FEDERAL REGISTER

Vol. 83 Wednesday,

No. 220 November 14, 2018

Pages 56699–57306

OFFICE OF THE FEDERAL REGISTER

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How To Cite This Publication: Use the volume number and the page number. Example: 83 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0408; Product Identifier 2017–NM–146–AD; Amendment 39–19495; AD 2018–23–09]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding Airworthiness Directive (AD) 2016–13–16, which applied to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. AD 2016–13–16 required an inspection or records check to determine if affected horizontal stabilizers are installed, related investigative actions, and, for affected horizontal stabilizers, repetitive inspections for any crack of the horizontal stabilizer rear spar upper chord, and corrective action if necessary. This AD requires retaining the requirements of AD 2016–13–16, with revised service information that clarifies the inspection areas and serial number information of the horizontal stabilizer. This AD was prompted by reports of a manufacturing oversight, in which a supplier omitted the required protective finish on certain bushings installed in the rear spar upper chord on horizontal stabilizers, which could lead to galvanic corrosion and consequent cracking of the rear spar upper chord. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 19, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 19, 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–2018–0408.

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–2018–0408; 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 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: Lu Lu, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3525; email: *lu.lu@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2016–13–16, Amendment 39–18581 (81 FR 44503, July 8, 2016) (''AD 2016–13–16''). AD 2016–13–16 applied to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and –900ER series airplanes. The NPRM published in the **Federal Register** on May 15, 2018 (83 FR 22417). The NPRM was prompted by a determination that clarification of inspection areas and serial number information of the horizontal stabilizer is necessary and reports of a manufacturing oversight, in which a supplier omitted the required protective finish on certain bushings installed in the rear spar upper chord on horizontal stabilizers, which could lead to galvanic corrosion and consequent cracking of the rear spar upper chord. The NPRM proposed to continue to require an inspection or records check to determine if affected horizontal stabilizers are installed, related investigative actions, and, for affected horizontal stabilizers, repetitive inspections for any crack of the horizontal stabilizer rear spar upper chord, and corrective action if necessary. The NPRM also proposed to clarify the inspection areas and serial number information of the horizontal stabilizer. We are issuing this AD to address cracking of the rear spar upper chord, which could result in the failure of the upper chord, consequent departure of the horizontal stabilizer from the airplane, and loss of control of the airplane.

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. Air Line Pilots Association, International (ALPA), Boeing, and United Airlines stated that they supported the NPRM.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that accomplishing the supplemental type certificate (STC) ST00830SE does not affect the actions specified in the NPRM.

We concur with the commenter. We have redesignated paragraph (c) of the proposed AD as paragraph (c)(1) of this AD and added paragraph (c)(2) to this AD to state that installation of STC ST00830SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST00830SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

Request To Review Parts Installation Limitations Paragraph

Southwest Airlines (SWA) requested that we review the ''Parts Installation Limitation'' paragraph in the proposed AD. SWA stated that Boeing Alert Service Bulletin 737–55A1097, Revision

1, dated September 20, 2017, specifies that an operator can either do a check of delivery and maintenance records to find the serial number of the horizontal stabilizer installed on the airplane during production and to determine if the horizontal stabilizer has been exchanged, or an operator can gain access to the horizontal stabilizer identification plate and do an inspection of the identification plate to find the serial numbers of the horizontal stabilizers.

SWA stated that it does not agree with the use of maintenance records to validate serial numbers based on the potential error of not recording the full serial number (manufacturer code and serial number) from the identification plate within the maintenance record documentation. SWA commented that it has determined that the delivery record and physical verification are correct methods in confirming that the serial numbers are installed.

We partially agree with the commenter's request. We have reviewed the effectiveness of performing a records check. We disagree with the commenter that a records check is not a valid method and note that it is acceptable for complying with certain actions required by paragraph (g) of this AD. As specified in Note 17 of paragraph 3.A., ''General Information'' of the Accomplishment Instructions of Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017, ''A check of the airplane maintenance and delivery records is an acceptable method to determine if the left and right horizontal stabilizers are affected provided the installed components can be conclusively determined from that check.'' We agree that if an operator is not confident that it cannot positively identify the affected stabilizers by using maintenance records, then this method should not be used. In addition, Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017, specifies a check of delivery and maintenance records with a table for the affected manufacturer code and serial number combination to ensure all the affected parts are captured.

In regards to the ''Parts Installation Limitation'' paragraph in this AD, there is no option to do a check of the airplane maintenance and delivery records. As specified in paragraph (i)(1) of this AD, a horizontal stabilizer may be installed if the part is inspected in accordance with ''Part 2: Horizontal Stabilizer Identification Plate Inspection'' of the Accomplishments Instructions of Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017, and no affected serial number is found. As specified in paragraph (i)(2) of this AD, a horizontal stabilizer may be installed if the part is inspected in accordance with ''Part 2: Horizontal Stabilizer Identification Plate Inspection'' of the Accomplishments Instructions of Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017, and an affected serial number is found, provided the actions specified in paragraphs (i)(2)(i) and (i)(2)(ii) of this AD are done, as applicable. We have not changed this AD in this regard.

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 change 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 addressing 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

We reviewed Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017. This service information describes procedures for an identification plate inspection or records check to determine whether affected horizontal stabilizers are installed, related investigative actions, and for affected horizontal stabilizers, repetitive high frequency eddy current (HFEC) inspections for any crack of the horizontal stabilizer rear spar upper chord, and corrective action. 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 1,748 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 or records check to determine the serial number of the horizontal stabilizer.	1 work-hour × $85 per hour = $85	$0	$85	$148,580.
HFEC inspection (horizontal stabilizer with affected serial number).	6 work-hour × $85 per hour = 510	0	510	Up to $891,480.

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, all 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

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) 2016–13–16, Amendment 39–18581 (81 FR 44503, July 8, 2016), and adding the following new AD:

2018–23–09 The Boeing Company: Amendment 39–19495; Docket No. FAA–2018–0408; Product Identifier 2017–NM–146–AD.

(a) Effective Date

This AD is effective December 19, 2018.

(b) Affected ADs

This AD replaces AD 2016–13–16, Amendment 39–18581 (81 FR 44503, July 8, 2016) (''AD 2016–13–16'').

(c) Applicability

(1) This AD applies to all The Boeing Company Model 737–600, –700, –700C, –800, –900, and 900ER series airplanes, certificated in any category.

(2) Installation of Supplemental Type Certificate (STC) ST00830SE does not affect the ability to accomplish the actions required by this AD. Therefore, for airplanes on which STC ST00830SE is installed, a ''change in product'' alternative method of compliance (AMOC) approval request is not necessary to comply with the requirements of 14 CFR 39.17.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by reports of a manufacturing oversight, in which a supplier omitted the required protective finish on certain bushings installed in the rear spar upper chord on horizontal stabilizers, which could lead to galvanic corrosion and consequent cracking of the rear spar upper chord. We are issuing this AD to address cracking of the rear spar upper chord, which could result in the failure of the upper chord, consequent departure of the horizontal stabilizer from the airplane, and loss of control of the airplane.

