satisfy the acquisition requirements of section 168(k)(2)(E)(ii)(II). Any portion of basis determined by section 732(a)(1) fails to satisfy section 179(d)(2)(C) because it is determined by reference to the partnership's basis in the distributed property. Similarly, any portion of basis determined by section 732(a)(2) or (b) fails to satisfy section 179(d)(3) because it is determined by reference to the distributee partner's basis in its partnership interest (reduced by any money distributed in the same transaction).

iv. Section 734(b) Adjustments

Section 734(b)(1) provides that, in the case of a distribution of property to a partner with respect to which a section 754 election is in effect (or when there is a substantial basis reduction under section 734(d)), the partnership will increase the adjusted basis of partnership property by the sum of (A) the amount of any gain recognized to the distributee partner under section 731(a)(1), and (B) in the case of distributed property to which section 732(a)(2) or (b) applies, the excess of the adjusted basis of the distributed property to the partnership immediately before the distribution (as adjusted by section 732(d)) over the basis of the distributed property to the distributee, as determined under section 732.

Because a section 734(b) basis adjustment is made to the basis of partnership property (*i.e.,* non-partner specific basis) and the partnership used the property prior to the partnership distribution giving rise to the basis adjustment, a section 734(b) basis adjustment fails the original use clause in section 168(k)(2)(A)(ii) and also fails the used property requirement in section 168(k)(2)(E)(ii)(I). The proposed regulations therefore provide that section 734(b) basis adjustments are not eligible for the additional first year depreciation deduction.

v. Section 743(b) Adjustments

Section 743(b)(1) provides that, in the case of a transfer of a partnership interest, either by sale or exchange or as a result of the death of a partner, a partnership that has a section 754 election in effect (or if there is a substantial built-in loss immediately after such partnership interest transfer under section 743(d)), will increase the adjusted basis of partnership property by the excess of the transferee's basis in the transferred partnership interest over the transferee's share of the adjusted basis of partnership's property. This increase is an adjustment to the basis of partnership property with respect to the transferee partner only and, therefore, is a partner specific basis adjustment to partnership property. The section 743(b) basis adjustment is allocated among partnership properties under section 755. As stated above, prior to the Act, a section 743(b) basis adjustment would always fail the original use requirement in section 168(k)(2)(A)(ii) because partnership property to which a section 743(b) basis adjustment relates would have been previously used by the partnership and its partners prior to the transfer that gave rise to the section 743(b) adjustment. After the Act, while a section 743(b) basis adjustment still fails the original use clause in section 168(k)(2)(A)(ii), a transaction giving rise to a section 743(b) basis adjustment may satisfy the used property clause in section 168(k)(2)(A)(ii) because of the used property acquisition requirements of section 168(k)(2)(E)(ii), depending on the facts and circumstances.

Because a section 743(b) basis adjustment is a partner specific basis adjustment to partnership property, the proposed regulations take an aggregate view and provide that, in determining whether a section 743(b) basis adjustment meets the used property acquisition requirements of section 168(k)(2)(E)(ii), each partner is treated as having owned and used the partner's proportionate share of partnership property. In the case of a transfer of a partnership interest, section 168(k)(2)(E)(ii)(I) will be satisfied if the partner acquiring the interest, or a predecessor of such partner, has not used the portion of the partnership property to which the section 743(b) basis adjustment relates at any time prior to the acquisition (that is, the transferee has not used the transferor's portion of partnership property prior to the acquisition), notwithstanding the fact that the partnership itself has previously used the property. Similarly, for purposes of applying section 179(d)(2)(A), (B), and (C), the partner acquiring a partnership interest is treated as acquiring a portion of partnership property, and the partner who is transferring a partnership interest is treated as the person from whom the property is acquired.

For example, the relationship between the transferor partner and the transferee partner must not be a prohibited relationship under section 179(d)(2)(A). Also, the transferor partner and transferee partner may not be part of the same controlled group under section 179(d)(2)(B). Finally, the transferee partner's basis in the transferred partnership interest may not be determined in whole or in part by reference to the transferor's adjusted basis, or under section 1014.

The same result will apply regardless of whether the transferee partner is a new partner or an existing partner purchasing an additional partnership interest from another partner. Assuming that the transferor partner's specific

interest in partnership property that is acquired by the transferee partner has not previously been used by the transferee partner or a predecessor, the corresponding section 743(b) basis adjustment will be eligible for the additional first year depreciation deduction in the hands of the transferee partner, provided all other requirements of section 168(k) are satisfied (and assuming § 1.743–1(j)(4)(i)(B)(*2*) does not apply). This treatment is appropriate notwithstanding the fact that the transferee partner may have an existing interest in the underlying partnership property, because the transferee's existing interest in the underlying partnership property is distinct from the interest being transferred.

Finally, the proposed regulations provide that a section 743(b) basis adjustment in a class of property (not including the property class for section 743(b) basis adjustments) may be recovered using the additional first year depreciation deduction under section 168(k) without regard to whether the partnership elects out of the additional first year depreciation deduction under section 168(k)(7) for all other qualified property in the same class of property and placed in service in the same taxable year. Similarly, a partnership may make the election out of the additional first year depreciation deduction under section 168(k)(7) for a section 743(b) basis adjustment in a class of property (not including the property class for section 743(b) basis adjustments), and this election will not bind the partnership to such election for all other qualified property of the partnership in the same class of property and placed in service in the same taxable year.

D. Syndication Transaction

The syndication transaction rule in the proposed regulations is based on the rules in section 168(k)(2)(E)(iii) for syndication transactions. For new or used property, the proposed regulations provide that if (1) a lessor has a depreciable interest in the property and the lessor and any predecessor did not previously have a depreciable interest in the property, (2) the property is sold by the lessor or any subsequent purchaser within three months after the date the property was originally placed in service by the lessor (or, in the case of multiple units of property subject to the same lease, within three months after the date the final unit is placed in service, so long as the period between the time the first unit is placed in service and the time the last unit is placed in service does not exceed 12 months), and (3) the user (lessee) of the property after the last sale during the three-month period remains the same as when the property was originally placed in service by the lessor, then the purchaser of the property in the last sale during the three-month period is considered the taxpayer that acquired the property and the taxpayer that originally placed the property in service, but not earlier than the date of the last sale. Thus, if a transaction is within the rules described above, the purchaser of the property in the last sale during the three-month period is eligible to claim the additional first year depreciation for the property (assuming all requirements are met), and the earlier purchasers of the property are not.

4. Placed-in-Service Date

The proposed regulations generally retain the placed-in-service date rules in § 1.168(k)–1(b)(5). Pursuant to the effective date in section 13201(h) of the Act and section 168(k)(2)(A)(iii) and (k)(2)(B)(i)(II), the proposed regulations provide that qualified property must be placed in service by the taxpayer after September 27, 2017, and before January 1, 2027, or, in the case of property described in section 168(k)(2)(B) or (C), before January 1, 2028. Because section 13201 of the Act removed the rules regarding sale-leaseback transactions, the proposed regulations do not retain the placed-in-service date rules in § 1.168(k)–1(b)(5)(ii)(A) and (C) regarding such transactions, including a sale-leaseback transaction followed by a syndication transaction.

Further, the proposed regulations provide rules for specified plants. Pursuant to section 168(k)(5)(A), if the taxpayer has made an election to apply section 168(k)(5) for a specified plant, the proposed regulations provide that the specified plant must be planted before January 1, 2027, or grafted before January 1, 2027, to a plant that has already been planted, by the taxpayer in the ordinary course of the taxpayer's farming business, as defined in section 263A(e)(4).

Pursuant to section 168(k)(2)(H), the proposed regulations also provide that a qualified film or television production is treated as placed in service at the time of initial release or broadcast as defined under § 1.181–1(a)(7), and a qualified live theatrical production is treated as placed in service at the time of the initial live staged performance. The proposed regulations also provide that the initial live staged performance of a qualified live theatrical production is the first commercial exhibition of a production to an audience. An initial live staged performance does not include limited exhibition, prior to commercial exhibition to general audiences, if the limited exhibition is primarily for purposes of publicity, determining the need for further production activity, or raising funds for the completion of production. For example, the initial live staged performance does not include a preview of the production if the preview is primarily to determine the need for further production activity.

5. Date of Acquisition

The proposed regulations provide rules applicable to the acquisition requirements of the effective date under section 13201(h) of the Act. The proposed regulations provide that these rules apply to all property, including self-constructed property or property described in section 168(k)(2)(B) or (C).

A. Written Binding Contract

Pursuant to section 13201(h)(1)(A) of the Act, the proposed regulations provide that the property must be acquired by the taxpayer after September 27, 2017, or, acquired by the taxpayer pursuant to a written binding contract entered into by the taxpayer after September 27, 2017. Because of the clear language of section 13201(h)(1) of the Act regarding written binding contracts, the proposed regulations also provide that property that is manufactured, constructed, or produced for the taxpayer by another person under a written binding contract that is entered into prior to the manufacture, construction, or production of the property for use by the taxpayer in its trade or business or for its production of income is acquired pursuant to a written binding contract. Further, if the written binding contract states the date on which the contract was entered into and a closing date, delivery date, or other similar date, the date on which the contract was entered into is the date the taxpayer acquired the property. The proposed regulations retain the rules in § 1.168(k)–1(b)(4)(ii) defining a binding contract. Additionally, the proposed regulations provide that a letter of intent for an acquisition is not a binding contract.

B. Self-Constructed Property

If a taxpayer manufactures, constructs, or produces property for its own use, the Treasury Department and the IRS recognize that the written binding contract rule in section 13201(h)(1) of the Act does not apply. In such case, the proposed regulations provide that the acquisition rules in section 13201(h)(1) of the Act are treated as met if the taxpayer begins

manufacturing, constructing, or producing the property after September 27, 2017. The proposed regulations provide rules similar to those in § 1.168(k)–1(b)(4)(iii)(B) for defining when manufacturing, construction, or production begins, including the safe harbor, and in § 1.168(k)–1(b)(4)(iii)(C) for a contract to acquire, or for the manufacture, construction, or production of, a component of the larger self-constructed property. As stated in the preceding paragraph, these self-constructed rules in the proposed regulations do not apply to property that is manufactured, constructed, or produced for the taxpayer by another person under a written binding contract that is entered into prior to the manufacture, construction, or production of the property.

C. Qualified Film, Television, or Live Theatrical Productions

The proposed regulations also provide rules for qualified film, television, or live theatrical productions. For purposes of section 13201(h)(1)(A) of the Act, the proposed regulations provide that a qualified film or television production is treated as acquired on the date principal photography commences, and a qualified live theatrical production is treated as acquired on the date when all of the necessary elements for producing the live theatrical production are secured. These elements may include a script, financing, actors, set, scenic and costume designs, advertising agents, music, and lighting.

D. Specified Plants

Pursuant to section 13201(h)(2) of the Act, if the taxpayer makes an election to apply section 168(k)(5) for a specified plant, the proposed regulations provide that the specified plant must be planted after September 27, 2017, or grafted after September 27, 2017, to a plant that has already been planted, by the taxpayer in the ordinary course of the taxpayer's farming business, as defined in section 263A(e)(4).

6. Longer Production Period Property or Certain Aircraft Property

The proposed regulations provide rules for determining when longer production period property or certain aircraft property described in section 168(k)(2)(B) or (C) meets the acquisition requirements of section 168(k)(2)(B)(i)(III) or (k)(2)(C)(i), as applicable. Pursuant to section 168(k)(2)(B)(i)(III) and (k)(2)(C)(i), the proposed regulations provide that property described in section 168(k)(2)(B) or (C) must be acquired by the taxpayer before January 1, 2027, or acquired by the taxpayer pursuant to a written binding contract that is entered into before January 1, 2027. These acquisition requirements are in addition to those in section 13201(h)(1) of the Act, which require acquisition to occur after September 27, 2017.

The proposed regulations provide that the written binding contract rules for longer production period property and certain aircraft property are the same rules that apply for purposes of determining whether the acquisition requirements of section 13201(h)(1) of the Act are met.

With respect to self-constructed property described in section 168(k)(2)(B) or (C), the proposed regulations follow the acquisition rule in section 168(k)(2)(E)(i) for self-constructed property and provide that the acquisition requirements of section 168(k)(2)(B)(i)(III) or (k)(2)(C)(i), as applicable, are met if a taxpayer manufactures, constructs, or produces the property for its own use and such manufacturing, construction, or productions begins before January 1, 2027. Further, only for purposes of section 168(k)(2)(B)(i)(III) and (k)(2)(C)(i), the proposed regulations provide that property that is manufactured, constructed, or produced for the taxpayer by another person under a written binding contract that is entered into prior to the manufacture, construction, or production of the property for use by the taxpayer in its trade or business or for its production of income is considered to be manufactured, constructed, or produced by the taxpayer. The proposed regulations also provide rules similar to those in § 1.168(k)–1(b)(4)(iii)(B) for defining when manufacturing, construction, or production begins, including the same safe harbor, and in § 1.168(k)–1(b)(4)(iii)(C) for a contract to acquire, or for the manufacture, construction, or production of, a component of the larger self-constructed property.

7. Computation of Additional First Year Depreciation Deduction and Otherwise Allowable Depreciation

Pursuant to section 168(k)(1)(A), the proposed regulations provide that the allowable additional first year depreciation deduction for qualified property is equal to the applicable percentage (as defined in section 168(k)(6)) of the unadjusted depreciable basis (as defined in § 1.168(b)–1(a)(3)) of the property. For qualified property described in section 168(k)(2)(B), the unadjusted depreciable basis (as defined in § 1.168(b)–1(a)(3)) of the property is limited to the property's basis attributable to manufacture, construction, or production of the property before January 1, 2027, as provided in section 168(k)(2)(B)(ii).

Pursuant to section 168(k)(2)(G), the proposed regulations also provide that the additional first year depreciation deduction is allowed for both regular tax and alternative minimum tax (AMT) purposes. However, for AMT purposes, the amount of the additional first year depreciation deduction is based on the unadjusted depreciable basis of the property for AMT purposes. The amount of the additional first year depreciation deduction is not affected by a taxable year of less than 12 months for either regular or AMT purposes.

The proposed regulations provide rules similar to those in § 1.168(k)–1(d)(2) for determining the amount of depreciation otherwise allowable for qualified property. That is, before determining the amount of depreciation otherwise allowable for qualified property, the proposed regulations require the taxpayer to first reduce the unadjusted depreciable basis (as defined in § 1.168(b)–1(a)(3)) of the property by the amount of the additional first year depreciation deduction allowed or allowable, whichever is greater (the remaining adjusted depreciable basis), as provided in section 168(k)(1)(B). Then, the remaining adjusted depreciable basis is depreciated using the applicable depreciation provisions of the Code for the property (for example, section 168 for MACRS property, section 167(f)(1) for computer software, and section 167 for film, television, or theatrical productions). This amount of depreciation is allowed for both regular tax and AMT purposes, and is affected by a taxable year of less than 12 months. However, for AMT purposes, the amount of depreciation allowed is determined by calculating the remaining adjusted depreciable basis of the property for AMT purposes and using the same depreciation method, recovery period, and convention that applies to the property for regular tax purposes. If a taxpayer uses the optional depreciation tables in Rev. Proc. 87–57 (1987–2 C.B. 687) to compute depreciation for qualified property that is MACRS property, the proposed regulations also provide that the remaining adjusted depreciable basis of the property is the basis to which the annual depreciation rates in those tables apply.

8. Special Rules

The proposed regulations also provide rules similar to those in § 1.168(k)–1(f) for certain situations. However, the

special rules in § 1.168(k)–1(f)(9) regarding the increase in basis due to a section 754 election are addressed in the proposed regulations regarding the used property acquisition requirements. Further, the special rules in § 1.168(k)–1(f)(1)(iii) regarding property placed in service and transferred in a section 168(i)(7) transaction in the same taxable year, and in § 1.168(k)–1(f)(5) regarding like-kind exchanges or involuntary conversions, are updated to reflect the used property acquisition requirements in section 168(k)(2)(E)(ii). The special rules in the proposed regulations also are updated to reflect the applicable dates under section 168(k), and the changes by the Act to technical terminations of partnerships and the rehabilitation credit.

The proposed regulations provide rules for the following situations: (1) Qualified property placed in service or planted or grafted, as applicable, and disposed of in the same taxable year; (2) redetermination of basis of qualified property; (3) recapture of additional first year depreciation for purposes of section 1245 and section 1250; (4) a certified pollution control facility that is qualified property; (5) like-kind exchanges and involuntary conversions of qualified property; (6) a change in use of qualified property; (7) the computation of earnings and profits; (8) the increase in the limitation of the amount of depreciation for passenger automobiles; (9) the rehabilitation credit under section 47; and (10) computation of depreciation for purposes of section 514(a)(3).

The proposed regulations provide a special rule for qualified property that is placed in service in a taxable year and then contributed to a partnership under section 721(a) in the same taxable year when one of the other partners previously had a depreciable interest in the property. Situation 1 of Rev. Rul. 99–5 (1999–1 C.B. 434) is an example of such a fact pattern. Under § 1.168(k)–1(f)(1)(iii) and its cross-reference to § 1.168(d)–1(b)(7)(ii), the additional first year depreciation deduction associated with the contributed property would be allocated between the contributing partner and the partnership based on the proportionate time the contributing partner and the partnership held the property throughout the taxable year. The partnership could then allocate a portion of the deduction to the partner with a previous depreciable interest in the property. The Treasury Department and the IRS believe that allocating any portion of the deduction to a partner who previously had a depreciable interest in the property would be inconsistent with section 168(k)(2)(E)(ii)(I). Therefore, the proposed regulations provide that, in this situation, the additional first year depreciation deduction with respect to the contributed property is not allocated under the general rules of § 1.168(d)–1(b)(7)(ii). Instead, the additional first year depreciation deduction is allocated entirely to the contributing partner prior to the section 721(a) transaction and not to the partnership.

With respect to like-kind exchanges and involuntary conversions, § 1.168(k)–1(f)(5) provides that the exchanged basis and excess basis, if any, of the replacement property is eligible for the additional first year depreciation deduction if the replacement property is qualified property. The proposed regulations retain this rule if the replacement property also meets the original use requirement. Pursuant to section 168(k)(2)(E)(ii)(II) and its cross-reference to section 179(d)(3), the proposed regulations also provide that only the excess basis, if any, of the replacement property is eligible for the additional first year depreciation deduction if the replacement property is qualified property and also meets the used property acquisition requirements. These rules also apply when a taxpayer makes the election under § 1.168(i)–6(i)(1) to treat, for depreciation purposes only, the total of the exchanged basis and excess basis, if any, in the replacement MACRS property as property placed in service by the taxpayer at the time of replacement and the adjusted depreciable basis of the relinquished MACRS property as disposed of by the taxpayer at the time of disposition. The proposed regulations also retain the other rules in § 1.168(k)–1(f)(5) for like-kind exchanges and involuntary conversions, but update the definitions to be consistent with the definitions in § 1.168(i)–6, which addresses how to compute depreciation of property involved in like-kind exchanges or involuntary conversions.

Proposed Applicability Date

These regulations are proposed to apply to qualified property placed in service or planted or grafted, as applicable, by the taxpayer during or after the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. Pending the issuance of the final regulations, a taxpayer may choose to apply these proposed regulations to qualified property acquired and placed in service or planted or grafted, as applicable, after September 27, 2017, by the taxpayer during taxable years ending on or after September 28, 2017.

Special Analyses

The Administrator of the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, has waived review of this proposed rule in accordance with section 6(a)(3)(A) of Executive Order 12866. OIRA will subsequently make a significance determination of the final rule, pursuant to section 3(f) of Executive Order (E.O.) 12866 and the April 11, 2018, Memorandum of Agreement between the Department of Treasury and the Office of Management and Budget (OMB).

The proposed regulations do not impose a collection of information on small entities and provide clarifying rules for taxpayers to enjoy the tax benefit of 100-percent additional first year depreciation as provided by the amendments to section 168 by the Act. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act (5 U.S.C. chapter 6). Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. The Treasury Department and the IRS request comments on all aspects of the proposed rules. All comments will be available at *http://www.regulations.gov* or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal authors of these proposed regulations are Kathleen Reed and Elizabeth R. Binder of the Office of Associate Chief Counsel (Income Tax and Accounting). However, other personnel from the Treasury Department and the IRS participated in their development.

Statement of Availability

The IRS Revenue Procedures and Revenue Rulings cited in this document are published in the Internal Revenue Bulletin (or Cumulative Bulletin) and are available from the Superintendent of Documents, U.S. Government

Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www.irs.gov.*

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by adding an entry for § 1.168(k)—2 in numerical order to read in part as follows:

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

* * * * *

Section 1.168(k)–2 also issued under 26 U.S.C. 1502.