(f) Compliance

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

(g) Required Actions

Except as required by paragraph (h) of this AD: At the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017, do all applicable actions identified as ''RC'' (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017.

(h) Exceptions to Service Information

(1) For purposes of determining compliance with the requirements of this AD: Where Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017, uses the phrase ''the Revision 1 date of this service bulletin,'' this AD requires using ''the effective date of this AD.''

(2) Where Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017, specifies contacting Boeing, and specifies that action as RC: This AD requires repair using a method approved in accordance with the procedures specified in paragraph (k) of this AD.

(i) Parts Installation Limitations

As of the effective date of this AD, no person may install a horizontal stabilizer on any airplane, except as specified in paragraphs (i)(1) or (i)(2) of this AD.

(1) A horizontal stabilizer may be installed if the part is inspected in accordance with ''Part 2: Horizontal Stabilizer Identification Plate Inspection'' of the Accomplishments Instructions of Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017, and no affected serial number is found.

(2) A horizontal stabilizer may be installed if the part is inspected in accordance with ''Part 2: Horizontal Stabilizer Identification Plate Inspection'' of the Accomplishments Instructions of Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017, and an affected serial number is found, provided that the actions specified in paragraphs (i)(2)(i) and (i)(2)(ii) of this AD are done, as applicable.

(i) Initial and repetitive high frequency eddy current (HFEC) inspections, which are part of the required actions specified in paragraph (g) of this AD, are completed within the compliance times specified in paragraph (g) of this AD.

(ii) All applicable corrective actions, which are part of the required actions specified in paragraph (g) of this AD, are done within the compliance times specified in paragraph (g) of this AD.

(j) Credit for Previous Actions

For Groups 1 and 2, Configuration 1 airplanes, as identified in Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017: This paragraph provides credit for the actions specified in paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Alert Service Bulletin 737–55A1097, dated July 1, 2015.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (l)(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, FAA, to make those findings. To be

approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved previously for AD 2016–13–16 are approved as AMOCs for the corresponding provisions of Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017, that are required by paragraph (g) of this AD.

(5) Except as required by paragraph (h)(2) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (k)(5)(i) and (k)(5)(ii) of this AD apply.

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

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

(l) Related Information

(1) For more information about this AD, contact Lu Lu, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3525; email: *lu.lu@faa.gov.*

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

(m) Material Incorporated by Reference

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

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

(i) Boeing Alert Service Bulletin 737–55A1097, Revision 1, dated September 20, 2017.

(ii) [Reserved]

(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 November 2, 2018.

Jeffrey E. Duven,

Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–24684 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0758; Product Identifier 2018–NM–093–AD; Amendment 39–19493; AD 2018–23–07]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS 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 SAS Model A350–941 airplanes. This AD was prompted by a review of the Airbus A350 structure design principles database for type definition that revealed that the balancer fitting part, installed on the tail cone, on a certain frame (FR) has several corrosion-resistant stainless steel nuts that do not meet the requirements for protection against corrosion. This AD requires application of a new additional overcoat sealant and elastic varnish on the affected nuts and fasteners. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 19, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 19, 2018.

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *continued-airworthiness.a350@airbus.com;* internet *http://www.airbus.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–2018–0758.

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–2018–0758; 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 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: Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

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 SAS Model A350–941 airplanes. The NPRM published in the **Federal Register** on August 16, 2018 (83 FR 40708). The NPRM was prompted by a review of the Airbus A350 structure design principles database for type definition that revealed that the balancer fitting part, installed on the tail cone, on a certain FR has several corrosion-resistant stainless steel nuts that do not meet the requirements for protection against corrosion. The NPRM proposed to require application of a new additional overcoat sealant and elastic varnish on the affected nuts and fasteners.

We are issuing this AD to address several corrosion-resistant stainless steel nuts installed on elementary aluminum parts, which do not meet the requirements for protection against corrosion, and if not corrected, could reduce the structural integrity of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0123, dated June 4, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus SAS Model A350–941 airplanes. The MCAI states:

Following a complete review of the Airbus A350 structure design principles database for type definition, it was revealed that the balancer fitting part, installed on the tail cone, lower section of Frame (FR) 103, has several corrosion resistant stainless steel nuts installed on elementary aluminium parts, which does not meet the requirements for protection against corrosion.

This condition, if not corrected, could reduce the structural integrity of the aeroplane.

To address this unsafe condition, Airbus developed production mod 110319 to improve protection against corrosion, and issued the SB [Airbus Service Bulletin A350–53–P024] to provide modification instructions for in-service pre-mod aeroplanes. At the same time the production mod 110348 is equivalent to in-service solution.

For the reasons described above, this [EASA] AD requires a modification, adding new additional overcoat sealant and elastic varnish on the affected nuts and fastener heads.

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–2018–0758.

Comments

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

Support for the NPRM

The Air Line Pilots Association, International (ALPA) indicated their support for the NPRM.

Request To Clarify the Proposed AD's Applicability

The commenter Mary Dunn inquired about the proposed AD's effect on similar airplanes and if the actions proposed in the NPRM are proactive or retroactive.

We acknowledge the comment and note that this AD will only affect certain Airbus SAS Model A350–941 airplanes, not airplanes similar to Airbus SAS Model A350–941 airplanes. The unsafe condition has only been identified to affect Airbus SAS Model A350–941 airplanes, not other models, so no action is needed on other airplane models. This AD does have both proactive and retroactive components, in that this AD applies to existing Airbus SAS Model A350–941 airplanes, as specified in paragraph (c) of this AD, while the actions required by paragraph (g) of this AD will be embodied on future Airbus SAS Model A350–941 airplanes in production. No change to this AD has been made in this regard.

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

Airbus has issued Service Bulletin A350–53–P024, dated April 3, 2018. This service information describes procedures for application of a new additional overcoat sealant and elastic varnish on the affected nuts and fasteners. 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 7 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
2 work-hours × $85 per hour = $170	$500	$670	$4,690

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

2018–23–07 Airbus SAS: Amendment 39–19493; Docket No. FAA–2018–0758; Product Identifier 2018–NM–093–AD.

(a) Effective Date

This AD is effective December 19, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A350–941 airplanes, certificated in any category, except those on which Airbus modification 110319 or Airbus modification 110348 has been embodied in production.

(d) Subject

Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Reason

This AD was prompted by a review of the Airbus A350 structure design principles database for type definition that revealed that the balancer fitting part, installed on the tail cone, lower section of frame (FR) 103, has several corrosion-resistant stainless steel nuts installed on elementary aluminum parts, and this configuration does not meet the requirements for protection against corrosion. We are issuing this AD to address this condition, which if not corrected, could reduce the structural integrity of the airplane.

(f) Compliance

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

(g) Required Action

Within 72 months since the date of issuance of the original airworthiness certificate or the date of issuance of the original export certificate of airworthiness, apply additional overcoat sealant and elastic varnish to the fastener heads and the anchor nuts of the balancer fitting at FR 103, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A350–53–P024, dated April 3, 2018.

(h) 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 (i)(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 SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* 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.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0123, dated June 4, 2018, 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–2018–0758.

(2) For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

(j) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A350–53–P024, dated April 3, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *continued-airworthiness.a350@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 November 2, 2018.

Jeffrey E. Duven,

Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–24683 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0297; Product Identifier 2017–NM–181–AD; Amendment 39–19497; AD 2018–23–11]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS 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 SAS Model A319 series airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. This AD was prompted by investigations that revealed that the cover seal of the brake dual distribution valve (BDDV) was damaged and did not ensure efficient sealing. This AD requires identifying the BDDV part number installed on the airplane, and modifying or replacing BDDVs having certain part numbers. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 19, 2018.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 19, 2018.

ADDRESSES: 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 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–2018–0297.

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–2018–0297; 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 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 SAS Model A319 series airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The NPRM published in the **Federal Register** on April 17, 2018 (83 FR 16799). The NPRM was prompted by investigations that revealed that the cover seal of the BDDV was damaged and did not ensure efficient sealing. The NPRM proposed to require identifying the BDDV part number installed on the airplane, and modifying or replacing BDDVs having certain part numbers.

We are issuing this AD to address water ingestion in the BDDV, freezing of the BDDV in flight, and consequent loss of braking system function after landing. These conditions could possibly result in damage to the airplane and injury to occupants.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2017–0119, dated July 11, 2017 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus SAS Model A319 series airplanes; Model A320–211, –212, –214, –231, –232, and –233 airplanes; and Model A321–111, –112, –131, –211, –212, –213, –231, and –232 airplanes. The MCAI states:

> In 1998, an operator experienced a dual loss of braking systems. Investigation results revealed that the cover seal of the BDDV was damaged and did not ensure the sealing efficiency.
>
> This condition, if not corrected, could lead to water ingestion in the BDDV, freezing of the BDDV in flight, and consequent loss of braking system function after landing, possibly resulting in damage to the aeroplane and injury to occupants.
>
> To address this potential unsafe condition, Airbus issued Alert Operator Telex (AOT) 32–19 and Service Bulletin (SB) A320–32–1199, providing instructions for repetitive functional tests. In addition, Airbus developed mod 28301 and published SB A320–32–1203 to provide modification instructions.
>
> Consequently, DGAC [Directorate General for Civil Aviation] France issued AD 2000–258–146 [which corresponds to FAA AD 2001–15–10, Amendment 39–12344 (66 FR 39413, July 31, 2001) (''AD 2001–15–10'')] to require repetitive functional tests as a temporary solution (valid for a period of 15 months) and modification of the BDDV with a new cover and installation of a draining tube with a cap, which was terminating action for the repetitive functional tests. For pre-mod 27833 and pre-SB A320–32–1200 aeroplanes, repetitive inspections per SB A320–32–1199 were required as interim action, prior to the terminating action modification per SB A320–32–1203.
>
> After that [DGAC] AD was issued, following a new event, Airbus developed a new modification of the BDDV drain tube which leaves it open, ensuring continuous drainage of any ingested water, thereby preventing freezing of the brake system.
>
> Consequently, EASA issued AD 2014–0251 (later revised), partially retaining the requirements of DGAC France AD 2000–258–146, which was superseded, and requiring an additional modification of the BDDV drain tube and re-identification of the BDDV.
>
> Since EASA AD 2014–0251R1 [which corresponds to FAA AD 2016–06–13, Amendment 39–18444 (81 FR 17365, March 29, 2016) (''AD 2016–06–13'')] was issued, comments were received that indicated a need for correction and clarification. Consequently, this [EASA] AD retains the requirements of EASA AD 2014–0251R1, which is superseded, and expands the list of BDDV Part Numbers (P/N) which must be removed from service and are no longer eligible for installation on an aeroplane [and includes replacing affected part numbers as an option]. This [EASA] AD also clarifies the intended requirements of EASA AD 2014–0251 and introduces editorial changes, not affecting the requirements.

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–2018–0297.

Comments

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

Supportive Comments

Air Line Pilots Association, International stated its support for the NPRM. In addition, United Airlines (UAL) stated it concurs with the expansion of the affected BDDV part numbers as identified in Figure 1 to paragraphs (g) and (h) of the proposed AD.

Request To Withdraw the NPRM

Delta Air lines (DAL) requested that we withdraw the NPRM. DAL stated that the NPRM does not address an unsafe condition and, therefore, it is unnecessary. DAL commented that airplanes included in paragraph (c) of the proposed AD are already required to comply with the actions required by AD 2001–15–10, depending on modification status. DAL also commented that the NPRM does not add any airplanes to the applicability of AD 2001–15–10 and 2016–06–13. DAL stated that tracking compliance with the redundant requirements of the proposed AD would place an undue burden on airlines.

DAL stated that paragraphs (j)(1)(i) and (j)(2)(i) of the proposed AD give credit for actions accomplished using previously issued service information. DAL commented that FAA Letter ANM–116–16–491, dated September 27, 2016, gives operators the authority to accomplish paragraph (g) of AD 2016–06–13 as an alternative method of compliance (AMOC), and it is also a terminating action for the actions required by paragraphs (e) and (f) of AD 2001–15–10. DAL stated that the compliance times for AD 2001–15–10 and AD 2016–06–13 have passed, therefore, all airplanes must be in compliance.

We partially agree with the commenter's request. We agree that airplanes included in paragraph (c) of this AD are also required to comply with AD 2001–15–10 and AD 2016–06–13, and that this AD does not add any new Model airplanes related to those listed in AD 2001–15–10 and AD 2016–06–13. However, as stated in paragraph (i) of this AD, compliance with paragraph (g) of this AD terminates the requirements in paragraphs (e) and (f) of AD 2001–15–10 (which terminates all requirements of AD 2001–15–10 for Model A318, A319 and A320 series airplanes) and all requirements of AD 2016–06–13. For clarification, we have modified paragraph (i)(1) of this AD to state that compliance with paragraph (g) of this AD terminates all requirements of AD 2001–15–10 for Model A319, A320 and A321 series airplanes. We agree that operators will be required to track certain ADs with expired compliance times, but we are in process of rescinding some of those ADs through future rulemaking. We agree that AMOC letter ANM–116–16–491 dated September 27, 2016, will still be applicable to AD 2016–06–13.