* * * * *

■ **Par. 2.** Section 1.48–12 is amended by:

■ 1. In the last sentence in paragraph (a)(2)(i), removing ''The last sentence'' and adding ''The next to last sentence'' in its place;

■ 2. Adding two sentences at the end of paragraph (a)(2)(i); and

■ 3. Adding a sentence to the end of paragraph (c)(8)(i).

The additions read as follows:

§ 1.48–12 Qualified rehabilitated building; expenditures incurred after December 31, 1981.

(a) * * *

(2) * * *

(i) * * * The last sentence of paragraph (c)(8)(i) of this section applies to qualified rehabilitation expenditures that are qualified property under section 168(k)(2) and placed in service by a taxpayer during or after the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. However, a taxpayer may rely on the last sentence in paragraph (c)(8)(i) of this section in these proposed regulations for qualified rehabilitation expenditures that are qualified property under section 168(k)(2) and acquired and placed in service after September 27, 2017, by the taxpayer during taxable years ending on or after September 28, 2017, and ending before the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

* * * * *

(c) * * *

(8) * * *

(i) * * * Further, see § 1.168(k)–2(f)(9) if the qualified rehabilitation expenditures are qualified property under section 168(k), as amended by the Tax Cuts and Jobs Act, Public Law 115–97 (131 Stat. 2054 (December 22, 2017)).

* * * * *

■ **Par. 3.** Section 1.167(a)–14 is amended by:

■ 1. In the third sentence in paragraph (b)(1), removing ''under section 168(k)(2) or § 1.168(k)–1,'' and adding ''under section 168(k)(2) and § 1.168(k)–1 or 1.168(k)–2, as applicable,'' in its place;

■ 2. In the last sentence in paragraph (e)(3), removing ''and before 2010''; and

■ 3. Adding two sentences at the end of paragraph (e)(3).

The addition reads as follows:

§ 1.167(a)–14 Treatment of certain intangible property excluded from section 197.

* * * * *

(e) * * *

(3) * * * The language ''or § 1.168(k)–2, as applicable,'' in the third sentence in paragraph (b)(1) of this section applies to computer software that is qualified property under section 168(k)(2) and placed in service by a taxpayer during or after the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. However, a taxpayer may rely on the language ''or § 1.168(k)–2, as applicable,'' in the third sentence in paragraph (b)(1) of this section in these proposed regulations for computer software that is qualified property under section 168(k)(2) and acquired and placed in service after September 27, 2017, by the taxpayer during taxable years ending on or after September 28, 2017, and ending before the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

■ **Par. 4.** Section 1.168(b)–1 is amended by adding paragraph (a)(5) and revising paragraph (b) to read as follows:

§ 1.168(b)–1 Definitions.

(a) * * *

(5) *Qualified improvement property*—(i) Is any improvement that is section 1250 property to an interior portion of a building, as defined in § 1.48–1(e)(1), that is nonresidential real property, as defined in section 168(e)(2)(B), if the improvement is placed in service by the taxpayer after the date the building was first placed in service by any person and if—

(A) For purposes of section 168(e)(6), the improvement is placed in service by the taxpayer after December 31, 2017;

(B) For purposes of section 168(k)(3) as in effect on the day before amendment by section 13204(a)(4)(B) of the Tax Cuts and Jobs Act, Public Law 115–97 (131 Stat. 2054 (December 22, 2017)) (''Act''), the improvement is acquired by the taxpayer before September 28, 2017, the improvement is placed in service by the taxpayer before January 1, 2018, and the improvement meets the original use requirement in section 168(k)(2)(A)(ii) as in effect on the day before amendment by section 13201(c)(1) of the Act; or

(C) For purposes of section 168(k)(3) as in effect on the day before amendment by section 13204(a)(4)(B) of the Act, the improvement is acquired by the taxpayer after September 27, 2017; the improvement is placed in service by the taxpayer after September 27, 2017, and before January 1, 2018; and the improvement meets the requirements in section 168(k)(2)(A)(ii) as amended by section 13201(c)(1) of the Act; and

(ii) Does not include any qualified improvement for which an expenditure is attributable to—

(A) The enlargement, as defined in § 1.48–12(c)(10), of the building;

(B) Any elevator or escalator, as defined in § 1.48–1(m)(2); or

(C) The internal structural framework, as defined in § 1.48–12(b)(3)(iii), of the building.

(b) *Effective date*—(1) *In general.* Except as provided in paragraph (b)(2) of this section, this section is applicable on or after February 27, 2004.

(2) *Application of paragraph (a)(5) of this section*—(i) *In general.* Except as provided in paragraph (b)(2)(ii) of this section, paragraph (a)(5) of this section is applicable on or after the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

(ii) *Early application of paragraph (a)(5) of this section.* A taxpayer may rely on the provisions of paragraph (a)(5) of this section in these proposed regulations for the taxpayer's taxable years ending on or after September 28, 2017, and ending before the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

■ **Par. 5.** Section 1.168(d)–1 is amended by:

■ 1. Adding a sentence at the end of paragraph (b)(3)(ii);

■ 2. Adding a sentence at the end of paragraph (b)(7)(ii); and

■ 3. Adding two sentences at the end of paragraph (d)(2).

The additions read as follows:

§ 1.168(d)–1 Applicable conventions—half-year and mid-quarter conventions.

* * * * *

(b) * * *

(3) * * *

(ii) * * * Further, see § 1.168(k)–2(f)(1) for rules relating to qualified property under section 168(k), as amended by the Tax Cuts and Jobs Act, Public Law 115–97 (131 Stat. 2054 (December 22, 2017)), that is placed in service by the taxpayer in the same taxable year in which either a partnership is terminated as a result of a technical termination under section 708(b)(1)(B) or the property is transferred in a transaction described in section 168(i)(7).

* * * * *

(7) * * *

(ii) * * * However, see § 1.168(k)–2(f)(1)(iii) for a special rule regarding the allocation of the additional first year depreciation deduction in the case of certain contributions of property to a partnership under section 721.

* * * * *

(d) * * *

(2) * * * The last sentences in paragraphs (b)(3)(ii) and (b)(7)(ii) of this section apply to qualified property under section 168(k)(2) placed in service by a taxpayer during or after the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. However, a taxpayer may rely on the last sentences in paragraphs (b)(3)(ii) and (b)(7)(ii) of this section in these proposed regulations for qualified property under section 168(k)(2) acquired and placed in service after September 27, 2017, by the taxpayer during taxable years ending on or after September 28, 2017, and ending before the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

* * * * *

■ **Par. 6.** Section 1.168(i)–4 is amended by:

■ 1. In the penultimate sentence in paragraph (b)(1), removing ''§§ 1.168(k)–1T(f)(6)(iii) and 1.1400L(b)–1T(f)(6)'' and adding ''§ 1.168(k)–1(f)(6)(iii) or 1.168(k)–2(f)(6)(iii), as applicable, and § 1.1400L(b)–1(f)(6)'' in its place;

■ 2. In the fifth sentence in paragraph (c), removing ''§§ 1.168(k)–1T(f)(6)(ii) and 1.1400L(b)–1T(f)(6)'' and adding ''§ 1.168(k)–1(f)(6)(ii) or 1.168(k)–2(f)(6)(ii), as applicable, and § 1.1400L(b)–1(f)(6)'' in its place;

■ 3. In the second sentence in paragraph (d)(3)(i)(C), removing ''§§ 1.168(k)–1T(f)(6)(iv) and 1.400L(b)–1T(f)(6)'' and adding ''§ 1.168(k)–1(f)(6)(iv) or 1.168(k)–2(f)(6)(iv), as applicable, and § 1.400L(b)–1(f)(6)'' in its place;

■ 4. In the last sentence in paragraph (d)(4)(i), removing ''§§ 1.168(k)–1T(f)(6)(iv) and 1.1400L(b)–1T(f)(6)'' and adding ''§ 1.168(k)–1(f)(6)(iv) or 1.168(k)–2(f)(6)(iv), as applicable, and § 1.400L(b)–1(f)(6)'' in its place;

■ 5. Revising the first sentence in paragraph (g)(1); and

■ 6. Redesignating paragraph (g)(2) as paragraph (g)(3) and adding new paragraph (g)(2).

The addition and revision read as follows:

§ 1.168(i)–4 Changes in use.

* * * * *

(g) * * *

(1) * * * Except as provided in paragraph (g)(2) of this section, this section applies to any change in the use of MACRS property in a taxable year ending on or after June 17, 2004. * * *

(2) *Qualified property under section 168(k) acquired and placed in service after September 27, 2017.* The language ''or § 1.168(k)–2(f)(6)(iii), as applicable'' in paragraph (b)(1) of this section, the language ''or § 1.168(k)–2(f)(6)(ii), as applicable'' in paragraph (c) of this section, and the language ''or § 1.168(k)–2(f)(6)(iv), as applicable'' in paragraphs (d)(3)(i)(C) and (d)(4)(i) of this section applies to any change in use of MACRS property, which is qualified property under section 168(k)(2), by a taxpayer during or after the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. However, a taxpayer may rely on the language ''or § 1.168(k)–2(f)(6)(iii), as applicable'' in paragraph (b)(1) of this section, the language ''or § 1.168(k)–2(f)(6)(ii), as applicable'' in paragraph (c) of this section, and the language ''or § 1.168(k)–2(f)(6)(iv), as applicable'' in paragraphs (d)(3)(i)(C) and (d)(4)(i) of this section in these proposed regulations for any change in use of MACRS property, which is qualified property under section 168(k)(2) and acquired and placed in service after September 27, 2017, by the taxpayer during taxable years ending on or after September 28, 2017, and ending before the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

* * * * *

■ **Par. 7.** Section 1.168(i)–6 is amended by:

■ 1. In paragraph (d)(3)(ii)(B), removing ''1.168(k)–1(f)(5) or § 1.1400L(b)–1(f)(5)'' wherever it appears and adding ''1.168(k)–1(f)(5), 1.168(k)–2(f)(5), or 1.1400L(b)–1(f)(5)'' in its place;

■ 2. In paragraph (d)(3)(ii)(E), removing ''1.168(k)–1(f)(5) or § 1.1400L(b)–1(f)(5)'' and adding ''1.168(k)–1(f)(5), 1.168(k)–2(f)(5), or 1.1400L(b)–1(f)(5)'' in its place;

■ 3. Adding a sentence at the end of paragraph (d)(4);

■ 4. Adding a sentence at the end of paragraph (h); and

■ 5. Adding paragraph (k)(4).

The additions read as follows:

§ 1.168(i)–6 Like-kind exchanges and involuntary conversions.

* * * * *

(d) * * *

(4) * * * Further, see § 1.168(k)–2(f)(5)(iv) for replacement MACRS property that is qualified property under section 168(k), as amended by the Tax Cuts and Jobs Act, Public Law 115–97 (131 Stat. 2054 (December 22, 2017)).

* * * * *

(h) * * * Further, see § 1.168(k)–2(f)(5) for qualified property under section 168(k), as amended by the Tax Cuts and Jobs Act, Public Law 115–97 (131 Stat. 2054 (December 22, 2017)).

* * * * *

(k) * * *

(4) *Qualified property under section 168(k) acquired and placed in service after September 27, 2017.* The language ''1.168(k)–2(f)(5),'' in paragraphs (d)(3)(ii)(B) and (E) of this section and the last sentences in paragraphs (d)(4) and (h) of this section apply to a like-kind exchange or an involuntary conversion of MACRS property, which is qualified property under section 168(k)(2), for which the time of replacement occurs on or after the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. However, a taxpayer may rely on the language ''1.168(k)–2(f)(5),'' in paragraphs (d)(3)(ii)(B) and (E) of this section and the last sentences in paragraphs (d)(4) and (h) of this section in these proposed regulations for a like-kind exchange or an involuntary conversion of MACRS property, which is qualified property under section 168(k)(2), for which the time of replacement occurs on or after September 28, 2017, and occurs before the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

■ **Par. 8.** Section 1.168(k)–0 is amended by revising the introductory text and adding an entry for § 1.168(k)–2 in numerical order to the table of contents to read as follows:

§ 1.168(k)–0 Table of contents.

This section lists the major paragraphs contained in §§ 1.168(k)–1 and 1.168(k)–2.

* * * * *

§ 1.168(k)–2 Additional first year depreciation deduction for property acquired and placed in service after September 27, 2017.

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(ii) Original use.
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(A) In general.
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(C) Special rules for a series of related transactions.
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(A) Section 704(c) remedial allocations.
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(C) Section 734(b) adjustments.
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(C) Options.
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(A) In general.
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(d) Computation of depreciation deduction for qualified property.
(1) Additional first year depreciation deduction.
(i) Allowable taxable year.
(ii) Computation.
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(iv) Alternative minimum tax.
(A) In general.
(B) Special rules.
(2) Otherwise allowable depreciation deduction.
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(3) Examples.
(e) Elections under section 168(k).
(1) Election not to deduct additional first year depreciation.
(i) In general.
(ii) Definition of class of property.
(iii) Time and manner for making election.
(A) Time for making election.
(B) Manner of making election.
(iv) Failure to make election.
(2) Election to apply section 168(k)(5) for specified plants.
(i) In general.
(ii) Time and manner for making election.
(A) Time for making election.
(B) Manner of making election.
(iii) Failure to make election.
(3) Election for qualified property placed in service during the 2017 taxable year.
(i) In general.
(ii) Time and manner for making election.
(A) Time for making election.
(B) Manner of making election.
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(4) Alternative minimum tax.
(5) Revocation of election.
(i) In general.
(ii) Automatic 6-month extension.
(f) Special rules.
(1) Property placed in service and disposed of in the same taxable year.
(i) In general.
(ii) Technical termination of a partnership.
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(iv) Examples.
(2) Redetermination of basis.
(i) Increase in basis.
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(i) Scope.
(ii) Definitions.
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(A) In general.
(B) Year of disposition and year of replacement.
(C) Property described in section 168(k)(2)(B).
(D) Effect of § 1.168(i)–6(i)(1) election.
(E) Alternative minimum tax.
(iv) Replacement MACRS property or replacement computer software that is acquired and placed in service before disposition of relinquished MACRS property or relinquished computer software.
(v) Examples.
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(A) During the same taxable year.
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(v) Examples.
(7) Earnings and profits.
(8) Limitation of amount of depreciation for certain passenger automobiles.
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(ii) Example.
(10) Coordination with section 514(a)(3).
(g) Applicability dates.
(1) In general.
(2) Early application.

■ **Par. 9.** Section 1.168(k)–2 is added to read as follows:

§ 1.168 (k)–2 Additional first year depreciation deduction for property acquired and placed in service after September 27, 2017.

(a) *Scope and definitions*—(1) *Scope.* This section provides rules for determining the additional first year depreciation deduction allowable under section 168(k) for qualified property

acquired and placed in service after September 27, 2017.

(2) *Definitions.* For purposes of this section—

(i) *Act* is the Tax Cuts and Jobs Act, Public Law 115–97 (131 Stat. 2054 (December 22, 2017)); and

(ii) *Applicable percentage* is the percentage provided in section 168(k)(6).

(b) *Qualified property—(1) In general.* Qualified property is depreciable property, as defined in § 1.168(b)–1(a)(1), that meets all the following requirements in the first taxable year in which the property is subject to depreciation by the taxpayer whether or not depreciation deductions for the property are allowable:

(i) The requirements in § 1.168(k)–2(b)(2) (description of qualified property);

(ii) The requirements in § 1.168(k)–2(b)(3) (original use or used property acquisition requirements);

(iii) The requirements in § 1.168(k)–2(b)(4) (placed-in-service date); and

(iv) The requirements in § 1.168(k)–2(b)(5) (acquisition of property).

(2) *Description of qualified property*—(i) *In general.* Depreciable property will meet the requirements of this paragraph (b)(2) if the property is—

(A) MACRS property, as defined in § 1.168(b)–1(a)(2), that has a recovery period of 20 years or less. For purposes of this paragraph (b)(2)(i)(A) and section 168(k)(2)(A)(i)(I), the recovery period is determined in accordance with section 168(c) regardless of any election made by the taxpayer under section 168(g)(7). This paragraph (b)(2)(i)(A) includes the following MACRS property that is acquired by the taxpayer after September 27, 2017, and placed in service by the taxpayer after September 27, 2017, and before January 1, 2018:

(*1*) Qualified leasehold improvement property as defined in section 168(e)(6) as in effect on the day before amendment by section 13204(a)(1) of the Act;

(*2*) Qualified restaurant property, as defined in section 168(e)(7) as in effect on the day before amendment by section 13204(a)(1) of the Act, that is qualified improvement property as defined in § 1.168(b)–1(a)(5)(i)(C) and (a)(5)(ii); and

(*3*) Qualified retail improvement property as defined in section 168(e)(8) as in effect on the day before amendment by section 13204(a)(1) of the Act;

(B) Computer software as defined in, and depreciated under, section 167(f)(1) and the regulations under section 167(f)(1);

(C) Water utility property as defined in section 168(e)(5) and depreciated under section 168;

(D) Qualified improvement property as defined in § 1.168(b)–1(a)(5)(i)(C) and (a)(5)(ii) and depreciated under section 168;

(E) Qualified film or television production, as defined in section 181(d) and § 1.181–3, for which a deduction would have been allowable under section 181 without regard to section 181(a)(2) and (g), or section 168(k);

(F) Qualified live theatrical production, as defined in section 181(e), for which a deduction would have been allowable under section 181 without regard to section 181(a)(2) and (g), or section 168(k); or

(G) A specified plant, as defined in section 168(k)(5)(B), for which the taxpayer has properly made an election to apply section 168(k)(5) for the taxable year in which the specified plant is planted, or grafted to a plant that has already been planted, by the taxpayer in the ordinary course of the taxpayer's farming business, as defined in section 263A(e)(4) (for further guidance, see paragraph (e) of this section).

(ii) *Property not eligible for additional first year depreciation deduction.* Depreciable property will not meet the requirements of this paragraph (b)(2) if the property is—

(A) Described in section 168(f) (for example, automobiles for which the taxpayer uses the optional business standard mileage rate);

(B) Required to be depreciated under the alternative depreciation system of section 168(g) pursuant to section 168(g)(1)(A), (B), (C), (D), (F), or (G), or other provisions of the Internal Revenue Code (for example, property described in section 263A(e)(2)(A) if the taxpayer or any related person, as defined in section 263A(e)(2)(B), has made an election under section 263A(d)(3), or property described in section 280F(b)(1));

(C) Included in any class of property for which the taxpayer elects not to deduct the additional first year depreciation (for further guidance, see paragraph (e) of this section);

(D) A specified plant that is placed in service by the taxpayer during the taxable year and for which the taxpayer made an election to apply section 168(k)(5) for a prior taxable year;

(E) Included in any class of property for which the taxpayer elects to apply section 168(k)(4). This paragraph (b)(2)(ii)(E) applies to property placed in service in any taxable year beginning before January 1, 2018;

(F) Described in section 168(k)(9)(A) and placed in service in any taxable year beginning after December 31, 2017; or

(G) Described in section 168(k)(9)(B) and placed in service in any taxable year beginning after December 31, 2017.

(3) *Original use or used property acquisition requirements*—(i) *In general.* Depreciable property will meet the requirements of this paragraph (b)(3) if the property meets the original use requirements in paragraph (b)(3)(ii) of this section or if the property meets the used property acquisition requirements in paragraph (b)(3)(iii) of this section.

(ii) *Original use*—(A) *In general.* Depreciable property will meet the requirements of this paragraph (b)(3)(ii) if the original use of the property commences with the taxpayer. Except as provided in paragraphs (b)(3)(ii)(B) and (C) of this section, original use means the first use to which the property is put, whether or not that use corresponds to the use of the property by the taxpayer. Additional capital expenditures incurred by a taxpayer to recondition or rebuild property acquired or owned by the taxpayer satisfy the original use requirement. However, the cost of reconditioned or rebuilt property does not satisfy the original use requirement (but may satisfy the used property acquisition requirements in paragraph (b)(3)(iii) of this section). The question of whether property is reconditioned or rebuilt property is a question of fact. For purposes of this paragraph (b)(3)(ii)(A), property that contains used parts will not be treated as reconditioned or rebuilt if the cost of the used parts is not more than 20 percent of the total cost of the property, whether acquired or self-constructed.