We disagree with the commenter's request to withdraw this AD. We, along with EASA, have determined that water ingestion in the BDDV, freezing of the BDDV in flight, and consequent loss of braking system function after landing, could possibly result in damage to the airplane and injury to occupants, and therefore, does constitute an unsafe condition, and that additional mandatory actions in this AD are required to mitigate the risks associated with the unsafe condition. Further, even if the current U.S.-Registered fleet is in compliance with the requirements of this AD, the issuance of the rule is still necessary to ensure that any affected airplane imported and placed on the U.S. Register in the future would be required to be in compliance as well. This AD expands the list of BDDV part numbers, which must be removed from service and are no longer eligible for installation on an airplane. Therefore, all U.S.-Registered airplanes might not be in compliance with the actions of this AD even when in full compliance with AD 2001–15–10 and AD 2016–06–13. However, if DAL concludes that it is in compliance with the requirements of this AD, then it may utilize the provision in paragraph (f) to demonstrate compliance. We have not changed this AD in this regard.

Request To Correct Certain Wording

DAL observed that the word ''actions'' was inadvertently omitted from the first sentence in paragraph (g)(2) of the proposed AD after the word ''corrective.'' We agree and have added the missing word accordingly.

Request To Revise Certain Wording for Clarification

UAL requested that we revise the wording in certain paragraphs of the proposed AD for clarification. UAL suggested that paragraph (g)(3) of the proposed AD be reworded because the way it is currently written, it could be interpreted as ''a part number specified as new P/N in figure 2 to paragraphs (g)(3) and (h)(2)'' cannot be installed.

UAL also suggested that paragraph (h) of the proposed AD be revised to eliminate paragraphs (h)(1) and (h)(2) and be reworded to simply prohibit the installation of affected BDDVs as specified in figure 1 to paragraphs (g) and (h) of the proposed AD.

We partially agree to the commenter's requests. We agree to clarify paragraph (g)(3) of this AD. We have revised paragraph (g)(3) of this AD to clarify that operators should replace the old part number with a new part number as specified in figure 2 to paragraphs (g)(3) and (h)(2) of this AD.

However, we disagree to simply prohibit installation of discrepant parts that are specified in figure 1 to paragraphs (g) and (h) of this AD from the effective date of this AD. Paragraph (h) provides operators flexibility by providing the full compliance time as specified in paragraph (g) to modify or replace discrepant parts, unless the discrepant part is either currently installed as of the effective date of this AD and is subsequently modified or replaced (after the effective date of this AD) as stated in paragraph (h)(1) of this AD, or has already been modified or replaced as of the effective date of this AD as stated in paragraph (h)(2) of this AD. Operators have the discretion to prohibit operation with a discrepant part in figure 1 to paragraphs (g) and (h) of this AD from the effective date of this AD. We have not changed the AD in this regard.

Request To Clarify the Compliance Requirements

JetBlue requested that we clarify the compliance requirements in paragraphs (g)(2), (g)(3), and (h)(2) of the proposed AD because of contradictory requirements. The commenter did not clearly identify which requirements needed clarification.

We do not agree to revise paragraph (g)(2) of this AD. This AD and the Accomplishment Instructions of Airbus Service Bulletin A320–32–1415, Revision 02, dated December 10, 2015, specify that, if corrosion is found in a non-permitted area, replace the BDDV before further flight. We have not changed this AD in this regard.

As we stated previously, we have revised paragraph (g)(3) of this AD to clarify that operators should replace the old part number with a new part number as specified in figure 2 to paragraphs (g)(3) and (h)(2) of this AD.

We agree to clarify the compliance requirements of paragraph (h)(2) of this AD. As stated in the previous comment response, paragraph (h) is intended to provide operators flexibility by providing the full compliance time as specified in paragraph (g) to modify or replace discrepant parts. However, paragraph (h)(2) of this AD specifically prohibits installation of a discrepant part as of the effective date of this AD if the discrepant part has already been modified or replaced as of the effective date of this AD. Paragraph (h)(1) of this AD prohibits installation of a discrepant part as of the effective date of this AD, if a discrepant part is currently installed as of the effective of this AD, but is modified or replaced after the effective date of this AD. Operators have the discretion to prohibit operation with a discrepant part in figure 1 to paragraphs (g) and (h) of this AD from the effective date of this AD. We have not changed the AD in this regard.

Conclusion

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

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

Related Service Information Under 1 CFR Part 51

Airbus SAS has issued Service Bulletin A320–32–1203, Revision 02, dated February 9, 2001. This service information describes procedures for identifying the BDDV part number installed on the airplane, and modifying or replacing BDDVs having certain part numbers.

Airbus SAS has also issued Service Bulletin A320–32–1415, Revision 02, dated December 10, 2015. This service information describes procedures for

modifying and re-identifying the BDDV. The modification includes modifying the drain hose of the BDDV, and doing all related investigative and corrective actions if applicable. The related investigative actions include an inspection for corrosion. Corrective actions include replacing the BDDV.

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 1,136 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
Identification and modification or replacement.	Up to 6 work-hours × $85 per hour = $510.	Up to $395	Up to $905	Up to $1,028,080.

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

Authority for This Rulemaking

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

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 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):

2018–23–11 Airbus SAS: Amendment 39–19497; Docket No. FAA–2018–0297; Product Identifier 2017–NM–181–AD.

(a) Effective Date

This AD is effective December 19, 2018.

(b) Affected ADs

This AD affects AD 2001–15–10, Amendment 39–12344 (66 FR 39413, July 31, 2001) (''AD 2001–15–10''), and AD 2016–06–13, Amendment 39–18444 (81 FR 17365, March 29, 2016) (''AD 2016–06–13'').

(c) Applicability

This AD applies to the airplanes identified in paragraphs (c)(1) through (c)(3) of this AD, certificated in any category, all manufacturer serial numbers, except those on which Airbus Modification 26925 has been embodied in production, which introduces a modified alternate braking system that removes the brake dual distribution valve (BDDV).

(1) Airbus SAS Model A319–111, –112, –113, –114, –115, –131, –132, and –133 airplanes.

(2) Airbus SAS Model A320–211, –212, –214, –231, –232, and –233 airplanes.

(3) Airbus SAS Model A321–111, –112, –131,–211,–212, –213, –231, and –232 airplanes.

(d) Subject

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

(e) Reason

This AD was prompted by investigations that revealed that the cover seal of the brake dual distribution valve (BDDV) was damaged and did not ensure efficient sealing. We are issuing this AD to prevent water ingestion in the BDDV, freezing of the BDDV in flight, and consequent loss of braking system function after landing. These conditions could possibly result in damage to the airplane and injury to occupants.

(f) Compliance

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

(g) Identification and Modification or Replacement

Within 3 months after the effective date of this AD, identify the BDDV part number installed on the airplane. For each affected BDDV part number specified in figure 1 to paragraphs (g) and (h) of this AD, within 3 months after the effective date of this AD, do the actions in paragraph (g)(1), (g)(2), or (g)(3) of this AD. A review of airplane maintenance records is acceptable to identify the BDDV part number if the part number of the BDDV can be conclusively determined from that review.

Figure 1 to paragraphs (g) and (h) of this AD – *Affected BDDV part number*

P/N				
A25434005-1	A25434005-100	A25434005-101	A25434006-1	A25434006-100
A25434005-2	A25434005-200	A25434005-201	A25434006-2	A25434006-101
A25434005-3	A25434005-300	A25434005-301	A25434006-3	A25434006-200
A25434005-4	A25434005-400	A25434005-401		

(1) Modify and re-identify the affected BDDV, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–32–1203, Revision 02, dated February 9, 2001.

(2) Modify and re-identify the affected BDDV, and do all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Airbus Service Bulletin A320–32–1415, Revision 02, dated December 10, 2015. Do all applicable related investigative and corrective actions before further flight.

(3) Replace the affected BDDV with a BDDV having a part number not specified in figure 1 to paragraphs (g) and (h) of this AD, or replace the old part number with a new part number as specified in figure 2 to paragraphs (g)(3) and (h)(2) of this AD. Do the replacement using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Airbus SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

Figure 2 to paragraphs (g)(3) and (h)(2) of this AD – *BDDV part number re-identification*

Old P/N	New P/N
A25434006-3	A25434006-3000
A25434005-101	A25434005-1010
A25434005-201	A25434005-2010
A25434005-301	A25434005-3010
A25434005-401	A25434005-4010
A25434006-101	A25434006-1010

(h) Parts Installation Prohibition

As of the applicable time specified in paragraph (h)(1) or (h)(2) of this AD, no person may install a BDDV having a part number specified in figure 1 to paragraphs (g) and (h) of this AD, on any airplane.

(1) For any airplane that, on the effective date of this AD, has a BDDV installed with a part number specified in figure 1 to paragraphs (g) and (h) of this AD: After modification or replacement of the BDDV, as required by paragraph (g) of this AD.

(2) For any airplane that, on the effective date of this AD, has a BDDV installed or replaced with a part number specified as 'new P/N' in figure 2 to paragraphs (g)(3) and (h)(2) of this AD, or has a BDDV installed or replaced with a part number not specified in figure 1 to paragraphs (g) and (h) of this AD: As of the effective date of this AD.

(i) Terminating Action for Other ADs

(1) Doing the actions in paragraph (g) of this AD terminates the requirements in paragraphs (e) and (f) of AD 2001–15–10 for Model A319, A320 and A321 series airplanes.

(2) Doing the actions in paragraph (g) of this AD terminates all of the requirements of AD 2016–06–13.

(j) Credit for Previous Actions

(1) This paragraph provides credit for actions required by paragraph (g)(1) of this AD, if those actions were performed before the effective date of this AD using the service information in paragraphs (j)(1)(i) or (j)(1)(ii) of this AD.

(i) Airbus Service Bulletin A320–32–1203, dated June 4, 1999, which was incorporated by reference in AD 2001–15–10.

(ii) Airbus Service Bulletin A320–32–1203, Revision 01, dated October 12, 2000.

(2) This paragraph provides credit for actions required by paragraph (g)(2) of this AD, if those actions were performed before the effective date of this AD using the service information in paragraphs (j)(2)(i) or (j)(2)(ii) of this AD.

(i) Airbus Service Bulletin A320–32–1415, dated September 2, 2014, which was incorporated by reference in AD 2016–06–13.

(ii) Airbus Service Bulletin A320–32–1415, Revision 01, dated April 23, 2015.

(k) 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 (l)(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 EASA; or Airbus SAS's EASA DOA. If approved by the DOA, the approval must include the DOA-authorized signature.

(3) Required for Compliance (RC): 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.

(l) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2017–0119, dated July 11, 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–2018–0297.

(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 (m)(3) and (m)(4) of this AD.

(m) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A320–32–1203, Revision 02, dated February 9, 2001.

(ii) Airbus Service Bulletin A320–32–1415, Revision 02, dated December 10, 2015.

(3) 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.*

(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 November 5, 2018.

Christopher Spangenberg,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–24688 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2018–0637; Product Identifier 2018–NM–091–AD; Amendment 39–19496; AD 2018–23–10]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS 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 SAS Model A350–941 airplanes. This AD was prompted by leakage of shrouded pipe T-boxes in the potable water system. This AD requires replacement of the affected potable water T-boxes and clamps with new parts. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 19, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 19, 2018.

ADDRESSES: For service information identified in this final rule, contact Airbus SAS, Airworthiness Office—EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *continued-airworthiness.a350@airbus.com;* internet *http://www.airbus.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–2018–0637.

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–2018–0637; 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 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: Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

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 SAS Model A350–941 airplanes. The NPRM published in the **Federal Register** on August 2, 2018 (83 FR 37766). The NPRM was prompted by leakage of shrouded pipe T-boxes in the potable water system. The NPRM proposed to require replacement of the affected potable water T-boxes and clamps with new parts.

We are issuing this AD to address the possible leakage of water into the avionics bay. This condition, if not corrected, could lead to the loss of systems/equipment located inside the avionics bay and possible loss of control of the airplane.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2018–0111R1, dated May 30, 2018 (referred to after this as the Mandatory Continuing Airworthiness Information, or ''the MCAI''), to correct an unsafe condition for certain Airbus SAS Model A350–941 airplanes. The MCAI states:

> During a pressure test on the A350 Final Assembly Line (FAL), leakage was observed on the potable water system shrouded pipes, due to a crack failure on the T-Boxes. Leakage of a primary pipe may cause water ingress into the avionics bay. Additionally, during another pressure proof test on the A350 FAL, loss of torque was detected on the clamps used to attach the shrouded pipes on the T-Boxes.
>
> This condition, if not corrected, could lead to loss of systems/equipment located inside the avionics bay, possibly resulting in an unsafe condition.
>
> Prompted by these findings, Airbus developed improved potable water T-Boxes and clamps, which are embodied in production through Airbus mod 111435 or mod 111440, and introduced in service through the SB [Service Bulletin A350–38–P004].
>
> For the reasons described above, this [EASA] AD requires replacement of the affected potable water shrouded pipe T-Boxes and clamps with new parts.
>
> This [EASA] AD was revised to exclude post-mod 111440 aeroplanes from the Applicability.

You may examine the MCAI in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0637.

Comments

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

Request To Reference Maintenance Procedure (MP) Task for Additional Information

Delta Air Lines (DAL) requested that we reference Airbus MP Task A350–A–20–51–64–01001–25BA–A in the proposed AD as a guide for installing and torqueing the hardware. DAL stated that the additional information provided in the MP task would ensure a more complete set of installation instructions.

We agree with the commenter, because the referenced MP task does provide proper torque values. We have added a reference to the specified MP task as a note to paragraph (g) of this AD.

Request To Remove Leak Test Requirement

DAL requested that we remove the system leak test requirement from the proposed AD. DAL stated that Airbus gave them permission to forego the test because the potable water system requires no maintenance, and that the test is therefore unnecessary.