(B) *Conversion to business or income-producing use*—(*1*) *Personal use to business or income-producing use.* If a taxpayer initially acquires new property for personal use and subsequently uses the property in the taxpayer's trade or business or for the taxpayer's production of income, the taxpayer is considered the original user of the property. If a person initially acquires new property for personal use and a taxpayer subsequently acquires the property from the person for use in the taxpayer's trade or business or for the taxpayer's production of income, the taxpayer is not considered the original user of the property.

(*2*) *Inventory to business or income-producing use.* If a taxpayer initially acquires new property and holds the property primarily for sale to customers in the ordinary course of the taxpayer's business and subsequently withdraws the property from inventory and uses the property primarily in the taxpayer's trade or business or primarily for the

taxpayer's production of income, the taxpayer is considered the original user of the property. If a person initially acquires new property and holds the property primarily for sale to customers in the ordinary course of the person's business and a taxpayer subsequently acquires the property from the person for use primarily in the taxpayer's trade or business or primarily for the taxpayer's production of income, the taxpayer is considered the original user of the property. For purposes of this paragraph (b)(3)(ii)(B)(*2*), the original use of the property by the taxpayer commences on the date on which the taxpayer uses the property primarily in the taxpayer's trade or business or primarily for the taxpayer's production of income.

(C) *Fractional interests in property.* If, in the ordinary course of its business, a taxpayer sells fractional interests in new property to third parties unrelated to the taxpayer, each first fractional owner of the property is considered as the original user of its proportionate share of the property. Furthermore, if the taxpayer uses the property before all of the fractional interests of the property are sold but the property continues to be held primarily for sale by the taxpayer, the original use of any fractional interest sold to a third party unrelated to the taxpayer subsequent to the taxpayer's use of the property begins with the first purchaser of that fractional interest. For purposes of this paragraph (b)(3)(ii)(C), persons are not related if they do not have a relationship described in section 267(b) or 707(b) and the regulations under section 267(b) or 707(b).

(iii) *Used property acquisition requirements*—(A) *In general.* Depreciable property will meet the requirements of this paragraph (b)(3)(iii) if the acquisition of the used property meets the following requirements:

(*1*) Such property was not used by the taxpayer or a predecessor at any time prior to such acquisition;

(*2*) The acquisition of such property meets the requirements of section 179(d)(2)(A), (B), and (C), and § 1.179–4(c)(1)(ii), (iii), and (iv), or 1.179–4(c)(2) (property is acquired by purchase); and

(*3*) The acquisition of such property meets the requirements of section 179(d)(3) and § 1.179–4(d) (cost of property) (for further guidance regarding like-kind exchanges and involuntary conversions, see paragraph (f)(5) of this section).

(B) *Property was not used by the taxpayer at any time prior to acquisition*—(*1*) *In general.* Solely for purposes of paragraph (b)(3)(iii)(A)(*1*) of this section, the property is treated as used by the taxpayer or a predecessor at any time prior to acquisition by the taxpayer or predecessor if the taxpayer or the predecessor had a depreciable interest in the property at any time prior to such acquisition, whether or not the taxpayer or the predecessor claimed depreciation deductions for the property. If a lessee has a depreciable interest in the improvements made to leased property and subsequently the lessee acquires the leased property of which the improvements are a part, the unadjusted depreciable basis, as defined in § 1.168(b)–1(a)(3), of the acquired property that is eligible for the additional first year depreciation deduction, assuming all other requirements are met, must not include the unadjusted depreciable basis attributable to the improvements.

(*2*) *Taxpayer has a depreciable interest in a portion of the property.* If a taxpayer initially acquires a depreciable interest in a portion of the property and subsequently acquires a depreciable interest in an additional portion of the same property, such additional depreciable interest is not treated as used by the taxpayer at any time prior to its acquisition by the taxpayer. This paragraph (b)(3)(iii)(B)(*2*) does not apply if the taxpayer or a predecessor previously had a depreciable interest in the subsequently acquired additional portion. For purposes of this paragraph (b)(3)(iii)(B)(*2*), a portion of the property is considered to be the percentage interest in the property. If a taxpayer holds a depreciable interest in a portion of the property, sells that portion or a part of that portion, and subsequently acquires a depreciable interest in another portion of the same property, the taxpayer will be treated as previously having a depreciable interest in the property up to the amount of the portion for which the taxpayer held a depreciable interest in the property before the sale.

(*3*) *Application to members of a consolidated group*—(*i*) *Same consolidated group.* Solely for purposes of applying paragraph (b)(3)(iii)(A)(*1*) of this section, if a member of a consolidated group, as defined in § 1.1502–1(h), acquires depreciable property in which the consolidated group had a depreciable interest at any time prior to the member's acquisition of the property, the member will be treated as having a depreciable interest in the property prior to the acquisition. For purposes of this paragraph (b)(3)(iii)(B)(*3*)(*i*), a consolidated group will be treated as having a depreciable interest in property during the time any current or previous member of the group had a depreciable interest in the property while a member of the group.

(*ii*) *Certain acquisitions pursuant to a series of related transactions.* Solely for purposes of applying paragraph (b)(3)(iii)(A)(*1*) of this section, if a series of related transactions includes one or more transactions in which property is acquired by a member of a consolidated group and one or more transactions in which a corporation that had a depreciable interest in the property becomes a member of the group, the member that acquires the property will be treated as having a depreciable interest in the property prior to the time of its acquisition.

(*iii*) *Time for testing membership.* Solely for purposes of applying paragraph (b)(3)(iii)(B)(*3*)(*i*) and (*ii*) of this section, if a series of related transactions includes one or more transactions in which property is acquired by a member of a consolidated group and one or more transactions in which the transferee of the property ceases to be a member of a consolidated group, whether the taxpayer is a member of a consolidated group is tested immediately after the last transaction in the series.

(C) *Special rules for a series of related transactions.* Solely for purposes of section 168(k)(2)(E)(ii) and paragraph (b)(3)(iii)(A) of this section, in the case of a series of related transactions (for example, a series of related transactions including the transfer of a partnership interest, the transfer of partnership assets, or the disposition of property and the disposition, directly or indirectly, of the transferor or transferee of the property)—

(*1*) The property is treated as directly transferred from the original transferor to the ultimate transferee; and

(*2*) The relation between the original transferor and the ultimate transferee is tested immediately after the last transaction in the series.

(iv) *Application to partnerships*—(A) *Section 704(c) remedial allocations.* Remedial allocations under section 704(c) do not satisfy the requirements of paragraph (b)(3) of this section. See § 1.704–3(d)(2).

(B) *Basis determined under section 732.* Any basis of distributed property determined under section 732 does not satisfy the requirements of paragraph (b)(3) of this section.

(C) *Section 734(b) adjustments.* Any increase in basis of depreciable property under section 734(b) does not satisfy the requirements of paragraph (b)(3) of this section.

(D) *Section 743(b) adjustments*—(*1*) *In general.* For purposes of determining whether the transfer of a partnership

interest meets the requirements of paragraph (b)(3)(iii)(A) of this section, each partner is treated as having a depreciable interest in the partner's proportionate share of partnership property. Any increase in basis of depreciable property under section 743(b) satisfies the requirements of paragraph (b)(3)(iii)(A) of this section if—

(*i*) At any time prior to the transfer of the partnership interest that gave rise to such basis increase, neither the transferee partner nor a predecessor of the transferee partner had any depreciable interest in the portion of the property deemed acquired to which the section 743(b) adjustment is allocated under section 755 and the regulations under section 755; and

(*ii*) The transfer of the partnership interest that gave rise to such basis increase satisfies the requirements of paragraphs (b)(3)(iii)(A)(*2*) and (*3*) of this section.

(*2*) *Relatedness tested at partner level.* Solely for purposes of paragraph (b)(3)(iv)(D)(*1*)(*ii*) of this section, whether the parties are related or unrelated is determined by comparing the transferor and the transferee of the transferred partnership interest.

(v) *Syndication transaction.* If a lessor has a depreciable interest in the property and the lessor and any predecessor did not previously have a depreciable interest in the property, and the property is sold by the lessor or any subsequent purchaser within three months after the date the property was originally placed in service by the lessor (or, in the case of multiple units of property subject to the same lease, within three months after the date the final unit is placed in service, so long as the period between the time the first unit is placed in service and the time the last unit is placed in service does not exceed 12 months), and the user of the property after the last sale during the three-month period remains the same as when the property was originally placed in service by the lessor, the purchaser of the property in the last sale during the three-month period is considered the taxpayer that acquired the property for purposes of applying paragraphs (b)(3)(ii) and (iii) of this section.

(vi) *Examples.* The application of this paragraph (b)(3) is illustrated by the following examples. Unless the facts specifically indicate otherwise, assume that the parties are not related within the meaning of section 179(d)(2)(A) or (B) and § 1.179–4(c), no corporation is a member of a consolidated or controlled group, and the parties do not have predecessors:

Example 1. (i) On August 1, 2018, *A* buys a new machine for $35,000 from an unrelated party for use in *A*'s trade or business. On July 1, 2020, *B* buys that machine from *A* for $20,000 for use in *B*'s trade or business. On October 1, 2020, *B* makes a $5,000 capital expenditure to recondition the machine. *B* did not have any depreciable interest in the machine before *B* acquired it on July 1, 2020.

(ii) *A*'s purchase price of $35,000 satisfies the original use requirement of paragraph (b)(3)(ii) of this section and, assuming all other requirements are met, qualifies for the additional first year depreciation deduction.

(iii) *B*'s purchase price of $20,000 does not satisfy the original use requirement of paragraph (b)(3)(ii) of this section, but it does satisfy the used property acquisition requirements of paragraph (b)(3)(iii) of this section. Assuming all other requirements are met, the $20,000 purchase price qualifies for the additional first year depreciation deduction. Further, *B*'s $5,000 expenditure satisfies the original use requirement of paragraph (b)(3)(ii) of this section and, assuming all other requirements are met, qualifies for the additional first year depreciation deduction, regardless of whether the $5,000 is added to the basis of the machine or is capitalized as a separate asset.

Example 2. C, an automobile dealer, uses some of its automobiles as demonstrators in order to show them to prospective customers. The automobiles that are used as demonstrators by *C* are held by *C* primarily for sale to customers in the ordinary course of its business. On November 1, 2017, *D* buys from *C* an automobile that was previously used as a demonstrator by *C. D* will use the automobile solely for business purposes. The use of the automobile by *C* as a demonstrator does not constitute a ''use'' for purposes of the original use requirement and, therefore, *D* will be considered the original user of the automobile for purposes of paragraph (b)(3)(ii) of this section. Assuming all other requirements are met, *D*'s purchase price of the automobile qualifies for the additional first year depreciation deduction for *D,* subject to any limitation under section 280F.

Example 3. On April 1, 2015, *E* acquires a horse to be used in *E*'s thoroughbred racing business. On October 1, 2018, *F* buys the horse from *E* and will use the horse in *F*'s horse breeding business. *F* did not have any depreciable interest in the horse before *F* acquired it on October 1, 2018. The use of the horse by *E* in its racing business prevents *F* from satisfying the original use requirement of paragraph (b)(3)(ii) of this section. However, *F*'s acquisition of the horse satisfies the used property acquisition requirements of paragraph (b)(3)(iii) of this section. Assuming all other requirements are met, *F*'s purchase price of the horse qualifies for the additional first year depreciation deduction for *F.*

Example 4. In the ordinary course of its business, *G* sells fractional interests in its aircraft to unrelated parties. *G* holds out for sale eight equal fractional interests in an aircraft. On October 1, 2017, *G* sells five of the eight fractional interests in the aircraft to *H* and *H* begins to use its proportionate share of the aircraft immediately upon purchase. On February 1, 2018, *G* sells to *I* the remaining unsold 3/8 fractional interests in the aircraft. *H* is considered the original user as to its 5/8 fractional interest in the aircraft and *I* is considered the original user as to its 3/8 fractional interest in the aircraft. Thus, assuming all other requirements are met, *H*'s purchase price for its 5/8 fractional interest in the aircraft qualifies for the additional first year depreciation deduction and *I*'s purchase price for its 3/8 fractional interest in the aircraft qualifies for the additional first year depreciation deduction.

Example 5. On September 1, 2017, *J,* an equipment dealer, buys new tractors that are held by *J* primarily for sale to customers in the ordinary course of its business. On October 15, 2017, *J* withdraws the tractors from inventory and begins to use the tractors primarily for producing rental income. The holding of the tractors by *J* as inventory does not constitute a ''use'' for purposes of the original use requirement and, therefore, the original use of the tractors commences with *J* on October 15, 2017, for purposes of paragraph (b)(3)(ii) of this section. However, the tractors are not eligible for the 100-percent additional first year depreciation deduction because *J* acquired the tractors before September 28, 2017.

Example 6. K is in the trade or business of leasing equipment to others. During 2016, *K* buys a new machine (Machine #1) and then leases it to *L* for use in *L*'s trade or business. The lease between *K* and *L* for Machine #1 is a true lease for federal income tax purposes. During 2018, *L* enters into a written binding contract with *K* to buy Machine #1 at its fair market value on May 15, 2018. *L* did not have any depreciable interest in Machine #1 before *L* acquired it on May 15, 2018. As a result, *L*'s acquisition of Machine #1 satisfies the used property acquisition requirements of paragraph (b)(3)(iii) of this section. Assuming all other requirements are met, *L*'s purchase price of Machine #1 qualifies for the additional first year depreciation deduction for *L.*

Example 7. The facts are the same as in *Example 6* of this paragraph (b)(3)(vi), except that *K* and *L* are related parties within the meaning of section 179(d)(2)(A) or (B) and § 1.179–4(c). As a result, *L*'s acquisition of Machine #1 does not satisfy the used property acquisition requirements of paragraph (b)(3)(iii) of this section. Thus, Machine #1 is not eligible for the additional first year depreciation deduction for *L.*

Example 8. The facts are the same as in *Example 6* of this paragraph (b)(3)(vi), except *L* incurred capital expenditures of $5,000 to improve Machine #1 on September 5, 2017, and has a depreciable interest in such improvements. *L*'s purchase price of $5,000 for the improvements to Machine #1 satisfies the original use requirement of § 1.168(k)–1(b)(3)(i) and, assuming all other requirements are met, qualifies for the 50-percent additional first year depreciation deduction. Because *L* had a depreciable interest only in the improvements to Machine #1, *L*'s acquisition of Machine #1, excluding *L*'s improvements to such machine, satisfies the used property acquisition requirements of paragraph (b)(3)(iii) of this section. Assuming all other requirements are met, *L*'s unadjusted

depreciable basis of Machine #1, excluding the amount of such unadjusted depreciable basis attributable to *L*'s improvements to Machine #1, qualifies for the 100-percent additional first year depreciation deduction.

Example 9. During 2016, *M* and *N* purchased used equipment for use in their trades or businesses and each own a 50 percent interest in such equipment. Prior to this acquisition, *M* and *N* did not have any depreciable interest in the equipment. Assume this ownership arrangement is not a partnership. During 2018, *N* enters into a written binding contract with *M* to buy *M*'s interest in the equipment. Pursuant to paragraph (b)(3)(iii)(B)(*2*) of this section, *N* is not treated as using *M*'s interest in the equipment prior to *N*'s acquisition of *M*'s interest. As a result, *N*'s acquisition of *M*'s interest in the equipment satisfies the used property acquisition requirements of paragraph (b)(3)(iii) of this section. Assuming all other requirements are met, *N*'s purchase price of *M*'s interest in the equipment qualifies for the additional first year depreciation deduction for *N*.

Example 10. The facts are the same as in *Example 9* of this paragraph (b)(3)(vi), except *N* had a 100 percent depreciable interest in the equipment prior to 2016 and *M* purchased from *N* a 50 percent interest in the equipment during 2016. As a result, *N*'s acquisition of *M*'s interest in the equipment during 2018 does not satisfy the used property acquisition requirements of paragraphs (b)(3)(iii)(A)(*1*) and (b)(3)(iii)(B)(*1*) of this section. Paragraph (b)(3)(iii)(B)(*2*) of this section does not apply because *N* initially acquired a 100 percent depreciable interest in the equipment. Accordingly, *N*'s purchase price of *M*'s interest in the equipment during 2018 does not qualify for the additional first year depreciation deduction for *N*.

Example 11. The facts are the same as in *Example 9* of this paragraph (b)(3)(vi), except during 2018, *M* also enters into a written binding contract with *N* to buy *N*'s interest in the equipment. Pursuant to paragraph (b)(3)(iii)(B)(*2*) of this section, both *M* and *N* are treated as previously having a depreciable interest in a 50-percent portion of the equipment. Accordingly, the acquisition by *M* of *N*'s 50-percent interest and the acquisition by *N* of *M*'s 50-percent interest in the equipment during 2018 do not qualify for the additional first year depreciation deduction.

Example 12. O and *P* form an equal partnership, *OP,* in 2018. *O* contributes cash to *OP,* and *P* contributes equipment to *OP. OP*'s basis in the equipment contributed by *P* is determined under section 723. Because *OP*'s basis in such equipment is determined in whole or in part by reference to *P*'s adjusted basis in such equipment, *OP*'s acquisition of such equipment does not satisfy section 179(d)(2)(C) and § 1.179–4(c)(1)(iv) and, thus, does not satisfy the used property acquisition requirements of paragraph (b)(3)(iii) of this section. Accordingly, *OP*'s acquisition of such equipment is not eligible for the additional first year depreciation deduction.

Example 13. Q, R, and *S* form an equal partnership, *QRS,* in 2019. Each partner contributes $100, which *QRS* uses to purchase a retail motor fuels outlet for $300. Assume this retail motor fuels outlet is *QRS'* only property and is qualified property under section 168(k)(2)(A)(i). *QRS* makes an election not to deduct the additional first year depreciation for all qualified property placed in service during 2019. *QRS* has a section 754 election in effect. *QRS* claimed depreciation of $15 for the retail motor fuels outlet for 2019. During 2020, when the retail motor fuels outlet's fair market value is $600, *Q* sells all of his partnership interest to *T* in a fully taxable transaction for $200. *T* never previously had a depreciable interest in the retail motor fuels outlet. *T* takes an outside basis of $200 in the partnership interest previously owned by *Q. T*'s share of the partnership's previously taxed capital is $95. Accordingly, *T*'s section 743(b) adjustment is $105 and is allocated entirely to the retail motor fuels outlet under section 755. Assuming all other requirements are met, *T*'s section 743(b) adjustment qualifies for the additional first year depreciation deduction.

Example 14. The facts are the same as in *Example 13* of this paragraph (b)(3)(vi), except that *Q* sells his partnership interest to *U,* a related person within the meaning of section 179(d)(2)(A) or (B) and § 1.179–4(c). *U*'s section 743(b) adjustment does not qualify for the additional first year depreciation deduction.

Example 15. The facts are the same as in *Example 13* of this paragraph (b)(3)(vi), except that *Q* dies and his partnership interest is transferred to *V. V* takes a basis in *Q*'s partnership interest under section 1014. As a result, section 179(d)(2)(C)(ii) and § 1.179–4(c)(1)(iv) are not satisfied, and *V*'s section 743(b) adjustment does not qualify for the additional first year depreciation deduction.

Example 16. The facts are the same as in *Example 13* of this paragraph (b)(3)(vi), except that *QRS* purchased the retail motor fuels outlet from *T* prior to *T* purchasing *Q*'s partnership interest in *QRS. T* had a depreciable interest in such retail motor fuels outlet. Because *T* had a depreciable interest in the retail motor fuels outlet before *T* acquired its interest in *QRS, T*'s section 743(b) adjustment does not qualify for the additional first year depreciation deduction.

Example 17. In November 2017, AA Corporation purchases a used drill press costing $10,000 and is granted a trade-in allowance of $2,000 on its old drill press. The used drill press is qualified property under section 168(k)(2)(A)(i). The old drill press had a basis of $1,200. Under sections 1012 and 1031(d), the basis of the used drill press is $9,200 ($1,200 basis of old drill press plus cash expended of $8,000). Only $8,000 of the basis of the used drill press satisfies the requirements of section 179(d)(3) and § 1.179–4(d) and, thus, satisfies the used property acquisition requirement of paragraph (b)(3)(iii) of this section. The remaining $1,200 of the basis of the used drill press does not satisfy the requirements of section 179(d)(3) and § 1.179–4(d) because it is determined by reference to the old drill press. Accordingly, assuming all other requirements are met, only $8,000 of the basis of the used drill press is eligible for the additional first year depreciation deduction.