We disagree with removing the required test, because we have insufficient evidence to warrant removing a required test from this AD for all operators. DAL may request approval of an alternative method of compliance (AMOC), if it can provide sufficient data to substantiate that skipping the test would provide an acceptable level of safety for DAL's fleet. We have not changed this AD in this regard.

Request To Provide Alternative Hardware Solution

DAL requested that we modify the proposed AD by raising the required torque value or requiring a lockwire for the clamp screw. DAL asserted that the torque value given in the service information is very low for this type of clamp, and that if the screw loses its torque, the clamp could depart the shell and fall into the avionics bay, creating a possible hazard to safe navigation.

We disagree with DAL's request because we have confirmed with Airbus and EASA that the clamp torque specified in the referenced service information is correct. Concerned operators may request approval of an AMOC for a lockwire solution under the provisions of paragraph (h) of this AD. We have not changed this AD in this regard.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the change 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 addressing 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 final rule.

Related Service Information Under 1 CFR Part 51

Airbus has issued Service Bulletin A350–38–P004, dated April 11, 2018. This service information describes procedures for replacing the affected potable water T-boxes and clamps with new parts. 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 7 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 16 work-hours × $85 per hour = $1,360.	Up to $2,050	Up to $3,410	Up to $23,870.

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

2018–23–10 Airbus SAS: Amendment 39–19496; Docket No. FAA–2018–0637; Product Identifier 2018–NM–091–AD.

(a) Effective Date

This AD is effective December 19, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Airbus SAS Model A350–941 airplanes, certificated in any category, except those on which Airbus modification (mod) 111435 or mod 111440 has been embodied in production.

(d) Subject

Air Transport Association (ATA) of America Code 38, Water/waste.

(e) Reason

This AD was prompted by leakage of shrouded pipe T-boxes in the potable water system. We are issuing this AD to address the possible leakage of water into the avionics bay. This condition, if not corrected, could lead to the loss of systems/equipment located inside the avionics bay and possible loss of control of the airplane.

(f) Compliance

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

(g) Required Actions

Within 36 months after the effective date of this AD: Replace the affected potable water T-boxes and clamps with new parts in accordance with the Accomplishment Instructions of Airbus Service Bulletin A350–38–P004, dated April 11, 2018.

Note 1 to paragraph (g) of this AD: Airbus Maintenance Procedure (MP) Task A350–A–20–51–64–01001–25BA–A provides additional information for installing and torqueing the hardware.

(h) 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 (i)(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 SAS's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(3) *Required for Compliance (RC):* 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.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0111R1, dated May 30, 2018, 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–2018–0637.

(2) For more information about this AD, contact Kathleen Arrigotti, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3218.

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

(j) Material Incorporated by Reference

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

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

(i) Airbus Service Bulletin A350–38–P004, dated April 11, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Airbus SAS, Airworthiness Office—EAL, Rond-Point Emile Dewoitine No: 2, 31700 Blagnac Cedex, France; telephone +33 5 61 93 36 96; fax +33 5 61 93 45 80; email *continued-airworthiness.a350@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 November 5, 2018.

Chris Spangenberg,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–24686 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2018–0125; Airspace Docket No. 18–AAL–5]

RIN 2120–AA66

Amendment of Class D and Class E Airspace, and Revocation of Class E Airspace; Juneau, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class D airspace, Class E surface area airspace, Class E airspace extending upward from 700 feet above the surface, and removes Class E airspace designated as an extension at Juneau International

Airport, Juneau, AK. Airspace redesign is necessary as the FAA transitions from ground-based to satellite-based navigation for the safety and management of instrument flight rules (IFR) operations at this airport. This action also updates the airport's geographic coordinates to match the FAA's aeronautical database for the associated Class D and E airspace areas, and replaces the outdated term Airport/Facility Directory with Chart Supplement in the Class D airspace legal description.

DATES: Effective 0901 UTC, January 3, 2019. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11C, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA).

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

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

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Operations Support Group, Western Service Center, 2200 S 216th Street, Des Moines, WA 98198–6547; telephone (206) 231–2245.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies Class D airspace, Class E surface area airspace, Class E airspace extending upward from 700 feet above the surface, and removes Class E airspace designated as an extension at Juneau International Airport, Juneau, AK, to support IFR operations at this airport.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (83 FR 19653; May 4, 2018) for Docket No. FAA–2018–0125 to modify Class D airspace, Class E surface area airspace, Class E airspace extending upward from 700 feet above the surface and remove Class E airspace designated as an extension at Juneau International Airport, Juneau, AK. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. One commenter was concerned that VFR operations would be problematic because the Airport Traffic Control Tower (ATCT) would not be able to see to the lateral boundaries of the proposed Class D area and weather may be inconsistent between the outer areas of the proposed Class D and the area closer to the airport.

The FAA's response is that these conditions exist in several locations across the CONUS and Air Traffic Control is skilled at operations within these environments. Pilots operating under Visual Flight Rules (VFR) at the lateral boundaries of the proposed Class D may continue to operate VFR provided weather minimums can be maintained and Special VFR requirements are applied, when appropriate.

In addition, the commenter wrote that communication below 1,500 feet above ground level (AGL) was limited in the proposed airspace to the west.

The FAA performed a communication analysis at both 1,000 and 1,500 feet AGL and determined that communication in the area is provided by both a Remote Communications Air/Ground facility (RCAG) and a Back Up Emergency Communication (BUEC) facility. The analysis determined that, while some terrain features may create communication difficulties in specific locations, the available systems should provide communication coverage either on the primary frequency with Juneau ATCT or the BUEC through Anchorage Air Route Traffic Control Center.

Class D and Class E airspace designations are published in paragraph 5000, 6002, 6004, and 6005, respectively, of FAA Order 7400.11C, dated August 13, 2018, and effective September 15, 2018, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018. FAA Order 7400.11C is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11C lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 modifies Class D airspace, Class E surface area airspace, Class E airspace extending upward from 700 feet above the surface and removes Class E designated as an extension at Juneau International Airport, Juneau, AK.

Class D airspace is modified to within a 3-mile radius of Juneau International Airport and within 2.5 miles each side of the 271° bearing from the airport extending from the 3-mile radius to 5.2 miles west of the airport, and within 1 mile southwest and 2.6 miles northeast of the airport 135° bearing extending from the airport 3-mile radius to 5 miles southeast of the airport, excluding that airspace below 2,000 feet MSL within the area bounded by a line beginning at lat. 58°19′35″ N, long. 134°24′31″ W, to lat. 58°19′02″ N, long. 134°25′33″ W, to lat. 58°20′16″ N, long. 134°27′28″ W, to lat. 58°20′34″ N, long. 134°26′22″ W, thence to the point of beginning. The areas to the west and southeast of the airport contains IFR departures and arrivals. A small area within the extended area to the southeast near Salmon Creek is excluded from Class D airspace below 2,000 feet MSL to ensure 2-way radio communication with the Juneau Airport Traffic Control Tower is possible prior to entering Class D airspace from that area.

Class E surface area airspace is modified to be coincident with the Class D airspace area described above.

Class E airspace designated as an extension is removed since the Class D airspace contains arrival aircraft within 1,000 feet of the surface, and a Class E arrival extension is not required.

Class E airspace extending upward from 700 feet above the surface is modified to a polygon approximately 12–18 miles wide by 42-miles long (from approximately 48 miles wide by 70 miles long) oriented northwest to

southeast (from west to east). The area is defined as that airspace upward from 700 feet above the surface within the area bounded by a line beginning at lat. 58°27′33″ N, long. 134°37′40″ W, to lat. 58°13′13″ N, long. 134°11′51″ W, to lat. 58°05′59″ N, long. 134°21′04″ W, to lat. 58°10′51″ N, long. 134°59′18″ W, to lat. 58°23′41″ N, long. 135°31′13″ W, to lat. 58°32′22″ N, long. 135°18′32″ W, to lat. 58°27′17″ N, long. 135°01′27″ W, thence to the point of beginning. This modification reduces the airspace area to only that area necessary to contain IFR operations as they transition between the airport and en route environments. Also, Class E airspace extending upward from 1,200 feet above the surface designated for Juneau International Airport is removed since this airspace is wholly contained within the Southeast Alaska Class E en route airspace, and duplication is not necessary.

This action also makes an editorial change to the Class D airspace legal description replacing Airport/Facility Directory with Chart Supplement.

Regulatory Notices and Analyses

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

Environmental Review

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

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11C, Airspace Designations and Reporting Points, dated August 13, 2018, and effective September 15, 2018, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

AAL AK D Juneau, AK [Amended]

Juneau International Airport, AK
(Lat. 58°21′17″ N, long. 134°34′42″ W)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 3-mile radius of Juneau International Airport, and within 2.5 miles each side of the 271° bearing from the airport extending from the 3-mile radius to 5.2 miles west of the airport, and within 1 mile southwest and 2.6 miles northeast of the airport 135° bearing extending from the airport 3-mile radius to 5 miles southeast of the airport, excluding that airspace below 2,000 feet MSL within the area bounded by a line beginning at lat. 58°19′35″ N, long. 134°24′31″ W, to lat. 58°19′02″ N, long. 134°25′33″ W, to lat. 58°20′16″ N, long. 134°27′28″ W, to lat. 58°20′34″ N, long. 134°26′22″ W, thence to the point of beginning. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6002 Class E Airspace Areas Designated as Surface Areas.

* * * * *

AAL AK E2 Juneau, AK [Amended]

Juneau International Airport, AK
(Lat. 58°21′17″ N, long. 134°34′42″ W)

That airspace extending upward from the surface within a 3-mile radius of Juneau International Airport, and within 2.5 miles each side of the 271° bearing from the airport extending from the 3-mile radius to 5.2 miles west of the airport, and within 1 mile southwest and 2.6 miles northeast of the airport 135° bearing extending from the airport 3-mile radius to 5 miles southeast of the airport, excluding that airspace below 2,000 feet MSL within the area bounded by a line beginning at lat. 58°19′35″ N, long. 134°24′31″ W, to lat. 58°19′02″ N, long. 134°25′33″ W, to lat. 58°20′16″ N, long. 134°27′28″ W, to lat. 58°20′34″ N, long. 134°26′22″ W, thence to the point of beginning. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Designated as an Extension to a Class D or Class E Surface Area.

* * * * *

AAL AK E4 Juneau, AK [Removed]

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

* * * * *

AAL AK E5 Juneau, AK [Amended]

Juneau International Airport, AK
(Lat. 58°21′17″ N, long. 134°34′42″ W)

That airspace upward from 700 feet above the surface within the area bounded by a line beginning at lat. 58°27′33″ N, long. 134°37′40″ W, to lat. 58°13′13″ N, long. 134°11′51″ W, to lat. 58°05′59″ N, long. 134°21′04″ W, to lat. 58°10′51″ N, long. 134°59′18″ W, to lat. 58°23′41″ N, long. 135°31′13″ W, to lat. 58°32′22″ N, long. 135°18′32″ W, to lat. 58°27′17″ N, long. 135°01′27″ W, thence to the point of beginning.

Issued in Seattle, Washington, on November 1, 2018.

Shawn M. Kozica,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2018–24721 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51, 60, and 63

[EPA–HQ–OAR–2016–0510; FRL–9986–42–OAR]

RIN 2060–AS95

Testing Regulations for Air Emission Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This action amends certain existing testing regulations to reflect corrections, updates, and the addition of alternative equipment and methods for source testing of emissions. These revisions will improve the quality of data and provide flexibility in the use of

approved alternative procedures. The revisions do not impose any new substantive requirements on source owners or operators.

DATES: The final rule is effective on January 14, 2019. The incorporation by reference materials listed in the rule are approved by the Director of the Federal Register as of January 14, 2019.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OAR–2016–0510. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Lula H. Melton, Office of Air Quality Planning and Standards, Air Quality Assessment Division (E143–02), Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number: (919) 541–2910; fax number: (919) 541–0516; email address: *melton.lula@epa.gov.*

SUPPLEMENTARY INFORMATION: The supplementary information in this preamble is organized as follows:

Table of Contents

I. General Information

A. Does this action apply to me?

The revisions promulgated in this final rule apply to industries that are subject to the current provisions of 40 Code of Federal Regulations (CFR) parts 51, 60, and 63. We did not list all of the specific affected industries or their North American Industry Classification System (NAICS) codes herein since there are many affected sources in numerous NAICS categories. If you have any questions regarding the applicability of this action to a particular entity, consult either the air permitting authority for the entity or your EPA Regional representative as listed in 40 CFR 63.13.

B. What action is the agency taking?

We are promulgating corrections and updates to regulations for source testing of emissions. More specifically, we are correcting typographical and technical errors, updating obsolete testing procedures, adding approved testing alternatives, and clarifying testing requirements.

C. Judicial Review

Under section 307(b)(1) of the Clean Air Act (CAA), judicial review of this final rule is available by filing a petition for review in the United States Court of Appeals for the District of Columbia Circuit by January 14, 2019. Under section 307(d)(7)(B) of the CAA, only an objection to this final rule that was raised with reasonable specificity during the period for public comment can be raised during judicial review. Moreover, under section 307(b)(2) of the CAA, the requirements that are the subject of this final rule may not be challenged later in civil or criminal proceedings brought by the EPA to enforce these requirements.

II. Background

The revisions to testing regulations for air emission sources were proposed in the **Federal Register** on January 26, 2018 (83 FR 3636). The public comment period ended March 27, 2018, and 83 comment letters were received from the public; 23 of the comment letters were relevant, and the other 60 comment letters were considered beyond the scope of the proposed rule. This final rule was developed based on public comments that the agency received on the proposed rule.