Example 18. In a series of related transactions, a father sells a machine to an unrelated party who sells the machine to the father's daughter for use in the daughter's trade or business. Pursuant to paragraph (b)(3)(iii)(C) of this section, the transfers of the machine are treated as a direct transfer from the father to his daughter and the time to test whether the parties are related is immediately after the last transaction in the series. Because the father and the daughter are related parties within the meaning of section 179(d)(2)(A) and § 1.179–4(c)(ii), the daughter's acquisition of the machine does not satisfy the used property acquisition requirements of paragraph (b)(3)(iii) of this section. Further, because the transfers of the machine are treated as a direct transfer from the father to his daughter, the unrelated party's acquisition of the machine is not eligible for the additional first year depreciation deduction.

Example 19. Parent owns all of the stock of B Corporation and C Corporation. Parent, B Corporation, and C Corporation are all members of the Parent consolidated group. C Corporation has a depreciable interest in Equipment #1. During 2018, C Corporation sells Equipment #1 to B Corporation. Prior to this acquisition, B Corporation never had a depreciable interest in Equipment #1. B Corporation's acquisition of Equipment #1 does not satisfy the used property acquisition requirements of paragraph (b)(3)(iii) of this section for two reasons. First, B Corporation and C Corporation are related parties within the meaning of section 179(d)(2)(B) and § 1.179–4(c)(2)(iii). Second, pursuant to paragraph (b)(3)(iii)(B)(*3*)(*i*) of this section, B Corporation is treated as previously having a depreciable interest in Equipment #1 because B Corporation is a member of the Parent consolidated group and C Corporation, while a member of the Parent consolidated group, had a depreciable interest in Equipment #1. Accordingly, B Corporation's acquisition of Equipment #1 is not eligible for the additional first year depreciation deduction.

Example 20. (i) Parent owns all of the stock of D Corporation and E Corporation. Parent, D Corporation, and E Corporation are all members of the Parent consolidated group. D Corporation has a depreciable interest in Equipment #2. No other members of the Parent consolidated group ever had a depreciable interest in Equipment #2. During 2018, D Corporation sells Equipment #2 to *BA,* a person not related, within the meaning of section 179(d)(2)(A) or (B) and § 1.179–4(c), to any member of the Parent consolidated group. In an unrelated transaction during 2019, E Corporation acquires Equipment #2 from *BA* or another person not related to any member of the Parent consolidated group within the meaning of section 179(d)(2)(A) or (B) and § 1.179–4(c).

(ii) Pursuant to paragraph (b)(3)(iii)(B)(*3*)(*i*) of this section, E Corporation is treated as previously having a depreciable interest in Equipment #2 because E Corporation is a member of the Parent consolidated group, and D Corporation, while a member of the Parent consolidated group, had a depreciable interest in Equipment #2. As a result, E Corporation's acquisition of Equipment #2

does not satisfy the used property acquisition requirements of paragraph (b)(3)(iii) of this section. Thus, E Corporation's acquisition of Equipment #2 is not eligible for the additional first year depreciation deduction. The results would be the same if D Corporation had ceased to be a member of the Parent consolidated group prior to E Corporation's acquisition of Equipment #2.

Example 21. (i) Parent owns all of the stock of F Corporation and G Corporation. Parent, F Corporation, and G Corporation are all members of the Parent consolidated group. G Corporation has a depreciable interest in Equipment #3. No other members of the Parent consolidated group ever had a depreciable interest in Equipment #3. X Corporation is the common parent of a consolidated group and is not related, within the meaning of section 179(d)(2)(A) or (B) and § 1.179–4(c), to any member of the Parent consolidated group. No member of the X consolidated group ever had a depreciable interest in Equipment #3. In a series of related transactions, G Corporation sells Equipment #3 to F Corporation, and Parent sells all of the stock of F Corporation to X Corporation.

(ii) F Corporation was a member of the Parent consolidated group at the time it acquired Equipment #3 from G Corporation, another member of the group. Paragraph (b)(3)(iii)(B)(*3*)(*i*) of this section generally treats each member of a consolidated group as having a depreciable interest in property during the time any member of the group had a depreciable interest in such property while a member of the group. Nevertheless, because there is a series of related transactions that includes the acquisition of Equipment #3 and a transaction in which F Corporation, the transferee of the property, leaves the Parent consolidated group and joins the X consolidated group, the time to test whether F Corporation is a member of the Parent consolidated group for purposes of paragraph (b)(3)(iii)(B)(*3*)(*i*) of this section is met is immediately after the last transaction in the series, that is, the sale of the F Corporation stock to X Corporation. See paragraph (b)(3)(iii)(B)(*3*)(*iii*) of this section. Accordingly, because F Corporation is not a member of the Parent consolidated group after the last transaction of the series, F Corporation is not treated as previously having a depreciable interest in Equipment #3 by virtue of G Corporation's depreciable interest in Equipment #3 under paragraph (b)(3)(iii)(B)(*3*)(*i*) of this section.

(iii) After the sale of the F Corporation stock to X Corporation, F Corporation is a member of the X consolidated group. Because no member of the X consolidated group previously had a depreciable interest in Equipment #3, F Corporation is not treated as previously having a depreciable interest in Equipment #3 under paragraph (b)(3)(iii)(B)(*3*)(*i*) of this section.

(iv) Because relatedness is tested after F Corporation leaves the Parent consolidated group, F Corporation and G Corporation are not related within the meaning of section 179(d)(2)(A) or (B) and § 1.179–4(c). Accordingly, F Corporation's acquisition of Equipment #3 satisfies the used property acquisition requirements of paragraph (b)(3)(iii)(A)(*1*) of this section and, assuming all other requirements are met, F Corporation's acquisition of Equipment #3 is eligible for the additional first year depreciation deduction.

Example 22. (i) H Corporation, which is not a member of a consolidated group, has a depreciable interest in Equipment #4. Parent owns all the stock of I Corporation, and Parent and I Corporation are members of the Parent consolidated group. No member of the Parent consolidated group ever had a depreciable interest in Equipment #4. Neither Parent nor I Corporation is related to H Corporation within the meaning of section 179(d)(2)(A) or (B) and § 1.179–4(c). During 2018, H Corporation sells Equipment #4 to a person not related to H Corporation, Parent, or I Corporation within the meaning of section 179(d)(2)(A) or (B) and § 1.179–4(c). In a series of related transactions, during 2019, Parent acquires all of the stock of H Corporation, and I Corporation purchases Equipment #4 from an unrelated person.

(ii) In a series of related transactions, H Corporation became a member of the Parent consolidated group, and I Corporation, also a member of the Parent consolidated group, acquired Equipment #4. Because H Corporation previously had a depreciable interest in Equipment #4, pursuant to paragraph (b)(3)(iii)(B)(*3*)(*ii*) of this section, I Corporation is treated as having a depreciable interest in Equipment #4. As a result, I Corporation's acquisition of Equipment #4 does not satisfy the used property acquisition requirements of paragraph (b)(3)(iii) of this section. Accordingly, I Corporation's acquisition of Equipment #4 is not eligible for the additional first year depreciation deduction.

Example 23. (i) J Corporation, K Corporation, and L Corporation are unrelated parties within the meaning of section 179(d)(2)(A) or (B) and § 1.179–4(c). None of J Corporation, K Corporation, and L Corporation is a member of a consolidated group. J Corporation has a depreciable interest in Equipment #5. During 2018, J Corporation sells Equipment #5 to K Corporation. During 2020, J Corporation merges into L Corporation in a transaction described in section 368(a)(1)(A). In 2021, L Corporation acquires Equipment #5 from K Corporation.

(ii) Because J Corporation is the predecessor of L Corporation and J Corporation previously had a depreciable interest in Equipment #5, L Corporation's acquisition of Equipment #5 does not satisfy paragraphs (b)(3)(iii)(A)(*1*) and (b)(3)(iii)(B)(*1*) of this section and, thus, does not satisfy the used property acquisition requirements of paragraph (b)(3)(iii) of this section. Accordingly, L Corporation's acquisition of Equipment #5 is not eligible for the additional first year depreciation deduction.

Example 24. (i) M Corporation acquires and places in service a used airplane on March 26, 2018. Prior to this acquisition, M Corporation never had a depreciable interest in this airplane. On March 26, 2018, M Corporation also leases the used airplane to N Corporation, an airline company. On May 27, 2018, M Corporation sells to O Corporation the used airplane subject to the lease with N Corporation. M Corporation and O Corporation are related parties within the meaning of section 179(d)(2)(A) or (B) and § 1.179–4(c). As of May 27, 2018, N Corporation is still the lessee of the used airplane. Prior to this acquisition, O Corporation never had a depreciable interest in the used airplane. O Corporation is a calendar-year taxpayer.

(ii) The sale transaction of May 27, 2018, satisfies the requirements of paragraph (b)(3)(v) of this section. As a result, O Corporation is considered the taxpayer that acquired the used airplane for purposes of applying the used property acquisition requirements in paragraph (b)(3)(iii) of this section. In applying these rules, the fact that M Corporation and O Corporation are related parties is not taken into account because O Corporation, not M Corporation, is treated as acquiring the used airplane. Further, pursuant to paragraph (b)(4)(iv) of this section, the used airplane is treated as originally placed in service by O Corporation on May 27, 2018. Because O Corporation never had a depreciable interest in the used airplane and assuming all other requirements are met, O Corporation's purchase price of the used airplane qualifies for the 100-percent additional first year depreciation deduction for O Corporation.

Example 25. (i) The facts are the same as in *Example 24* of this paragraph (b)(3)(vi). Additionally, on September 5, 2018, O Corporation sells to P Corporation the used airplane subject to the lease with N Corporation. Prior to this acquisition, P Corporation never had a depreciable interest in the used airplane.

(ii) Because O Corporation, a calendar-year taxpayer, placed in service and disposed of the used airplane during 2018, the used airplane is not eligible for the additional first year depreciation deduction for O Corporation pursuant to paragraph (f)(1)(i) of this section.

(iii) Because P Corporation never had a depreciable interest in the used airplane and assuming all other requirements are met, P Corporation's purchase price of the used airplane qualifies for the 100-percent additional first year depreciation deduction for P Corporation.

(4) *Placed-in-service date*—(i) *In general.* Depreciable property will meet the requirements of this paragraph (b)(4) if the property is placed in service by the taxpayer for use in its trade or business or for production of income after September 27, 2017; and, except as provided in paragraphs (b)(2)(i)(A) and (D) of this section, before January 1, 2027, or, in the case of property described in section 168(k)(2)(B) or (C), before January 1, 2028.

(ii) *Specified plant.* If the taxpayer has properly made an election to apply section 168(k)(5) for a specified plant, the requirements of this paragraph (b)(4) are satisfied only if the specified plant is planted before January 1, 2027, or is grafted before January 1, 2027, to a plant that has already been planted, by the

taxpayer in the ordinary course of the taxpayer's farming business, as defined in section 263A(e)(4).

(iii) *Qualified film, television, or live theatrical production*—(A) For purposes of this paragraph (b)(4), a qualified film or television production is treated as placed in service at the time of initial release or broadcast as defined under § 1.181–1(a)(7).

(B) For purposes of this paragraph (b)(4), a qualified live theatrical production is treated as placed in service at the time of the initial live staged performance. Solely for purposes of this paragraph, the term *initial live staged performance* means the first commercial exhibition of a production to an audience. However, the term *initial live staged performance* does not include limited exhibition, prior to commercial exhibition to general audiences, if the limited exhibition is primarily for purposes of publicity, determining the need for further production activity, or raising funds for the completion of production. For example, an initial live staged performance does not include a preview of the production if the preview is primarily to determine the need for further production activity.

(iv) *Syndication transaction.* If a lessor has a depreciable interest in the property and the lessor and any predecessor did not previously have a depreciable interest in the property, and the property is sold by the lessor or any subsequent purchaser within three months after the date the property was originally placed in service by the lessor (or, in the case of multiple units of property subject to the same lease, within three months after the date the final unit is placed in service, so long as the period between the time the first unit is placed in service and the time the last unit is placed in service does not exceed 12 months), and the user of the property after the last sale during this three-month period remains the same as when the property was originally placed in service by the lessor, the property is treated as originally placed in service by the purchaser of the property in the last sale during the three-month period but not earlier than the date of the last sale.

(v) *Technical termination of a partnership.* For purposes of this paragraph (b)(4), in the case of a technical termination of a partnership under section 708(b)(1)(B) occurring in a taxable year beginning before January 1, 2018, qualified property placed in service by the terminated partnership during the taxable year of termination is treated as originally placed in service by the new partnership on the date the qualified property is contributed by the terminated partnership to the new partnership.

(vi) *Section 168(i)(7) transactions.* For purposes of this paragraph (b)(4), if qualified property is transferred in a transaction described in section 168(i)(7) in the same taxable year that the qualified property is placed in service by the transferor, the transferred property is treated as originally placed in service on the date the transferor placed in service the qualified property. In the case of multiple transfers of qualified property in multiple transactions described in section 168(i)(7) in the same taxable year, the placed-in-service date of the transferred property is deemed to be the date on which the first transferor placed in service the qualified property.

(5) *Acquisition of property*—(i) *In general.* This paragraph (b)(5) provides rules for the acquisition requirements in section 13201(h) of the Act. These rules apply to all property, including self-constructed property or property described in section 168(k)(2)(B) or (C).

(ii) *Acquisition date.* Except as provided in paragraph (b)(5)(vi) of this section, depreciable property will meet the requirements of this paragraph (b)(5) if the property is acquired by the taxpayer after September 27, 2017, or is acquired by the taxpayer pursuant to a written binding contract entered into by the taxpayer after September 27, 2017. Property that is manufactured, constructed, or produced for the taxpayer by another person under a written binding contract that is entered into prior to the manufacture, construction, or production of the property for use by the taxpayer in its trade or business or for its production of income is acquired pursuant to a written binding contract. If a taxpayer acquired the property pursuant to a written binding contract and such contract states the date on which the contract was entered into and a closing date, delivery date, or other similar date, the date on which the contract was entered into is the date the taxpayer acquired the property. See paragraph (b)(5)(v) of this section for when a qualified film, television, or live theatrical production is treated as acquired for purposes of this paragraph (b)(5).

(iii) *Definition of binding contract*—(A) *In general.* A contract is binding only if it is enforceable under State law against the taxpayer or a predecessor, and does not limit damages to a specified amount (for example, by use of a liquidated damages provision). For this purpose, a contractual provision that limits damages to an amount equal to at least 5 percent of the total contract price will not be treated as limiting damages to a specified amount. In determining whether a contract limits damages, the fact that there may be little or no damages because the contract price does not significantly differ from fair market value will not be taken into account. For example, if a taxpayer entered into an irrevocable written contract to purchase an asset for $100 and the contract did not contain a provision for liquidated damages, the contract is considered binding notwithstanding the fact that the asset had a fair market value of $99 and under local law the seller would only recover the difference in the event the purchaser failed to perform. If the contract provided for a full refund of the purchase price in lieu of any damages allowable by law in the event of breach or cancellation, the contract is not considered binding.

(B) *Conditions.* A contract is binding even if subject to a condition, as long as the condition is not within the control of either party or a predecessor. A contract will continue to be binding if the parties make insubstantial changes in its terms and conditions or if any term is to be determined by a standard beyond the control of either party. A contract that imposes significant obligations on the taxpayer or a predecessor will be treated as binding notwithstanding the fact that certain terms remain to be negotiated by the parties to the contract.

(C) *Options.* An option to either acquire or sell property is not a binding contract.

(D) *Letter of intent.* A letter of intent for an acquisition is not a binding contract.

(E) *Supply agreements.* A binding contract does not include a supply or similar agreement if the amount and design specifications of the property to be purchased have not been specified. The contract will not be a binding contract for the property to be purchased until both the amount and the design specifications are specified. For example, if the provisions of a supply or similar agreement state the design specifications of the property to be purchased, a purchase order under the agreement for a specific number of assets is treated as a binding contract.

(F) *Components.* A binding contract to acquire one or more components of a larger property will not be treated as a binding contract to acquire the larger property. If a binding contract to acquire the component does not satisfy the requirements of this paragraph (b)(5), the component does not qualify for the additional first year depreciation deduction.

(iv) *Self-constructed property*—(A) *In general.* If a taxpayer manufactures, constructs, or produces property for use by the taxpayer in its trade or business or for its production of income, the acquisition rules in paragraph (b)(5)(ii) of this section are treated as met for the property if the taxpayer begins manufacturing, constructing, or producing the property after September 27, 2017. This paragraph (b)(5)(iv) does not apply to property that is manufactured, constructed, or produced for the taxpayer by another person under a written binding contract that is entered into prior to the manufacture, construction, or production of the property for use by the taxpayer in its trade or business or for its production of income (for further guidance, see paragraphs (b)(5)(ii) and (iii) of this section).

(B) *When does manufacture, construction, or production begin*—(*1*) *In general.* For purposes of paragraph (b)(5)(iv)(A) of this section, manufacture, construction, or production of property begins when physical work of a significant nature begins. Physical work does not include preliminary activities such as planning or designing, securing financing, exploring, or researching. The determination of when physical work of a significant nature begins depends on the facts and circumstances. For example, if the taxpayer constructs a retail motor fuels outlet on-site for use by the taxpayer in its trade or business, construction begins when physical work of a significant nature commences at the site by the taxpayer; that is, when work begins on the excavation for footings, pouring the pads for the outlet, or the driving of foundation pilings into the ground. Preliminary work, such as clearing a site, test drilling to determine soil condition, or excavation to change the contour of the land (as distinguished from excavation for footings) does not constitute the beginning of construction. However, if the taxpayer assembles a retail motor fuels outlet on-site from modular units manufactured off-site by the taxpayer and delivered to the site where the outlet will be used, manufacturing begins when physical work of a significant nature commences at the off-site location by the taxpayer.

(*2*) *Safe harbor.* For purposes of paragraph (b)(5)(iv)(B)(*1*) of this section, a taxpayer may choose to determine when physical work of a significant nature begins in accordance with this paragraph (b)(5)(iv)(B)(*2*). Physical work of a significant nature will be considered to begin at the time the taxpayer incurs (in the case of an accrual basis taxpayer) or pays (in the case of a cash basis taxpayer) more than 10 percent of the total cost of the property (excluding the cost of any land and preliminary activities such as planning or designing, securing financing, exploring, or researching). A taxpayer chooses to apply this paragraph (b)(5)(iv)(B)(*2*) by filing a federal income tax return for the placed-in-service year of the property that determines when physical work of a significant nature begins consistent with this paragraph (b)(5)(iv)(B)(*2*).

(C) *Components of self-constructed property*—(*1*) *Acquired components.* If a binding contract, as defined in paragraph (b)(5)(iii) of this section, to acquire a component does not satisfy the requirements of paragraph (b)(5)(ii) of this section, the component does not qualify for the additional first year depreciation deduction. A binding contract described in the preceding sentence to acquire one or more components of a larger self-constructed property will not preclude the larger self-constructed property from satisfying the acquisition rules in paragraph (b)(5)(iv)(A) of this section. Accordingly, the unadjusted depreciable basis of the larger self-constructed property that is eligible for the additional first year depreciation deduction, assuming all other requirements are met, must not include the unadjusted depreciable basis of any component that does not satisfy the requirements of paragraph (b)(5)(ii) of this section. If the manufacture, construction, or production of the larger self-constructed property begins before September 28, 2017, the larger self-constructed property and any acquired components related to the larger self-constructed property do not qualify for the additional first year depreciation deduction under this section.

(*2*) *Self-constructed components.* If the manufacture, construction, or production of a component by the taxpayer does not satisfy the requirements of this paragraph (b)(5)(iv), the component does not qualify for the additional first year depreciation deduction. However, if the manufacture, construction, or production of a component does not satisfy the requirements of this paragraph (b)(5)(iv), but the manufacture, construction, or production of the larger self-constructed property satisfies the requirements of this paragraph (b)(5)(iv), the larger self-constructed property qualifies for the additional first year depreciation deduction, assuming all other requirements are met, even though the component does not qualify for the additional first year depreciation deduction. Accordingly, the unadjusted depreciable basis of the larger self-constructed property that is eligible for the additional first year depreciation deduction, assuming all other requirements are met, must not include the unadjusted depreciable basis of any component that does not qualify for the additional first year depreciation deduction. If the manufacture, construction, or production of the larger self-constructed property began before September 28, 2017, the larger self-constructed property and any self-constructed components related to the larger self-constructed property do not qualify for the additional first year depreciation deduction under this section.

(v) *Qualified film, television, or live theatrical production*—(A) For purposes of section 13201(h)(1)(A) of the Act, a qualified film or television production is treated as acquired on the date principal photography commences.

(B) For purposes of section 13201(h)(1)(A) of the Act, a qualified live theatrical production is treated as acquired on the date when all of the necessary elements for producing the live theatrical production are secured. These elements may include a script, financing, actors, set, scenic and costume designs, advertising agents, music, and lighting.

(vi) *Specified plant.* If the taxpayer has properly made an election to apply section 168(k)(5) for a specified plant, the requirements of this paragraph (b)(5) are satisfied if the specified plant is planted after September 27, 2017, or is grafted after September 27, 2017, to a plant that has already been planted, by the taxpayer in the ordinary course of the taxpayer's farming business, as defined in section 263A(e)(4).

(vii) *Examples.* The application of this paragraph (b)(5) is illustrated by the following examples. Unless the facts specifically indicate otherwise, assume that the parties are not related within the meaning of section 179(d)(2)(A) or (B) and § 1.179–4(c), and the parties do not have predecessors:

Example 1. On September 1, 2017, *BB,* a corporation, entered into a written agreement with *CC,* a manufacturer, to purchase 20 new lamps for $100 each within the next two years. Although the agreement specifies the number of lamps to be purchased, the agreement does not specify the design of the lamps to be purchased. Accordingly, the agreement is not a binding contract pursuant to paragraph (b)(5)(iii)(E) of this section.

Example 2. The facts are the same as in *Example 1* of this paragraph (b)(5)(vii). On December 1, 2017, *BB* placed a purchase order with *CC* to purchase 20 new model XPC5 lamps for $100 each for a total amount of $2,000. Because the agreement specifies the number of lamps to be purchased and the

purchase order specifies the design of the lamps to be purchased, the purchase order placed by *BB* with *CC* on December 1, 2017, is a binding contract pursuant to paragraph (b)(5)(iii)(E) of this section. Accordingly, assuming all other requirements are met, the cost of the 20 lamps qualifies for the 100-percent additional first year depreciation deduction.

Example 3. The facts are the same as in *Example 1* of this paragraph (b)(5)(vii), except that the written agreement between *BB* and *CC* is to purchase 100 model XPC5 lamps for $100 each within the next two years. Because this agreement specifies the amount and design of the lamps to be purchased, the agreement is a binding contract pursuant to paragraph (b)(5)(iii)(E) of this section. However, because the agreement was entered into before September 28, 2017, no lamp acquired by *BB* under this contract qualifies for the 100-percent additional first year depreciation deduction.

Example 4. On September 1, 2017, *DD* began constructing a retail motor fuels outlet for its own use. On November 1, 2018, *DD* ceases construction of the retail motor fuels outlet prior to its completion. Between September 1, 2017, and November 1, 2018, *DD* incurred $3,000,000 of expenditures for the construction of the retail motor fuels outlet. On May 1, 2019, *DD* resumed construction of the retail motor fuels outlet and completed its construction on August 31, 2019. Between May 1, 2019, and August 31, 2019, *DD* incurred another $1,600,000 of expenditures to complete the construction of the retail motor fuels outlet and, on September 1, 2019, *DD* placed the retail motor fuels outlet in service. None of *DD*'s total expenditures of $4,600,000 qualify for the 100-percent additional first year depreciation deduction because, pursuant to paragraph (b)(5)(iv)(A) of this section, *DD* began constructing the retail motor fuels outlet before September 28, 2017.

Example 5. The facts are the same as in *Example 4* of this paragraph (b)(5)(vii) except that *DD* began constructing the retail motor fuels outlet for its own use on October 1, 2017, and *DD* incurred the $3,000,000 between October 1, 2017, and November 1, 2018. *DD*'s total expenditures of $4,600,000 qualify for the 100-percent additional first year depreciation deduction because, pursuant to paragraph (b)(5)(iv)(A) of this section, *DD* began constructing the retail motor fuels outlet after September 27, 2017, and *DD* placed the retail motor fuels outlet in service on September 1, 2019. Accordingly, assuming all other requirements are met, the additional first year depreciation deduction for the retail motor fuels outlet will be $4,600,000, computed as $4,600,000 multiplied by 100 percent.

Example 6. On August 15, 2017, *EE* entered into a written binding contract with *FF* to manufacture an aircraft described in section 168(k)(2)(C) for use in *EE*'s trade or business. *FF* begins to manufacture the aircraft on October 1, 2017. *EE* places the aircraft in service on March 1, 2018. Pursuant to paragraph (b)(5)(ii) of this section, the aircraft is acquired by *EE* pursuant to a written binding contract. Because *EE* entered into such contract before September 28, 2017, the aircraft does not qualify for the 100-percent additional first year depreciation deduction.

Example 7. On June 1, 2017, *HH* entered into a written binding contract to acquire a new component part of property that is being constructed by *HH* for its own use in its trade or business. *HH* commenced construction of the property in November 2017, and placed the property in service in November 2018. Because *HH* entered into a written binding contract to acquire a component part prior to September 28, 2017, pursuant to paragraphs (b)(5)(ii) and (b)(5)(iv)(C)(*1*) of this section, the component part does not qualify for the 100-percent additional first year depreciation deduction. However, pursuant to paragraphs (b)(5)(iv)(A) and (b)(5)(iv)(C)(*1*) of this section, the property constructed by *HH* will qualify for the 100-percent additional first year depreciation deduction, because construction of the property began after September 27, 2017, assuming all other requirements are met. Accordingly, the unadjusted depreciable basis of the property that is eligible for the 100-percent additional first year depreciation deduction must not include the unadjusted depreciable basis of the component part.

Example 8. The facts are the same as in *Example 7* of this paragraph (b)(5)(vii) except that *HH* entered into the written binding contract to acquire the new component part on September 30, 2017, and *HH* commenced construction of the property on August 1, 2017. Pursuant to paragraphs (b)(5)(iv)(A) and (C) of this section, neither the property constructed by *HH* nor the component part will qualify for the 100-percent additional first year depreciation deduction, because *HH* began construction of the property prior to September 28, 2017.

Example 9. On September 1, 2017, *II* acquired and placed in service equipment. On October 15, 2017, *II* sells the equipment to *JJ* and leases the property back from *JJ* in a sale-leaseback transaction. Pursuant to paragraph (b)(5)(ii) of this section, *II*'s cost of the equipment does not qualify for the 100-percent additional first year depreciation deduction because *II* acquired the equipment prior to September 28, 2017. However, *JJ* acquired used equipment from an unrelated party after September 27, 2017, and, assuming all other requirements are met, *JJ*'s cost of the used equipment does qualify for the 100-percent additional first year depreciation deduction for *JJ.*

Example 10. On July 1, 2017, *KK* began constructing property for its own use in its trade or business. *KK* placed this property in service on September 15, 2017. On October 15, 2017, *KK* sells the property to *LL* and leases the property back from *LL* in a sale-leaseback transaction. Pursuant to paragraph (b)(5)(iv) of this section, *KK*'s cost of the property does not qualify for the 100-percent additional first year depreciation deduction because construction began prior to September 28, 2017. However, *LL* acquired used property from an unrelated party after September 27, 2017, and, assuming all other requirements are met, *LL*'s cost of the used property does qualify for the 100-percent additional first year depreciation deduction for *LL.*

(c) *Property described in section 168(k)(2)(B) or (C)*—(1) *In general.* Property described in section 168(k)(2)(B) or (C) will meet the acquisition requirements of section 168(k)(2)(B)(i)(III) or (k)(2)(C)(i) if the property is acquired by the taxpayer before January 1, 2027, or acquired by the taxpayer pursuant to a written binding contract that is entered into before January 1, 2027. Property described in section 168(k)(2)(B) or (C) also must meet the acquisition requirement in section 13201(h)(1)(A) of the Act (for further guidance, see paragraph (b)(5) of this section).

(2) *Definition of binding contract.* For purposes of this paragraph (c), the rules in paragraph (b)(5)(iii) of this section for a binding contract apply.

(3) *Self-constructed property*—(i) *In general.* If a taxpayer manufactures, constructs, or produces property for use by the taxpayer in its trade or business or for its production of income, the acquisition rules in paragraph (c)(1) of this section are treated as met for the property if the taxpayer begins manufacturing, constructing, or producing the property before January 1, 2027. Property that is manufactured, constructed, or produced for the taxpayer by another person under a written binding contract, as defined in paragraph (b)(5)(iii) of this section, that is entered into prior to the manufacture, construction, or production of the property for use by the taxpayer in its trade or business or for its production of income is considered to be manufactured, constructed, or produced by the taxpayer. If a taxpayer enters into a written binding contract, as defined in paragraph (b)(5)(iii) of this section, before January 1, 2027, with another person to manufacture, construct, or produce property described in section 168(k)(2)(B) or (C) and the manufacture, construction, or production of this property begins after December 31, 2026, the acquisition rule in paragraph (c)(1) of this section is met.

(ii) *When does manufacture, construction, or production begin*—(A) *In general.* For purposes of this paragraph (c)(3), manufacture, construction, or production of property begins when physical work of a significant nature begins. Physical work does not include preliminary activities such as planning or designing, securing financing, exploring, or researching. The determination of when physical work of a significant nature begins depends on the facts and circumstances. For example, if a retail motor fuels outlet is to be constructed on-site, construction begins when physical work of a significant nature commences at the

site; that is, when work begins on the excavation for footings, pouring the pads for the outlet, or the driving of foundation pilings into the ground. Preliminary work, such as clearing a site, test drilling to determine soil condition, or excavation to change the contour of the land (as distinguished from excavation for footings) does not constitute the beginning of construction. However, if a retail motor fuels outlet is to be assembled on-site from modular units manufactured off-site and delivered to the site where the outlet will be used, manufacturing begins when physical work of a significant nature commences at the off-site location.

(B) *Safe harbor.* For purposes of paragraph (c)(3)(ii)(A) of this section, a taxpayer may choose to determine when physical work of a significant nature begins in accordance with this paragraph (c)(3)(ii)(B). Physical work of a significant nature will be considered to begin at the time the taxpayer incurs (in the case of an accrual basis taxpayer) or pays (in the case of a cash basis taxpayer) more than 10 percent of the total cost of the property (excluding the cost of any land and preliminary activities such as planning or designing, securing financing, exploring, or researching). When property is manufactured, constructed, or produced for the taxpayer by another person, this safe harbor test must be satisfied by the taxpayer. For example, if a retail motor fuels outlet is to be constructed for an accrual basis taxpayer by another person for the total cost of $200,000 (excluding the cost of any land and preliminary activities such as planning or designing, securing financing, exploring, or researching), construction is deemed to begin for purposes of this paragraph (c)(3)(ii)(B) when the taxpayer has incurred more than 10 percent (more than $20,000) of the total cost of the property. A taxpayer chooses to apply this paragraph (c)(3)(ii)(B) by filing a federal income tax return for the placed-in-service year of the property that determines when physical work of a significant nature begins consistent with this paragraph (c)(3)(ii)(B).

(iii) *Components of self-constructed property*—(A) *Acquired components.* If a binding contract, as defined in paragraph (b)(5)(iii) of this section, to acquire a component does not satisfy the requirements of paragraph (c)(1) of this section, the component does not qualify for the additional first year depreciation deduction. A binding contract described in the preceding sentence to acquire one or more components of a larger self-constructed property will not preclude the larger self-constructed property from satisfying the acquisition rules in paragraph (c)(3)(i) of this section. Accordingly, the unadjusted depreciable basis of the larger self-constructed property that is eligible for the additional first year depreciation deduction, assuming all other requirements are met, must not include the unadjusted depreciable basis of any component that does not satisfy the requirements of paragraph (c)(1) of this section. If a binding contract to acquire the component is entered into before January 1, 2027, but the manufacture, construction, or production of the larger self-constructed property does not begin before January 1, 2027, the component qualifies for the additional first year depreciation deduction, assuming all other requirements are met, but the larger self-constructed property does not.

(B) *Self-constructed components.* If the manufacture, construction, or production of a component by the taxpayer does not satisfy the requirements of paragraph (c)(3)(i) of this section, the component does not qualify for the additional first year depreciation deduction. However, if the manufacture, construction, or production of a component does not satisfy the requirements of paragraph (c)(3)(i) of this section, but the manufacture, construction, or production of the larger self-constructed property satisfies the requirements of paragraph (c)(3)(i) of this section, the larger self-constructed property qualifies for the additional first year depreciation deduction, assuming all other requirements are met, even though the component does not qualify for the additional first year depreciation deduction. Accordingly, the unadjusted depreciable basis of the larger self-constructed property that is eligible for the additional first year depreciation deduction, assuming all other requirements are met, must not include the unadjusted depreciable basis of any component that does not qualify for the additional first year depreciation deduction. If the manufacture, construction, or production of a component begins before January 1, 2027, but the manufacture, construction, or production of the larger self-constructed property does not begin before January 1, 2027, the component qualifies for the additional first year depreciation deduction, assuming all other requirements are met, but the larger self-constructed property does not.

(iv) *Examples.* The application of this paragraph (c) is illustrated by the following examples:

Example 1. On June 1, 2017, *MM* decided to construct property described in section 168(k)(2)(B) for its own use. However, one of the component parts of the property had to be manufactured by another person for *MM.* On August 15, 2017, *MM* entered into a written binding contract with *NN* to acquire this component part of the property for $100,000. The manufacture of the component part commenced on September 1, 2018, and *MM* received the completed component part on February 1, 2020. The cost of this component part is 9 percent of the total cost of the property to be constructed by *MM. MM* began constructing the property described in section 168(k)(2)(B) on January 15, 2020, and placed this property, including all component parts, in service on November 1, 2021. Pursuant to paragraphs (b)(5)(iv)(C)(*1*) and (c)(1) of this section, the component part of $100,000 manufactured by *NN* for *MM* is not eligible for the 100-percent additional first year depreciation deduction because the written binding contract to acquire such component part was entered into before September 28, 2017. However, pursuant to paragraph (c)(3)(i) of this section, the cost of the property described in section 168(k)(2)(B), excluding the cost of the component part of $100,000 manufactured by *NN* for *MM,* is eligible for the 100-percent additional first year depreciation deduction, assuming all other requirements are met, because construction of the property began after September 27, 2017, and before January 1, 2027, and the property described in section 168(k)(2)(B) was placed in service by *MM* before January 1, 2028.

Example 2. On June 1, 2026, *OO* decided to construct property described in section 168(k)(2)(B) for its own use. However, one of the component parts of the property had to be manufactured by another person for *OO.* On August 15, 2026, *OO* entered into a written binding contract with *PP* to acquire this component part of the property for $100,000. The manufacture of the component part commenced on September 1, 2026, and *OO* received the completed component part on February 1, 2027. The cost of this component part is 9 percent of the total cost of the property to be constructed by *OO. OO* began constructing the property described in section 168(k)(2)(B) on January 15, 2027, and placed this property, including all component parts, in service on November 1, 2027. Pursuant to paragraph (c)(3)(iii)(B) of this section, the self-constructed component part of $100,000 manufactured by *PP* for *OO* is eligible for the additional first year depreciation deduction, assuming all other requirements are met, because the manufacturing of the component part began before January 1, 2027, and the property described in section 168(k)(2)(B), the larger self-constructed property, was placed in service by *OO* before January 1, 2028. However, pursuant to paragraph (c)(3)(i) of this section, the cost of the property described in section 168(k)(2)(B), excluding the cost of the self-constructed component part of $100,000 manufactured by *PP* for *OO,* is not eligible for the additional first year depreciation deduction because construction of the property began after December 31, 2026.

Example 3. On December 1, 2026, *QQ* entered into a written binding contract, as defined in paragraph (b)(5)(iii) of this section, with *RR* to manufacture an aircraft described in section 168(k)(2)(C) for use in *QQ*'s trade or business. *RR* begins to manufacture the aircraft on February 1, 2027. *QQ* places the aircraft in service on August 1, 2027. Pursuant to paragraph (c)(3)(i) of this section, the aircraft meets the requirements of paragraph (c)(1) of this section because the aircraft was acquired by *QQ* pursuant to a written binding contract entered into before January 1, 2027. Further, the aircraft was placed in service by *QQ* before January 1, 2028. Thus, assuming all other requirements are met, *QQ*'s cost of the aircraft is eligible for the additional first year depreciation deduction.

(d) *Computation of depreciation deduction for qualified property*—(1) *Additional first year depreciation deduction*—(i) *Allowable taxable year.* The additional first year depreciation deduction is allowable—

(A) Except as provided in paragraph (d)(1)(i)(B) or (f) of this section, in the taxable year in which the qualified property is placed in service by the taxpayer for use in its trade or business or for the production of income; or

(B) In the taxable year in which the specified plant is planted, or grafted to a plant that has already been planted, by the taxpayer in the ordinary course of the taxpayer's farming business, as defined in section 263A(e)(4), if the taxpayer properly made the election to apply section 168(k)(5) (for further guidance, see paragraph (e) of this section).

(ii) *Computation.* Except as provided in paragraph (f)(5) of this section, the allowable additional first year depreciation deduction for qualified property is determined by multiplying the unadjusted depreciable basis, as defined in § 1.168(b)-1(a)(3), of the qualified property by the applicable percentage. Except as provided in paragraph (f)(1) of this section, the additional first year depreciation deduction is not affected by a taxable year of less than 12 months. See paragraph (f)(1) of this section for qualified property placed in service or planted or grafted, as applicable, and disposed of during the same taxable year. See paragraph (f)(5) of this section for qualified property acquired in a like-kind exchange or as a result of an involuntary conversion.

(iii) *Property described in section 168(k)(2)(B).* For purposes of paragraph (d)(1)(ii) of this section, the unadjusted depreciable basis, as defined in § 1.168(b)-1(a)(3), of qualified property described in section 168(k)(2)(B) is limited to the property's unadjusted depreciable basis attributable to the property's manufacture, construction, or production before January 1, 2027.

(iv) *Alternative minimum tax*—(A) *In general.* The additional first year depreciation deduction is allowable for alternative minimum tax purposes—

(*1*) Except as provided in paragraph (d)(1)(iv)(A)(*2*) of this section, in the taxable year in which the qualified property is placed in service by the taxpayer; or

(*2*) In the taxable year in which a specified plant is planted by the taxpayer, or grafted by the taxpayer to a plant that was previously planted, if the taxpayer properly made the election to apply section 168(k)(5) (for further guidance, see paragraph (e) of this section).

(B) *Special rules.* In general, the additional first year depreciation deduction for alternative minimum tax purposes is based on the unadjusted depreciable basis of the property for alternative minimum tax purposes. However, see paragraph (f)(5)(iii)(E) of this section for qualified property acquired in a like-kind exchange or as a result of an involuntary conversion.

(2) *Otherwise allowable depreciation deduction*—(i) *In general.* Before determining the amount otherwise allowable as a depreciation deduction for the qualified property for the placed-in-service year and any subsequent taxable year, the taxpayer must determine the remaining adjusted depreciable basis of the qualified property. This remaining adjusted depreciable basis is equal to the unadjusted depreciable basis, as defined in § 1.168(b)-1(a)(3), of the qualified property reduced by the amount of the additional first year depreciation allowed or allowable, whichever is greater. The remaining adjusted depreciable basis of the qualified property is then depreciated using the applicable depreciation provisions under the Internal Revenue Code for the qualified property. The remaining adjusted depreciable basis of the qualified property that is MACRS property is also the basis to which the annual depreciation rates in the optional depreciation tables apply (for further guidance, see section 8 of Rev. Proc. 87–57 (1987–2 C.B. 687) and § 601.601(d)(2)(ii)(*b*) of this chapter). The depreciation deduction allowable for the remaining adjusted depreciable basis of the qualified property is affected by a taxable year of less than 12 months.

(ii) *Alternative minimum tax.* For alternative minimum tax purposes, the depreciation deduction allowable for the remaining adjusted depreciable basis of the qualified property is based on the remaining adjusted depreciable basis for alternative minimum tax purposes. The remaining adjusted depreciable basis of the qualified property for alternative minimum tax purposes is depreciated using the same depreciation method, recovery period (or useful life in the case of computer software), and convention that apply to the qualified property for regular tax purposes.

(3) *Examples.* This paragraph (d) is illustrated by the following examples:

Example 1. On March 1, 2023, *SS,* a calendar-year taxpayer, purchased and placed in service qualified property that costs $1 million and is 5-year property under section 168(e). *SS* depreciates its 5-year property placed in service in 2023 using the optional depreciation table that corresponds with the general depreciation system, the 200-percent declining balance method, a 5-year recovery period, and the half-year convention. For 2023, *SS* is allowed an 80-percent additional first year depreciation deduction of $800,000 (the unadjusted depreciable basis of $1 million multiplied by 0.80). Next, *SS* must reduce the unadjusted depreciable basis of $1 million by the additional first year depreciation deduction of $800,000 to determine the remaining adjusted depreciable basis of $200,000. Then, *SS'* depreciation deduction allowable in 2023 for the remaining adjusted depreciable basis of $200,000 is $40,000 (the remaining adjusted depreciable basis of $200,000 multiplied by the annual depreciation rate of 0.20 for recovery year 1).

Example 2. On June 1, 2023, *TT,* a calendar-year taxpayer, purchased and placed in service qualified property that costs $1,500,000. The property qualifies for the expensing election under section 179 and is 5-year property under section 168(e). *TT* did not purchase any other section 179 property in 2023. *TT* makes the election under section 179 for the property and depreciates its 5-year property placed in service in 2023 using the optional depreciation table that corresponds with the general depreciation system, the 200-percent declining balance method, a 5-year recovery period, and the half-year convention. Assume the maximum section 179 deduction for 2023 is $1,000,000. For 2023, *TT* is first allowed a $1,000,000 deduction under section 179. Next, *TT* must reduce the cost of $1,500,000 by the section 179 deduction of $1,000,000 to determine the unadjusted depreciable basis of $500,000. Then, for 2023, *TT* is allowed an 80-percent additional first year depreciation deduction of $400,000 (the unadjusted depreciable basis of $500,000 multiplied by 0.80). Next, *TT* must reduce the unadjusted depreciable basis of $500,000 by the additional first year depreciation deduction of $400,000 to determine the remaining adjusted depreciable basis of $100,000. Then, *TT*'s depreciation deduction allowable in 2023 for the remaining adjusted depreciable basis of $100,000 is $20,000 (the remaining adjusted depreciable basis of $100,000 multiplied by the annual depreciation rate of 0.20 for recovery year 1).

(e) *Elections under section 168(k)*—(1) *Election not to deduct additional first year depreciation*—(i) *In general.* A taxpayer may make an election not to deduct the additional first year depreciation for any class of property that is qualified property placed in service during the taxable year. If this election is made, the election applies to all qualified property that is in the same class of property and placed in service in the same taxable year, and no additional first year depreciation deduction is allowable for the property placed in service during the taxable year in the class of property, except as provided in § 1.743–1(j)(4)(i)(B)(*1*).

(ii) *Definition of class of property.* For purposes of this paragraph (e)(1), the term *class of property* means:

(A) Except for the property described in paragraphs (e)(1)(ii)(B) and (D), and (e)(2) of this section, each class of property described in section 168(e) (for example, 5-year property);

(B) Water utility property as defined in section 168(e)(5) and depreciated under section 168;

(C) Computer software as defined in, and depreciated under, section 167(f)(1) and the regulations under section 167(f)(1);

(D) Qualified improvement property as defined in § 1.168(b)–1(a)(5)(i)(C) and (a)(5)(ii), and depreciated under section 168;

(E) Each separate production, as defined in § 1.181–3(b), of a qualified film or television production;

(F) Each separate production, as defined in section 181(e)(2), of a qualified live theatrical production; or

(G) A partner's basis adjustment in partnership assets under section 743(b) for each class of property described in paragraphs (e)(1)(ii)(A) through (F), and (e)(2) of this section (for further guidance, see § 1.743–1(j)(4)(i)(B)(*1*)).

(iii) *Time and manner for making election*—(A) *Time for making election.* Any election specified in paragraph (e)(1)(i) of this section must be made by the due date, including extensions, of the Federal tax return for the taxable year in which the qualified property is placed in service by the taxpayer.

(B) *Manner of making election.* Any election specified in paragraph (e)(1)(i) of this section must be made in the manner prescribed on Form 4562, ''Depreciation and Amortization,'' and its instructions. The election is made separately by each person owning qualified property (for example, for each member of a consolidated group by the common parent of the group, by the partnership (including basis adjustments in the partnership assets under section 743(b)), or by the S corporation). If Form 4562 is revised or renumbered, any reference in this section to that form shall be treated as a reference to the revised or renumbered form.

(iv) *Failure to make election.* If a taxpayer does not make the election specified in paragraph (e)(1)(i) of this section within the time and in the manner prescribed in paragraph (e)(1)(iii) of this section, the amount of depreciation allowable for that property under section 167(f)(1) or 168, as applicable, must be determined for the placed-in-service year and for all subsequent taxable years by taking into account the additional first year depreciation deduction. Thus, any election specified in paragraph (e)(1)(i) of this section shall not be made by the taxpayer in any other manner (for example, the election cannot be made through a request under section 446(e) to change the taxpayer's method of accounting).

(2) *Election to apply section 168(k)(5) for specified plants*—(i) *In general.* A taxpayer may make an election to apply section 168(k)(5) to one or more specified plants that are planted, or grafted to a plant that has already been planted, by the taxpayer in the ordinary course of the taxpayer's farming business, as defined in section 263A(e)(4). If this election is made for a specified plant, such plant is not treated as qualified property under section 168(k) and this section in its placed-in-service year.

(ii) *Time and manner for making election*—(A) *Time for making election.* Any election specified in paragraph (e)(2)(i) of this section must be made by the due date, including extensions, of the Federal tax return for the taxable year in which the taxpayer planted or grafted the specified plant to which the election applies.

(B) *Manner of making election.* Any election specified in paragraph (e)(2)(i) of this section must be made in the manner prescribed on Form 4562, ''Depreciation and Amortization,'' and its instructions. The election is made separately by each person owning specified plants (for example, for each member of a consolidated group by the common parent of the group, by the partnership, or by the S corporation). If Form 4562 is revised or renumbered, any reference in this section to that form shall be treated as a reference to the revised or renumbered form.

(iii) *Failure to make election.* If a taxpayer does not make the election specified in paragraph (e)(2)(i) of this section for a specified plant within the time and in the manner prescribed in paragraph (e)(2)(ii) of this section, the specified plant is treated as qualified property under section 168(k), assuming all requirements are met, in the taxable year in which such plant is placed in service by the taxpayer. Thus, any election specified in paragraph (e)(2)(i) of this section shall not be made by the taxpayer in any other manner (for example, the election cannot be made through a request under section 446(e) to change the taxpayer's method of accounting).

(3) *Election for qualified property placed in service during the 2017 taxable year*—(i) *In general.* A taxpayer may make an election to deduct 50 percent, instead of 100 percent, additional first year depreciation for all qualified property acquired after September 27, 2017, by the taxpayer and placed in service by the taxpayer during its taxable year that includes September 28, 2017. If a taxpayer makes an election to apply section 168(k)(5) for its taxable year that includes September 28, 2017, the taxpayer also may make an election to deduct 50 percent, instead of 100 percent, additional first year depreciation for all specified plants that are planted, or grafted to a plant that has already been planted, after September 27, 2017, by the taxpayer in the ordinary course of the taxpayer's farming business during such taxable year.

(ii) *Time and manner for making election*—(A) *Time for making election.* Any election specified in paragraph (e)(3)(i) of this section must be made by the due date, including extensions, of the Federal tax return for the taxpayer's taxable year that includes September 28, 2017.

(B) *Manner of making election.* Any election specified in paragraph (e)(3)(i) of this section must be made in the manner prescribed on the 2017 Form 4562, ''Depreciation and Amortization,'' and its instructions. The election is made separately by each person owning qualified property (for example, for each member of a consolidated group by the common parent of the group, by the partnership, or by the S corporation).

(iii) *Failure to make election.* If a taxpayer does not make the election specified in paragraph (e)(3)(i) of this section within the time and in the manner prescribed in paragraph (e)(3)(ii) of this section, the amount of depreciation allowable for qualified property under section 167(f)(1) or 168, as applicable, acquired and placed in service, or planted or grafted, as applicable, by the taxpayer after September 27, 2017, must be determined for the taxable year that includes September 28, 2017, and for all subsequent taxable years by taking into account the 100-percent additional first

year depreciation deduction, unless the taxpayer makes the election specified in paragraph (e)(1)(i) of this section within the time and in the manner prescribed in paragraph (e)(1)(iii) of this section for the class of property in which the qualified property is included. Thus, any election specified in paragraph (e)(3)(i) of this section shall not be made by the taxpayer in any other manner (for example, the election cannot be made through a request under section 446(e) to change the taxpayer's method of accounting).

(4) *Alternative minimum tax.* If a taxpayer makes an election specified in paragraph (e)(1) of this section for a class of property or in paragraph (e)(2) of this section for a specified plant, the depreciation adjustments under section 56 and the regulations under section 56 do not apply to the property or specified plant, as applicable, to which that election applies for purposes of computing the taxpayer's alternative minimum taxable income. If a taxpayer makes an election specified in paragraph (e)(3) of this section for all qualified property, see paragraphs (d)(1)(iv) and (d)(2)(ii) of this section.

(5) *Revocation of election*—(i) *In general.* Except as provided in paragraph (e)(5)(ii) of this section, an election specified in this paragraph (e), once made, may be revoked only by filing a request for a private letter ruling and obtaining the Commissioner of Internal Revenue's written consent to revoke the election. The Commissioner may grant a request to revoke the election if the taxpayer acted reasonably and in good faith, and the revocation will not prejudice the interests of the Government. See generally § 301.9100–3 of this chapter. An election specified in this paragraph (e) may not be revoked through a request under section 446(e) to change the taxpayer's method of accounting.

(ii) *Automatic 6-month extension.* If a taxpayer made an election specified in this paragraph (e), an automatic extension of 6 months from the due date of the taxpayer's Federal tax return, excluding extensions, for the placed-in-service year or the taxable year in which the specified plant is planted or grafted, as applicable, is granted to revoke that election, provided the taxpayer timely filed the taxpayer's Federal tax return for the placed-in-service year or the taxable year in which the specified plant is planted or grafted, as applicable, and, within this 6-month extension period, the taxpayer, and all taxpayers whose tax liability would be affected by the election, file an amended Federal tax return for the placed-in-service year or the taxable year in which the specified plant is planted or grafted, as applicable, in a manner that is consistent with the revocation of the election.

(f) *Special rules*—(1) *Property placed in service and disposed of in the same taxable year*—(i) *In general.* Except as provided in paragraphs (f)(1)(ii) and (iii) of this section, the additional first year depreciation deduction is not allowed for qualified property placed in service or planted or grafted, as applicable, and disposed of during the same taxable year. Also if qualified property is placed in service and disposed of during the same taxable year and then reacquired and again placed in service in a subsequent taxable year, the additional first year depreciation deduction is not allowable for the property in the subsequent taxable year.

(ii) *Technical termination of a partnership.* In the case of a technical termination of a partnership under section 708(b)(1)(B) in a taxable year beginning before January 1, 2018, the additional first year depreciation deduction is allowable for any qualified property placed in service or planted or grafted, as applicable, by the terminated partnership during the taxable year of termination and contributed by the terminated partnership to the new partnership. The allowable additional first year depreciation deduction for the qualified property shall not be claimed by the terminated partnership but instead shall be claimed by the new partnership for the new partnership's taxable year in which the qualified property was contributed by the terminated partnership to the new partnership. However, if qualified property is both placed in service or planted or grafted, as applicable, and contributed to a new partnership in a transaction described in section 708(b)(1)(B) by the terminated partnership during the taxable year of termination, and if such property is disposed of by the new partnership in the same taxable year the new partnership received such property from the terminated partnership, then no additional first year depreciation deduction is allowable to either partnership.

(iii) *Section 168(i)(7) transactions.* If any qualified property is transferred in a transaction described in section 168(i)(7) in the same taxable year that the qualified property is placed in service or planted or grafted, as applicable, by the transferor, the additional first year depreciation deduction is allowable for the qualified property. The allowable additional first year depreciation deduction for the qualified property for the transferor's taxable year in which the property is placed in service or planted or grafted, as applicable, is allocated between the transferor and the transferee on a monthly basis. This allocation shall be made in accordance with the rules in § 1.168(d)–1(b)(7)(ii) for allocating the depreciation deduction between the transferor and the transferee. However, solely for purposes of this section, if the qualified property is transferred in a section 721(a) transaction to a partnership that has as a partner a person, other than the transferor, who previously had a depreciable interest in the qualified property, in the same taxable year that the qualified property is placed in service or planted or grafted, as applicable, by the transferor, the allowable additional first year depreciation deduction is allocated entirely to the transferor, and not to the partnership. Additionally, if qualified property is both placed in service or planted or grafted, as applicable, and transferred in a transaction described in section 168(i)(7) by the transferor during the same taxable year, and if such property is disposed of by the transferee, other than by a transaction described in section 168(i)(7), during the same taxable year the transferee received such property from the transferor, then no additional first year depreciation deduction is allowable to either party.

(iv) *Examples.* The application of this paragraph (f)(1) is illustrated by the following examples:

Example 1. UU and *VV* are equal partners in *Partnership JL,* a general partnership. *Partnership JL* is a calendar-year taxpayer. On October 1, 2017, *Partnership JL* purchased and placed in service qualified property at a cost of $30,000. On November 1, 2017, *UU* sells its entire 50 percent interest to *WW* in a transfer that terminates the partnership under section 708(b)(1)(B). As a result, terminated *Partnership JL* is deemed to have contributed the qualified property to new *Partnership JL.* Pursuant to paragraph (f)(1)(ii) of this section, new *Partnership JL,* not terminated *Partnership JL,* is eligible to claim the 100-percent additional first year depreciation deduction allowable for the qualified property for the taxable year 2017, assuming all other requirements are met.

Example 2. On January 5, 2018, XX purchased and placed in service qualified property for a total amount of $9,000. On August 20, 2018, XX transferred this qualified property to Partnership BC in a transaction described in section 721(a). No other partner of Partnership BC has ever had a depreciable interest in the qualified property. XX and Partnership BC are calendar-year taxpayers. Because the transaction between XX and Partnership BC is a transaction described in section 168(i)(7), pursuant to paragraph (f)(1)(iii) of this section, the 100-percent additional first year

depreciation deduction allowable for the qualified property is allocated between XX and Partnership BC in accordance with the rules in § 1.168(d)–1(b)(7)(ii) for allocating the depreciation deduction between the transferor and the transferee. Accordingly, the 100-percent additional first year depreciation deduction allowable of $9,000 for the qualified property for 2018 is allocated between XX and Partnership BC based on the number of months that XX and Partnership BC held the qualified property in service during 2018. Thus, because the qualified property was held in service by XX for 7 of 12 months, which includes the month in which XX placed the qualified property in service but does not include the month in which the qualified property was transferred, XX is allocated $5,250 (7/12 × $9,000 additional first year depreciation deduction). Partnership BC is allocated $3,750, the remaining 5/12 of the $9,000 additional first year depreciation deduction allowable for the qualified property.

(2) *Redetermination of basis.* If the unadjusted depreciable basis, as defined in § 1.168(b)–1(a)(3), of qualified property is redetermined (for example, due to contingent purchase price or discharge of indebtedness) before January 1, 2027, or in the case of property described in section 168(k)(2)(B) or (C), is redetermined before January 1, 2028, the additional first year depreciation deduction allowable for the qualified property is redetermined as follows:

(i) *Increase in basis.* For the taxable year in which an increase in basis of qualified property occurs, the taxpayer shall claim an additional first year depreciation deduction for qualified property by multiplying the amount of the increase in basis for this property by the applicable percentage for the taxable year in which the underlying property was placed in service by the taxpayer. For purposes of this paragraph (f)(2)(i), the additional first year depreciation deduction applies to the increase in basis only if the underlying property is qualified property. To determine the amount otherwise allowable as a depreciation deduction for the increase in basis of qualified property, the amount of the increase in basis of the qualified property must be reduced by the additional first year depreciation deduction allowed or allowable, whichever is greater, for the increase in basis and the remaining increase in basis of—

(A) Qualified property, except for computer software described in paragraph (b)(2)(i)(B) of this section, is depreciated over the recovery period of the qualified property remaining as of the beginning of the taxable year in which the increase in basis occurs, and using the same depreciation method and convention applicable to the qualified property that applies for the taxable year in which the increase in basis occurs; and

(B) Computer software, as defined in paragraph (b)(2)(i)(B) of this section, that is qualified property is depreciated ratably over the remainder of the 36-month period, the useful life under section 167(f)(1), as of the beginning of the first day of the month in which the increase in basis occurs.

(ii) *Decrease in basis.* For the taxable year in which a decrease in basis of qualified property occurs, the taxpayer shall reduce the total amount otherwise allowable as a depreciation deduction for all of the taxpayer's depreciable property by the excess additional first year depreciation deduction previously claimed for the qualified property. If, for such taxable year, the excess additional first year depreciation deduction exceeds the total amount otherwise allowable as a depreciation deduction for all of the taxpayer's depreciable property, the taxpayer shall take into account a negative depreciation deduction in computing taxable income. The excess additional first year depreciation deduction for qualified property is determined by multiplying the amount of the decrease in basis for this property by the applicable percentage for the taxable year in which the underlying property was placed in service by the taxpayer. For purposes of this paragraph (f)(2)(ii), the additional first year depreciation deduction applies to the decrease in basis only if the underlying property is qualified property. Also, if the taxpayer establishes by adequate records or other sufficient evidence that the taxpayer claimed less than the additional first year depreciation deduction allowable for the qualified property before the decrease in basis, or if the taxpayer claimed more than the additional first year depreciation deduction allowable for the qualified property before the decrease in basis, the excess additional first year depreciation deduction is determined by multiplying the amount of the decrease in basis by the additional first year depreciation deduction percentage actually claimed by the taxpayer for the qualified property before the decrease in basis. To determine the amount to reduce the total amount otherwise allowable as a depreciation deduction for all of the taxpayer's depreciable property for the excess depreciation previously claimed, other than the additional first year depreciation deduction, resulting from the decrease in basis of the qualified property, the amount of the decrease in basis of the qualified property must be adjusted by the excess additional first year depreciation deduction that reduced the total amount otherwise allowable as a depreciation deduction, as determined under this paragraph (f)(2)(ii), and the remaining decrease in basis of—

(A) Qualified property, except for computer software described in paragraph (b)(2)(i)(B) of this section, reduces the amount otherwise allowable as a depreciation deduction over the recovery period of the qualified property remaining as of the beginning of the taxable year in which the decrease in basis occurs, and using the same depreciation method and convention of the qualified property that applies in the taxable year in which the decrease in basis occurs. If, for any taxable year, the reduction to the amount otherwise allowable as a depreciation deduction, as determined under this paragraph (f)(2)(ii)(A), exceeds the total amount otherwise allowable as a depreciation deduction for all of the taxpayer's depreciable property, the taxpayer shall take into account a negative depreciation deduction in computing taxable income; and

(B) Computer software, as defined in paragraph (b)(2)(i)(B) of this section, that is qualified property reduces the amount otherwise allowable as a depreciation deduction over the remainder of the 36-month period, the useful life under section 167(f)(1), as of the beginning of the first day of the month in which the decrease in basis occurs. If, for any taxable year, the reduction to the amount otherwise allowable as a depreciation deduction, as determined under this paragraph (f)(2)(ii)(B), exceeds the total amount otherwise allowable as a depreciation deduction for all of the taxpayer's depreciable property, the taxpayer shall take into account a negative depreciation deduction in computing taxable income.

(iii) *Definitions.* Except as otherwise expressly provided by the Internal Revenue Code (for example, section 1017(a)), the regulations under the Internal Revenue Code, or other guidance published in the Internal Revenue Bulletin for purposes of this paragraph (f)(2)—

(A) An increase in basis occurs in the taxable year an amount is taken into account under section 461; and

(B) A decrease in basis occurs in the taxable year an amount would be taken into account under section 451.

(iv) *Examples.* The application of this paragraph (f)(2) is illustrated by the following examples:

Example 1. (i) On May 15, 2023, YY, a cash-basis taxpayer, purchased and placed in

service qualified property that is 5-year property at a cost of $200,000. In addition to the $200,000, YY agrees to pay the seller 25 percent of the gross profits from the operation of the property in 2023. On May 15, 2024, YY paid to the seller an additional $10,000. YY depreciates the 5-year property placed in service in 2023 using the optional depreciation table that corresponds with the general depreciation system, the 200-percent declining balance method, a 5-year recovery period, and the half-year convention.

(ii) For 2023, YY is allowed an 80-percent additional first year depreciation deduction of $160,000 (the unadjusted depreciable basis of $200,000 multiplied by 0.80). In addition, YY's depreciation deduction for 2023 for the remaining adjusted depreciable basis of $40,000 (the unadjusted depreciable basis of $200,000 reduced by the additional first year depreciation deduction of $160,000) is $8,000 (the remaining adjusted depreciable basis of $40,000 multiplied by the annual depreciation rate of 0.20 for recovery year 1).

(iii) For 2024, *YY*'s depreciation deduction for the remaining adjusted depreciable basis of $40,000 is $12,800 (the remaining adjusted depreciable basis of $40,000 multiplied by the annual depreciation rate of 0.32 for recovery year 2). In addition, pursuant to paragraph (f)(2)(i) of this section, *YY* is allowed an additional first year depreciation deduction for 2024 for the $10,000 increase in basis of the qualified property. Consequently, *YY* is allowed an additional first year depreciation deduction of $8,000 (the increase in basis of $10,000 multiplied by 0.80, the applicable percentage for 2023). Also, *YY* is allowed a depreciation deduction for 2024 attributable to the remaining increase in basis of $2,000 (the increase in basis of $10,000 reduced by the additional first year depreciation deduction of $8,000). The depreciation deduction allowable for 2024 attributable to the remaining increase in basis of $2,000 is $889 (the remaining increase in basis of $2,000 multiplied by 0.4444, which is equal to 1/remaining recovery period of 4.5 years at January 1, 2024, multiplied by 2). Accordingly, for 2024, *YY*'s total depreciation deduction allowable for the qualified property is $21,689 ($12,800 plus $8,000 plus $889).

Example 2. (i) On May 15, 2023, *ZZ,* a calendar-year taxpayer, purchased and placed in service qualified property that is 5-year property at a cost of $400,000. To purchase the property, *ZZ* borrowed $250,000 from Bank1. On May 15, 2024, Bank1 forgives $50,000 of the indebtedness. *ZZ* makes the election provided in section 108(b)(5) to apply any portion of the reduction under section 1017 to the basis of the depreciable property of the taxpayer. *ZZ* depreciates the 5-year property placed in service in 2023 using the optional depreciation table that corresponds with the general depreciation system, the 200-percent declining balance method, a 5-year recovery period, and the half-year convention.

(ii) For 2023, *ZZ* is allowed an 80-percent additional first year depreciation deduction of $320,000 (the unadjusted depreciable basis of $400,000 multiplied by 0.80). In addition, *ZZ*'s depreciation deduction allowable for 2023 for the remaining adjusted depreciable basis of $80,000 (the unadjusted depreciable basis of $400,000 reduced by the additional first year depreciation deduction of $320,000) is $16,000 (the remaining adjusted depreciable basis of $80,000 multiplied by the annual depreciation rate of 0.20 for recovery year 1).

(iii) For 2024, *ZZ*'s deduction for the remaining adjusted depreciable basis of $80,000 is $25,600 (the remaining adjusted depreciable basis of $80,000 multiplied by the annual depreciation rate 0.32 for recovery year 2). Although Bank1 forgave the indebtedness in 2024, the basis of the property is reduced on January 1, 2025, pursuant to sections 108(b)(5) and 1017(a) under which basis is reduced at the beginning of the taxable year following the taxable year in which the discharge of indebtedness occurs.

(iv) For 2025, *ZZ*'s deduction for the remaining adjusted depreciable basis of $80,000 is $15,360 (the remaining adjusted depreciable basis of $80,000 multiplied by the annual depreciation rate 0.192 for recovery year 3). However, pursuant to paragraph (f)(2)(ii) of this section, *ZZ* must reduce the amount otherwise allowable as a depreciation deduction for 2025 by the excess depreciation previously claimed for the $50,000 decrease in basis of the qualified property. Consequently, *ZZ* must reduce the amount of depreciation otherwise allowable for 2025 by the excess additional first year depreciation of $40,000 (the decrease in basis of $50,000 multiplied by 0.80, the applicable percentage for 2023). Also, *ZZ* must reduce the amount of depreciation otherwise allowable for 2025 by the excess depreciation attributable to the remaining decrease in basis of $10,000 (the decrease in basis of $50,000 reduced by the excess additional first year depreciation of $40,000). The reduction in the amount of depreciation otherwise allowable for 2025 for the remaining decrease in basis of $10,000 is $5,714 (the remaining decrease in basis of $10,000 multiplied by 0.5714, which is equal to (1/remaining recovery period of 3.5 years at January 1, 2025) multiplied by 2). Accordingly, assuming the qualified property is the only depreciable property owned by *ZZ,* for 2025, *ZZ* has a negative depreciation deduction for the qualified property of $30,354 ($15,360 minus $40,000 minus $5,714).

(3) *Sections 1245 and 1250 depreciation recapture.* For purposes of section 1245 and the regulations under section 1245, the additional first year depreciation deduction is an amount allowed or allowable for depreciation. Further, for purposes of section 1250(b) and the regulations under section 1250(b), the additional first year depreciation deduction is not a straight line method.

(4) *Coordination with section 169.* The additional first year depreciation deduction is allowable in the placed-in-service year of a certified pollution control facility, as defined in § 1.169–2(a), that is qualified property even if the taxpayer makes the election to amortize the certified pollution control facility under section 169 and the regulations under section 169 in the certified pollution control facility's placed-in-service year.

(5) *Like-kind exchanges and involuntary conversions*—(i) *Scope.* The rules of this paragraph (f)(5) apply to replacement MACRS property or replacement computer software that is qualified property at the time of replacement provided the time of replacement is after September 27, 2017, and before January 1, 2027; or, in the case of replacement MACRS property or replacement computer software that is qualified property described in section 168(k)(2)(B) or (C), the time of replacement is after September 27, 2017, and before January 1, 2028.

(ii) *Definitions.* For purposes of this paragraph (f)(5), the following definitions apply:

(A) *Replacement MACRS property* has the same meaning as that term is defined in § 1.168(i)–6(b)(1).

(B) *Relinquished MACRS property* has the same meaning as that term is defined in § 1.168(i)–6(b)(2).

(C) *Replacement computer software* is computer software, as defined in paragraph (b)(2)(i)(B) of this section, in the hands of the acquiring taxpayer that is acquired for other computer software in a like-kind exchange or in an involuntary conversion.

(D) *Relinquished computer software* is computer software that is transferred by the taxpayer in a like-kind exchange or in an involuntary conversion.

(E) *Time of disposition* has the same meaning as that term is defined in § 1.168(i)–6(b)(3) for relinquished MACRS property. For relinquished computer software, *time of disposition* is when the disposition of the relinquished computer software takes place under the convention determined under § 1.167(a)–14(b).

(F) Except as provided in paragraph (f)(5)(iv) of this section, the *time of replacement* has the same meaning as that term is defined in § 1.168(i)–6(b)(4) for replacement MACRS property. For replacement computer software, the *time of replacement* is, except as provided in paragraph (f)(5)(iv) of this section, the later of—

(*1*) When the replacement computer software is placed in service under the convention determined under § 1.167(a)–14(b); or

(*2*) The time of disposition of the relinquished property.

(G) *Exchanged basis* has the same meaning as that term is defined in § 1.168(i)–6(b)(7) for MACRS property, as defined in § 1.168(b)–1(a)(2). For computer software, the *exchanged basis*

is determined after the amortization deductions for the year of disposition are determined under § 1.167(a)–14(b) and is the lesser of—

(*1*) The basis in the replacement computer software, as determined under section 1031(d) and the regulations under section 1031(d), or section 1033(b) and the regulations under section 1033(b); or

(*2*) The adjusted depreciable basis of the relinquished computer software.

(H) *Excess basis* has the same meaning as that term is defined in § 1.168(i)–6(b)(8) for replacement MACRS property. For replacement computer software, the *excess basis* is any excess of the basis in the replacement computer software, as determined under section 1031(d) and the regulations under section 1031(d), or section 1033(b) and the regulations under section 1033(b), over the exchanged basis as determined under paragraph (f)(5)(ii)(G) of this section.

(I) *Remaining exchanged basis* is the exchanged basis as determined under paragraph (f)(5)(ii)(G) of this section reduced by—

(*1*) The percentage of such basis attributable to the taxpayer's use of property for the taxable year other than in the taxpayer's trade or business or for the production of income; and

(*2*) Any adjustments to basis provided by other provisions of the Code and the regulations under the Code (including section 1016(a)(2) and (3)) for periods prior to the disposition of the relinquished property.

(J) *Remaining excess basis* is the excess basis as determined under paragraph (f)(5)(ii)(H) of this section reduced by—

(*1*) The percentage of such basis attributable to the taxpayer's use of property for the taxable year other than in the taxpayer's trade or business or for the production of income;

(*2*) Any portion of the basis the taxpayer properly elects to treat as an expense under section 179 or 179C; and

(*3*) Any adjustments to basis provided by other provisions of the Code and the regulations under the Code.

(K) *Year of disposition* has the same meaning as that term is defined in § 1.168(i)–6(b)(5).

(L) *Year of replacement* has the same meaning as that term is defined in § 1.168(i)–6(b)(6).

(M) *Like-kind exchange* has the same meaning as that term is defined in § 1.168(i)–6(b)(11).

(N) *Involuntary conversion* has the same meaning as that term is defined in § 1.168(i)–6(b)(12).

(iii) *Computation*—(A) *In general.* If the replacement MACRS property or the replacement computer software, as applicable, meets the original use requirement in paragraph (b)(3)(ii) of this section and all other requirements of section 168(k) and this section, the remaining exchanged basis for the year of replacement and the remaining excess basis, if any, for the year of replacement for the replacement MACRS property or the replacement computer software, as applicable, are eligible for the additional first year depreciation deduction. If the replacement MACRS property or the replacement computer software, as applicable, meets the used property acquisition requirements in paragraph (b)(3)(iii) of this section and all other requirements of section 168(k) and this section, only the remaining excess basis for the year of replacement for the replacement MACRS property or the replacement computer software, as applicable, is eligible for the additional first year depreciation deduction. See paragraph (b)(3)(iii)(A)(*3*) of this section. The additional first year depreciation deduction applies to the remaining exchanged basis and any remaining excess basis, as applicable, of the replacement MACRS property or the replacement computer software, as applicable, if the time of replacement is after September 27, 2017, and before January 1, 2027; or, in the case of replacement MACRS property or replacement computer software, as applicable, described in section 168(k)(2)(B) or (C), the time of replacement is after September 27, 2017, and before January 1, 2028. The additional first year depreciation deduction is computed separately for the remaining exchanged basis and any remaining excess basis, as applicable.

(B) *Year of disposition and year of replacement.* The additional first year depreciation deduction is allowable for the replacement MACRS property or replacement computer software in the year of replacement. However, the additional first year depreciation deduction is not allowable for the relinquished MACRS property or the relinquished computer software, as applicable, if the relinquished MACRS property or the relinquished computer software, as applicable, is placed in service and disposed of in a like-kind exchange or in an involuntary conversion in the same taxable year.

(C) *Property described in section 168(k)(2)(B).* For purposes of paragraph (f)(5)(iii)(A) of this section, the total of the remaining exchanged basis and the remaining excess basis, if any, of the replacement MACRS property that is qualified property described in section 168(k)(2)(B) and meets the original use requirement in paragraph (b)(3)(ii) of this section is limited to the total of the property's remaining exchanged basis and remaining excess basis, if any, attributable to the property's manufacture, construction, or production after September 27, 2017, and before January 1, 2027. For purposes of paragraph (f)(5)(iii)(A) of this section, the remaining excess basis, if any, of the replacement MACRS property that is qualified property described in section 168(k)(2)(B) and meets the used property acquisition requirements in paragraph (b)(3)(iii) of this section is limited to the property's remaining excess basis, if any, attributable to the property's manufacture, construction, or production after September 27, 2017, and before January 1, 2027.

(D) *Effect of § 1.168(i)–6(i)(1) election.* If a taxpayer properly makes the election under § 1.168(i)–6(i)(1) not to apply § 1.168(i)–6 for any MACRS property, as defined in § 1.168(b)–1(a)(2), involved in a like-kind exchange or involuntary conversion and either of the following:

(*1*) The replacement MACRS property meets the original use requirement in paragraph (b)(3)(ii) of this section and all other requirements of section 168(k) and this section, the total of the exchanged basis, as defined in § 1.168(i)–6(b)(7), and the excess basis, as defined in § 1.168(i)–6(b)(8), if any, in the replacement MACRS property is eligible for the additional first year depreciation deduction; or

(*2*) The replacement MACRS property meets the used property acquisition requirements in paragraph (b)(3)(iii) of this section and all other requirements of section 168(k) and this section, only the excess basis, as defined in § 1.168(i)–6(b)(8), if any, in the replacement MACRS property is eligible for the additional first year depreciation deduction.

(E) *Alternative minimum tax.* The additional first year depreciation deduction is allowed for alternative minimum tax purposes for the year of replacement of replacement MACRS property or replacement computer software, as applicable, that is qualified property. If the replacement MACRS property or the replacement computer software, as applicable, meets the original use requirement in paragraph (b)(3)(ii) of this section and all other requirements of section 168(k) and this section, the additional first year depreciation deduction for alternative minimum tax purposes is based on the remaining exchanged basis and the remaining excess basis, if any, of the replacement MACRS property or the

replacement computer software, as applicable, for alternative minimum tax purposes. If the replacement MACRS property or the replacement computer software, as applicable, meets the used property acquisition requirements in paragraph (b)(3)(iii) of this section and all other requirements of section 168(k) and this section, the additional first year depreciation deduction for alternative minimum tax purposes is based on the remaining excess basis, if any, of the replacement MACRS property or the replacement computer software, as applicable, for alternative minimum tax purposes.

(iv) *Replacement MACRS property or replacement computer software that is acquired and placed in service before disposition of relinquished MACRS property or relinquished computer software.* If, in an involuntary conversion, a taxpayer acquires and places in service the replacement MACRS property or the replacement computer software, as applicable, before the time of disposition of the involuntarily converted MACRS property or the involuntarily converted computer software, as applicable; and the time of disposition of the involuntarily converted MACRS property or the involuntarily converted computer software, as applicable, is after December 31, 2026, or, in the case of property described in service 168(k)(2)(B) or (C), after December 31, 2027, then—

(A) The time of replacement for purposes of this paragraph (f)(5) is when the replacement MACRS property or replacement computer software, as applicable, is placed in service by the taxpayer, provided the threat or imminence of requisition or condemnation of the involuntarily converted MACRS property or involuntarily converted computer software, as applicable, existed before January 1, 2027, or, in the case of property described in section 168(k)(2)(B) or (C), existed before January 1, 2028; and

(B) The taxpayer depreciates the replacement MACRS property or replacement computer software, as applicable, in accordance with paragraph (d) of this section. However, at the time of disposition of the involuntarily converted MACRS property, the taxpayer determines the exchanged basis, as defined in § 1.168(i)–6(b)(7), and the excess basis, as defined in § 1.168(i)–6(b)(8), of the replacement MACRS property and begins to depreciate the depreciable exchanged basis, as defined in § 1.168(i)–6(b)(9), of the replacement MACRS property in accordance with § 1.168(i)–6(c). The depreciable excess basis, as defined in § 1.168(i)–6(b)(10), of the replacement MACRS property continues to be depreciated by the taxpayer in accordance with the first sentence of this paragraph (f)(5)(iv)(B). Further, in the year of disposition of the involuntarily converted MACRS property, the taxpayer must include in taxable income the excess of the depreciation deductions allowable, including the additional first year depreciation deduction allowable, on the unadjusted depreciable basis of the replacement MACRS property over the additional first year depreciation deduction that would have been allowable to the taxpayer on the remaining exchanged basis of the replacement MACRS property at the time of replacement, as defined in paragraph (f)(5)(v)(A) of this section, plus the depreciation deductions that would have been allowable, including the additional first year depreciation deduction allowable, to the taxpayer on the depreciable excess basis of the replacement MACRS property from the date the replacement MACRS property was placed in service by the taxpayer, taking into account the applicable convention, to the time of disposition of the involuntarily converted MACRS property. Similar rules apply to replacement computer software.

(v) *Examples.* The application of this paragraph (f)(5) is illustrated by the following examples:

Example 1. (i) In April 2016, *CSK,* a calendar-year corporation, acquired for $200,000 and placed in service Canopy V1, a gas station canopy. Canopy V1 is qualified property under section 168(k)(2), as in effect on the day before amendment by the Act, and is 5-year property under section 168(e). *CSK* depreciated Canopy V1 under the general depreciation system of section 168(a) by using the 200-percent declining balance method of depreciation, a 5-year recovery period, and the half-year convention. *CSK* elected to use the optional depreciation tables to compute the depreciation allowance for Canopy V1. In November 2017, Canopy V1 was destroyed in a fire and was no longer usable in *CSK*'s business. In December 2017, in an involuntary conversion, *CSK* acquired and placed in service Canopy W1 with all of the $160,000 of insurance proceeds *CSK* received due to the loss of Canopy V1. Canopy W1 is qualified property under section 168(k)(2) and this section, and is 5-year property under section 168(e). Canopy W1 also meets the original use requirement in paragraph (b)(3)(ii) of this section. *CSK* did not make the election under § 1.168(i)–6(i)(1).

(ii) For 2016, *CSK* is allowed a 50-percent additional first year depreciation deduction of $100,000 for Canopy V1 (the unadjusted depreciable basis of $200,000 multiplied by 0.50), and a regular MACRS depreciation deduction of $20,000 for Canopy V1 (the remaining adjusted depreciable basis of $100,000 multiplied by the annual depreciation rate of 0.20 for recovery year 1).

(iii) For 2017, *CSK* is allowed a regular MACRS depreciation deduction of $16,000 for Canopy V1 (the remaining adjusted depreciable basis of $100,000 multiplied by the annual depreciation rate of 0.32 for recovery year 2 × ½ year).

(iv) Pursuant to paragraph (f)(5)(iii)(A) of this section, the additional first year depreciation deduction allowable for Canopy W1 for 2017 equals $64,000 (100 percent of Canopy W1's remaining exchanged basis at the time of replacement of $64,000 (Canopy V1's remaining adjusted depreciable basis of $100,000 minus 2016 regular MACRS depreciation deduction of $20,000 minus 2017 regular MACRS depreciation deduction of $16,000)).

Example 2. (i) The facts are the same as in *Example 1* of this paragraph (f)(5)(v), except *CSK* elected not to deduct the additional first year depreciation for 5-year property placed in service in 2016. *CSK* deducted the additional first year depreciation for 5-year property placed in service in 2017.

(ii) For 2016, *CSK* is allowed a regular MACRS depreciation deduction of $40,000 for Canopy V1 (the unadjusted depreciable basis of $200,000 multiplied by the annual depreciation rate of 0.20 for recovery year 1).

(iii) For 2017, *CSK* is allowed a regular MACRS depreciation deduction of $32,000 for Canopy V1 (the unadjusted depreciable basis of $200,000 multiplied by the annual depreciation rate of 0.32 for recovery year 2 × ½ year).

(iv) Pursuant to paragraph (f)(5)(iii)(A) of this section, the additional first year depreciation deduction allowable for Canopy W1 for 2017 equals $128,000 (100 percent of Canopy W1's remaining exchanged basis at the time of replacement of $128,000 (Canopy V1's unadjusted depreciable basis of $200,000 minus 2016 regular MACRS depreciation deduction of $40,000 minus 2017 regular MACRS depreciation deduction of $32,000)).

Example 3. The facts are the same as in *Example 1* of this paragraph (f)(5)(v), except Canopy W1 meets the used property acquisition requirements in paragraph (b)(3)(iii) of this section. Because the remaining excess basis of Canopy W1 is zero, *CSK* is not allowed any additional first year depreciation for Canopy W1 pursuant to paragraph (f)(5)(iii)(A) of this section.

Example 4. (i) In December 2016, *AB,* a calendar-year corporation, acquired for $10,000 and placed in service Computer X2. Computer X2 is qualified property under section 168(k)(2), as in effect on the day before amendment by the Act, and is 5-year property under section 168(e). *AB* depreciated Computer X2 under the general depreciation system of section 168(a) by using the 200-percent declining balance method of depreciation, a 5-year recovery period, and the half-year convention. *AB* elected to use the optional depreciation tables to compute the depreciation allowance for Computer X2. In November 2017, *AB* acquired Computer Y2 by exchanging Computer X2 and $1,000 cash in a like-kind exchange. Computer Y2 is qualified property under section 168(k)(2) and this section, and

is 5-year property under section 168(e). Computer Y2 also meets the original use requirement in paragraph (b)(3)(ii) of this section. *AB* did not make the election under § 1.168(i)–6(i)(1).

(ii) For 2016, *AB* is allowed a 50-percent additional first year depreciation deduction of $5,000 for Computer X2 (unadjusted basis of $10,000 multiplied by 0.50), and a regular MACRS depreciation deduction of $1,000 for Computer X2 (the remaining adjusted depreciable basis of $5,000 multiplied by the annual depreciation rate of 0.20 for recovery year 1).

(iii) For 2017, *AB* is allowed a regular MACRS depreciation deduction of $800 for Computer X2 (the remaining adjusted depreciable basis of $5,000 multiplied by the annual depreciation rate of 0.32 for recovery year 2 × ½ year).

(iv) Pursuant to paragraph (f)(5)(iii)(A) of this section, the 100-percent additional first year depreciation deduction for Computer Y2 for 2017 is allowable for the remaining exchanged basis at the time of replacement of $3,200 (Computer X2's unadjusted depreciable basis of $10,000 minus additional first year depreciation deduction allowable of $5,000 minus the 2016 regular MACRS depreciation deduction of $1,000 minus the 2017 regular MACRS depreciation deduction of $800) and for the remaining excess basis at the time of replacement of $1,000 (cash paid for Computer Y2). Thus, the 100-percent additional first year depreciation deduction allowable for Computer Y2 totals $4,200 for 2017.

Example 5. (i) In July 2017, *BC,* a calendar-year corporation, acquired for $20,000 and placed in service Equipment X3. Equipment X3 is qualified property under section 168(k)(2), as in effect on the day before amendment by the Act, and is 5-year property under section 168(e). *BC* depreciated Equipment X3 under the general depreciation system of section 168(a) by using the 200-percent declining balance method of depreciation, a 5-year recovery period, and the half-year convention. *BC* elected to use the optional depreciation tables to compute the depreciation allowance for Equipment X3. In December 2017, *BC* acquired Equipment Y3 by exchanging Equipment X3 and $5,000 cash in a like-kind exchange. Equipment Y3 is qualified property under section 168(k)(2) and this section, and is 5-year property under section 168(e). Equipment Y3 also meets the used property acquisition requirements in paragraph (b)(3)(iii) of this section. *BC* did not make the election under § 1.168(i)–6(i)(1).

(ii) Pursuant to § 1.168(k)–1(f)(5)(iii)(B), no additional first year depreciation deduction is allowable for Equipment X3 and, pursuant to § 1.168(d)–1(b)(3)(ii), no regular depreciation deduction is allowable for Equipment X3, for 2017.

(iii) Pursuant to paragraph (f)(5)(iii)(A) of this section, no additional first year depreciation deduction is allowable for Equipment Y3's remaining exchanged basis at the time of replacement of $20,000 (Equipment X3's unadjusted depreciable basis of $20,000). However, pursuant to paragraph (f)(5)(iii)(A) of this section, the 100-percent additional first year depreciation deduction is allowable for Equipment Y3's remaining excess basis at the time of replacement of $5,000 (cash paid for Equipment Y3). Thus, the 100-percent additional first year depreciation deduction allowable for Equipment Y3 is $5,000 for 2017.

Example 6. (i) The facts are the same as in *Example 5* of this paragraph (f)(5)(v), except *BC* properly makes the election under § 1.168(i)–6(i)(1) not to apply § 1.168(i)–6 to Equipment X3 and Equipment Y3.

(ii) Pursuant to § 1.168(k)–1(f)(5)(iii)(B), no additional first year depreciation deduction is allowable for Equipment X3 and, pursuant to § 1.168(d)–1(b)(3)(ii), no regular depreciation deduction is allowable for Equipment X3, for 2017.

(iii) Pursuant to § 1.168(i)–6(i)(1), *BC* is treated as placing Equipment Y3 in service in December 2017 with a basis of $25,000 (the total of the exchanged basis of $20,000 and the excess basis of $5,000). However, pursuant to paragraph (f)(5)(iii)(D)(*2*) of this section, the 100-percent additional first year depreciation deduction is allowable only for Equipment Y3's excess basis at the time of replacement of $5,000 (cash paid for Equipment Y3). Thus, the 100-percent additional first year depreciation deduction allowable for Equipment Y3 is $5,000 for 2017.

(6) *Change in use*—(i) *Change in use of depreciable property.* The determination of whether the use of depreciable property changes is made in accordance with section 168(i)(5) and § 1.168(i)–4.

(ii) *Conversion to personal use.* If qualified property is converted from business or income-producing use to personal use in the same taxable year in which the property is placed in service by a taxpayer, the additional first year depreciation deduction is not allowable for the property.

(iii) *Conversion to business or income-producing use*—(A) *During the same taxable year.* If, during the same taxable year, property is acquired by a taxpayer for personal use and is converted by the taxpayer from personal use to business or income-producing use, the additional first year depreciation deduction is allowable for the property in the taxable year the property is converted to business or income-producing use, assuming all of the requirements in paragraph (b) of this section are met. See paragraph (b)(3)(ii) of this section relating to the original use rules for a conversion of property to business or income-producing use.

(B) *Subsequent to the acquisition year.* If property is acquired by a taxpayer for personal use and, during a subsequent taxable year, is converted by the taxpayer from personal use to business or income-producing use, the additional first year depreciation deduction is allowable for the property in the taxable year the property is converted to business or income-producing use, assuming all of the requirements in paragraph (b) of this section are met. For purposes of paragraphs (b)(4) and (5) of this section, the property must be acquired by the taxpayer for personal use after September 27, 2017, and converted by the taxpayer from personal use to business or income-producing use by January 1, 2027. See paragraph (b)(3)(ii) of this section relating to the original use rules for a conversion of property to business or income-producing use.

(iv) *Depreciable property changes use subsequent to the placed-in-service year*—(A) If the use of qualified property changes in the hands of the same taxpayer subsequent to the taxable year the qualified property is placed in service and, as a result of the change in use, the property is no longer qualified property, the additional first year depreciation deduction allowable for the qualified property is not redetermined.

(B) If depreciable property is not qualified property in the taxable year the property is placed in service by the taxpayer, the additional first year depreciation deduction is not allowable for the property even if a change in the use of the property subsequent to the taxable year the property is placed in service results in the property being qualified property in the taxable year of the change in use.

(v) *Examples.* The application of this paragraph (f)(6) is illustrated by the following examples:

Example 1. (i) On January 1, 2019, *FFF,* a calendar year corporation, purchased and placed in service several new computers at a total cost of $100,000. *FFF* used these computers within the United States for 3 months in 2019 and then moved and used the computers outside the United States for the remainder of 2019. On January 1, 2020, *FFF* permanently returns the computers to the United States for use in its business.

(ii) For 2019, the computers are considered as used predominantly outside the United States in 2019 pursuant to § 1.48–1(g)(1)(i). As a result, the computers are required to be depreciated under the alternative depreciation system of section 168(g). Pursuant to paragraph (b)(2)(ii)(B) of this section, the computers are not qualified property in 2019, the placed-in-service year. Thus, pursuant to paragraph (f)(6)(iv)(B) of this section, no additional first year depreciation deduction is allowed for these computers, regardless of the fact that the computers are permanently returned to the United States in 2020.

Example 2. (i) On February 8, 2023, *GGG,* a calendar year corporation, purchased and placed in service new equipment at a cost of $1,000,000 for use in its California plant. The equipment is 5-year property under section

168(e) and is qualified property under section 168(k). *GGG* depreciates its 5-year property placed in service in 2023 using the optional depreciation table that corresponds with the general depreciation system, the 200-percent declining balance method, a 5-year recovery period, and the half-year convention. On June 4, 2024, due to changes in *GGG's* business circumstances, *GGG* permanently moves the equipment to its plant in Mexico.

(ii) For 2023, *GGG* is allowed an 80-percent additional first year depreciation deduction of $800,000 (the adjusted depreciable basis of $1,000,000 multiplied by 0.80). In addition, *GGG's* depreciation deduction allowable in 2023 for the remaining adjusted depreciable basis of $200,000 (the unadjusted depreciable basis of $1,000,000 reduced by the additional first year depreciation deduction of $800,000) is $40,000 (the remaining adjusted depreciable basis of $200,000 multiplied by the annual depreciation rate of 0.20 for recovery year 1).

(iii) For 2024, the equipment is considered as used predominantly outside the United States pursuant to § 1.48–1(g)(1)(i). As a result of this change in use, the adjusted depreciable basis of $160,000 for the equipment is required to be depreciated under the alternative depreciation system of section 168(g) beginning in 2024. However, the additional first year depreciation deduction of $800,000 allowed for the equipment in 2023 is not redetermined.

(7) *Earnings and profits.* The additional first year depreciation deduction is not allowable for purposes of computing earnings and profits.

(8) *Limitation of amount of depreciation for certain passenger automobiles.* For a passenger automobile as defined in section 280F(d)(5), the limitation under section 280F(a)(1)(A)(i) is increased by $8,000 for qualified property acquired and placed in service by a taxpayer after September 27, 2017.

(9) *Coordination with section 47*—(i) *In general.* If qualified rehabilitation expenditures, as defined in section 47(c)(2) and § 1.48–12(c), incurred by a taxpayer with respect to a qualified rehabilitated building, as defined in section 47(c)(1) and § 1.48–12(b), are qualified property, the taxpayer may claim the rehabilitation credit provided by section 47(a), provided the requirements of section 47 are met—

(A) With respect to the portion of the basis of the qualified rehabilitated building that is attributable to the qualified rehabilitation expenditures if the taxpayer makes the applicable election under paragraph (e)(1)(i) of this section not to deduct any additional first year depreciation for the class of property that includes the qualified rehabilitation expenditures; or

(B) With respect to the portion of the remaining rehabilitated basis of the qualified rehabilitated building that is attributable to the qualified rehabilitation expenditures if the taxpayer claims the additional first year depreciation deduction on the unadjusted depreciable basis, as defined in § 1.168(b)–1(a)(3) but before the reduction in basis for the amount of the rehabilitation credit, of the qualified rehabilitation expenditures; and the taxpayer depreciates the remaining adjusted depreciable basis, as defined in paragraph (d)(2)(i) of this section, of such expenditures using straight line cost recovery in accordance with section 47(c)(2)(B)(i) and § 1.48–12(c)(7)(i). For purposes of this paragraph (f)(9)(i)(B), the remaining rehabilitated basis is equal to the unadjusted depreciable basis, as defined in § 1.168(b)–1(a)(3) but before the reduction in basis for the amount of the rehabilitation credit, of the qualified rehabilitation expenditures that are qualified property reduced by the additional first year depreciation allowed or allowable, whichever is greater.

(ii) *Example.* The application of this paragraph (f)(9) is illustrated by the following example:

Example. (i) Between February 8, 2023, and June 4, 2023, *JM,* a calendar-year taxpayer, incurred qualified rehabilitation expenditures of $200,000 with respect to a qualified rehabilitated building that is nonresidential real property under section 168(e). These qualified rehabilitation expenditures are qualified property and qualify for the 20-percent rehabilitation credit under section 47(a)(1). *JM's* basis in the qualified rehabilitated building is zero before incurring the qualified rehabilitation expenditures and *JM* placed the qualified rehabilitated building in service in July 2023. *JM* depreciates its nonresidential real property placed in service in 2023 under the general depreciation system of section 168(a) by using the straight line method of depreciation, a 39-year recovery period, and the mid-month convention. *JM* elected to use the optional depreciation tables to compute the depreciation allowance for its depreciable property placed in service in 2023. Further, for 2023, *JM* did not make any election under paragraph (e) of this section.

(ii) Because *JM* did not make any election under paragraph (e) of this section, *JM* is allowed an 80-percent additional first year depreciation deduction of $160,000 for the qualified rehabilitation expenditures for 2023 (the unadjusted depreciable basis of $200,000 (before reduction in basis for the rehabilitation credit) multiplied by 0.80). *JM* also is allowed to claim a rehabilitation credit of $8,000 for the remaining rehabilitated basis of $40,000 (the unadjusted depreciable basis (before reduction in basis for the rehabilitation credit) of $200,000 less the additional first year depreciation deduction of $160,000, multiplied by 0.20 to calculate the rehabilitation credit). For 2023, the ratable share of the rehabilitation credit of $8,000 is $1,600. Further, *JM's* depreciation deduction for 2023 for the remaining adjusted depreciable basis of $32,000 (the unadjusted depreciable basis (before reduction in basis for the rehabilitation credit) of $200,000 less the additional first year depreciation deduction of $160,000 less the rehabilitation credit of $8,000) is $376.64 (the remaining adjusted depreciable basis of $32,000 multiplied by the depreciation rate of 0.01177 for recovery year 1, placed in service in month 7).

(10) *Coordination with section 514(a)(3).* The additional first year depreciation deduction is not allowable for purposes of section 514(a)(3).

(g) *Applicability dates*—(1) *In general.* Except as provided in paragraph (g)(2) of this section, the rules of this section apply to—

(i) Qualified property under section 168(k)(2) that is placed in service by the taxpayer during or after the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**; and

(ii) A specified plant for which the taxpayer properly made an election to apply section 168(k)(5) and that is planted, or grafted to a plant that was previously planted, by the taxpayer during or after the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

(2) *Early application.* A taxpayer may rely on the provisions of this section in these proposed regulations for—

(i) Qualified property under section 168(k)(2) acquired and placed in service after September 27, 2017, by the taxpayer during taxable years ending on or after September 28, 2017, and ending before the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**; and

(ii) A specified plant for which the taxpayer properly made an election to apply section 168(k)(5) and that is planted, or grafted to a plant that was previously planted, after September 27, 2017, by the taxpayer during taxable years ending on or after September 28, 2017, and ending before the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

■ **Par. 10.** Section 1.169–3 is amended by adding a sentence at the end of paragraph (a) and adding two sentences at the end of paragraph (g) to read as follows:

§ 1.169–3 Amortizable basis.

(a) * * * Further, before computing the amortization deduction allowable

under section 169, the adjusted basis for purposes of determining gain for a facility that is acquired and placed in service after September 27, 2017, and that is qualified property under section 168(k), as amended by the Tax Cuts and Jobs Act, Public Law 115–97 (131 Stat. 2054 (December 22, 2017)) (the ''Act''), or § 1.168(k)–2, must be reduced by the amount of the additional first year depreciation deduction allowed or allowable, whichever is greater, under section 168(k), as amended by the Act.

* * * * *

(g) * * * The last sentence of paragraph (a) of this section applies to a certified pollution control facility that is qualified property under section 168(k)(2) and placed in service by a taxpayer during or after the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. However, a taxpayer may rely on the last sentence in paragraph (a) of this section in these proposed regulations for a certified pollution control facility that is qualified property under section 168(k)(2) and acquired and placed in service after September 27, 2017, by the taxpayer during taxable years ending on or after September 28, 2017, and ending before the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

■ **Par. 11.** Section 1.179–4 is amended by revising paragraph (c)(2) to read as follows:

§ 1.179–4 Definitions.

* * * * *

(c) * * *

(2) Property deemed to have been acquired by a new target corporation as a result of a section 338 election (relating to certain stock purchases treated as asset acquisitions) or a section 336(e) election (relating to certain stock dispositions treated as asset transfers) will be considered acquired by purchase.

* * * * *

■ **Par. 12.** Section 1.179–6 is amended by revising the first sentence in paragraph (a) and adding paragraph (e) to read as follows:

§ 1.179–6 Effective/applicability dates.

(a) * * * Except as provided in paragraphs (b), (c), (d), and (e) of this section, the provisions of §§ 1.179–1 through 1.179–5 apply for property placed in service by the taxpayer in taxable years ending after January 25, 1993. * * *

* * * * *

(e) *Application of § 1.179–4(c)(2)*—(1) *In general.* Except as provided in paragraph (e)(2) of this section, the provisions of § 1.179–4(c)(2) relating to section 336(e) are applicable on or after the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

(2) *Early application.* A taxpayer may rely on the provisions of § 1.179–4(c)(2) relating to section 336(e) in these proposed regulations for the taxpayer's taxable years ending on or after September 28, 2017, and ending before the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

■ **Par. 13.** Section 1.312–15 is amended by adding a sentence at the end of paragraph (a)(1) and adding paragraph (e) to read as follows:

§ 1.312–15 Effect of depreciation on earnings and profits.

(a) * * *

(1) * * * Further, see § 1.168(k)–2(f)(7) with respect to the treatment of the additional first year depreciation deduction allowable under section 168(k), as amended by the Tax Cuts and Jobs Act, Public Law 115–97 (131 Stat. 2054 (December 22, 2017)), for purposes of computing the earnings and profits of a corporation.

* * * * *

(e) *Applicability date of qualified property.* The last sentence of paragraph (a) of this section applies to the taxpayer's taxable years ending on or after the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. However, a taxpayer may rely on the last sentence in paragraph (a) of this section in these proposed regulations for the taxpayer's taxable years ending on or after September 28, 2017, and ending before the taxpayer's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

■ **Par. 14.** Section 1.704–1 is amended by adding two sentences at the end of paragraph (b)(1)(ii)(*a*) and adding a sentence at the end of paragraph (b)(2)(iv)(*g*)(*3*) to read as follows:

§ 1.704–1 Partner's distributive share.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(*a*) * * * The last sentence of paragraph (b)(2)(iv)(*g*)(*3*) of this section is applicable for partnership taxable years ending on or after the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. However, a partnership may rely on the last sentence in paragraph (b)(2)(iv)(*g*)(*3*) of this section in these proposed regulations for the partnership's taxable years ending on or after September 28, 2017, and ending before the partnership's taxable year that includes the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

* * * * *

(2) * * *

(iv) * * *

(*g*) * * *

(*3*) * * * For purposes of the preceding sentence, additional first year depreciation deduction under section 168(k) is not a reasonable method.

* * * * *

■ **Par. 15.** Section 1.704–3 is amended by:

■ 1. Adding a sentence at the end of paragraph (d)(2);

■ 2. Revising the first sentence in paragraph (f); and

■ 3. Adding two sentences at the end of paragraph (f).

The additions and revision read as follows:

§ 1.704–3 Contributed property.

* * * * *

(d) * * *

(2) * * * However, the additional first year depreciation deduction under section 168(k) is not a permissible method for purposes of the preceding sentence and, if a partnership has acquired property in a taxable year for which the additional first year depreciation deduction under section 168(k) has been used of the same type as the contributed property, the portion of the contributed property's book basis that exceeds its adjusted tax basis must be recovered under a reasonable method. See § 1.168(k)–2(b)(3)(iv)(B).

* * * * *

(f) * * * With the exception of paragraphs (a)(1), (a)(8)(ii) and (iii), and (a)(10) and (11) of this section, and of the last sentence in paragraph (d)(2) of this section, this section applies to properties contributed to a partnership and to restatements pursuant to § 1.704–1(b)(2)(iv)(*f*) on or after December 21, 1993. * * * The last sentence of paragraph (d)(2) of this section applies to property contributed to a partnership on or after the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. However, a taxpayer may rely on the last sentence in paragraph (d)(2) of this section in these proposed regulations for property contributed to a partnership on or after September 28,

2017, and ending before the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

* * * * *

■ **Par. 16.** Section 1.743–1 is amended by:

■ 1. Adding three sentences to the end of paragraph (j)(4)(i)(B)(*1*) and adding two sentences at the end of paragraph (l) to read as follows:

§ 1.743–1 Optional adjustment to basis of partnership property.

* * * * *

(*j*) * * *

(4) * * *

(i) * * *

(B) * * *

(*1*) * * * Notwithstanding the above, the partnership is allowed to deduct the additional first year depreciation under section 168(k) and § 1.168(k)–2 for an increase in the basis of qualified property, as defined in section 168(k) and § 1.168(k)–2, under section 743(b) in a class of property, as defined in § 1.168(k)–2(e)(1)(ii)(A) through (F), even if the partnership made the election under section 168(k)(7) and § 1.168(k)–2(e)(1) not to deduct the additional first year depreciation for all other qualified property of the partnership in the same class of property, as defined in § 1.168(k)–2(e)(1)(ii)(A) through (F), and placed in service in the same taxable year, provided the section 743(b) basis adjustment meets all requirements of section 168(k) and § 1.168(k)–2. Further, the partnership may make an election under section 168(k)(7) and § 1.168(k)–2(e)(1) not to deduct the additional first year depreciation for an increase in the basis of qualified property, as defined in section 168(k) and § 1.168(k)–2, under section 743(b) in a class of property, as defined in § 1.168(k)–2(e)(1)(ii)(A) through (F), and placed in service in the same taxable year, even if the partnership does not make that election for all other qualified property of the partnership in the same class of property, as defined in § 1.168(k)–2(e)(1)(ii)(A) through (F), and placed in service in the same taxable year. In this case, the section 743(b) basis adjustment must be recovered under a reasonable method.

* * * * *

(l) * * * The last three sentences of paragraph (j)(4)(i)(B)(*1*) of this section apply to transfers of partnership interests that occur on or after the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**. However, a partnership may rely on the last three sentences in paragraph (j)(4)(i)(B)(*1*) of this section in these proposed regulations for transfers of partnership interests that occur on or after September 28, 2017, and ending before the date of publication of a Treasury decision adopting these rules as final regulations in the **Federal Register**.

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

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