III. Summary of Amendments

A. Method 201A of Appendix M of Part 51

In Method 201A, in section 12.5, the denominator of equation 24 is corrected

as proposed; the proposed c'_p in the denominator is changed to C_p' to be consistent with the nomenclature in section 12.1. The c_p in the numerator is changed to C_p also to be consistent with the nomenclature in section 12.1.

B. Method 204 of Appendix M of Part 51

In Method 204, in section 8.2, the statement regarding equation 204–2 is corrected to ''The NEAR must be ≤0.05,'' as proposed.

C. Method 205 of Appendix M of Part 51

In Method 205, section 2.1.1 is revised to allow the use of National Institute of Standards and Technology (NIST)-traceable transfer standards to calibrate the gas dilution system as proposed. The agency continues to believe that these standards are widely available and provide the accuracy necessary to perform the calibration. Section 2.1.1 is also revised as proposed to require testers to report the results of the calibration of the dilution system to enable the regulatory authority to review this information.

D. General Provisions (Subpart A) of Part 60

In the General Provisions of part 60, § 60.17(h) is revised as proposed to add ASTM D6216–12 to the list of incorporations by reference and to re-number the remaining consensus standards that are incorporated by reference in alpha-numeric order.

E. Fossil-Fuel-Fired Steam Generators (Subpart D) Part 60

In a change from proposal, the allowed filter temperature in § 60.46(b)(2)(i) is not revised. Based on comments we received on the proposed revisions, we are deferring finalizing the proposed revisions of the temperature tolerances of probe and filter holder heating systems as part of this rulemaking. We will continue to review supporting information and data we received on the proposed rule and may propose either revisions or similar requirements as part of future rulemakings.

F. Electric Utility Steam Generating Units (Subpart Da) Part 60

In a change from proposal, the allowed filter temperature in § 60.50Da (b)(1)(ii)(A) is not revised. Based on comments we received on the proposed revisions, we are deferring finalizing the proposed revisions of the temperature tolerances of probe and filter holder heating systems as part of this rulemaking. We will continue to review supporting information and data we received on the proposed rule and may propose either revisions or similar requirements as part of future rulemakings.

G. Industrial-Commercial-Institutional Steam Generating Units (Subpart Db) Part 60

In a change from proposal, the allowed filter temperature in § 60.46b(d)(4) is not revised. Based on comments we received on the proposed revisions, we are deferring finalizing the proposed revisions of the temperature tolerances of probe and filter holder heating systems as part of this rulemaking. We will continue to review supporting information and data we received on the proposed rule and may propose either revisions or similar requirements as part of future rulemakings.

H. Small Industrial-Commercial-Institutional Steam Generating Units (Subpart Dc) Part 60

In a change from proposal, the allowed filter temperature in § 60.45c(a)(5) is not revised. Based on comments we received on the proposed revisions, we are deferring finalizing the proposed revisions of the temperature tolerances of probe and filter holder heating systems as part of this rulemaking. We will continue to review supporting information and data we received on the proposed rule and may propose either revisions or similar requirements as part of future rulemakings.

I. Municipal Waste Combustors for Which Construction is Commenced After December 20, 1989 and on or Before September 20, 1994 (Subpart Ea) Part 60

In a change from proposal, the allowed filter temperature in § 60.58a(b)(3) is not revised. Based on comments we received on the proposed revisions, we are deferring finalizing the proposed revisions of the temperature tolerances of probe and filter holder heating systems as part of this rulemaking. We will continue to review supporting information and data we received on the proposed rule and may propose either revisions or similar requirements as part of future rulemakings.

J. Glass Manufacturing Plants (Subpart CC) Part 60

In a change from proposal, the allowed filter temperatures in §§ 60.293(f) and 60.296(d)(2) are not revised. Based on comments we received on the proposed revisions, we are deferring finalizing the proposed revisions of the temperature tolerances of probe and filter holder heating systems as part of this rulemaking. We will continue to review supporting information and data we received on the proposed rule and may propose either revisions or similar requirements as part of future rulemakings.

K. New Residential Wood Heaters, New Residential Hydronic Heaters and Forced-Air Furnaces (Subpart QQQQ) Part 60

In subpart QQQQ, in Method 28WHH, in section 13.5.1, equation 8 is corrected as proposed.

L. Method 2B of Appendix A–1 of Part 60

In Method 2B, in section 12.1, the definition of ambient carbon dioxide concentration is revised as proposed. The agency continues to believe that the global monthly mean $(CO_2)_a$ concentration varies over time. Also, a website link is added to the definition as specified at proposal.

M. Method 5 of Appendix A–3 of Part 60

In a change from proposal, allowed filter temperatures in Method 5, sections 2.0, 6.1.1.2, 6.1.1.6, 6.1.1.7, and 8.5 are not revised. Based on comments we received on the proposed revisions, we are deferring finalizing the proposed revisions of the temperature tolerances of probe and filter holder heating systems as part of this rulemaking. We will continue to review supporting information and data we received on the proposed rule and may propose either revisions or similar requirements as part of future rulemakings.

Section 6.1.1.9 is revised as proposed to allow the use of a single temperature sensor in lieu of two temperature sensors on the dry gas meter as allowed by Technical Information Document 19 (TID–19) and the approved broadly applicable alternative, ALT–117 (see *https://www.epa.gov/emc*). Consistent with our response to the comment regarding allowing flexibility for the weighing container in section 11.2.1, Method 5B, the first sentence in section 11.2.1, Method 5 is revised similarly.

N. Method 5B of Appendix A–3 of Part 60

In a change from proposal, the allowed filter temperatures in Method 5B, sections 2.0, 6.1, and 8.2 are not revised. Based on comments we received on the proposed revisions, we are deferring finalizing the proposed revisions of the temperature tolerances of probe and filter holder heating

systems as part of this rulemaking. We will continue to review supporting information and data we received on the proposed rule and may propose either revisions or similar requirements as part of future rulemakings.

Section 11.0 is revised as proposed to replace the reference to Method 5, section 11.0 with specific analytical procedures and to report the results using Figure 5B–1 for complete data review. Section 17.0 is revised as proposed to delete the word ''Reserved'' from the title, and Figure 5B–1 (Analytical Data Sheet) is added.

O. Method 5I of Appendix A–3 of Part 60

In a change from proposal, Method 5I, sections 2.1 and 8.5.2.2 are not revised to tighten the allowed filter temperatures. Based on comments we received on the proposed revisions, we are deferring finalizing the proposed revisions of the temperature tolerances of probe and filter holder heating systems as part of this rulemaking. We will continue to review supporting information and data we received on the proposed rule and may propose either revisions or similar requirements as part of future rulemakings.

P. Method 7 of Appendix A–4 of Part 60

In Method 7, sections 10.1.2 and 11.3 reference erroneous sections; the correct section is inserted, as proposed. The proposed referenced section 10.1.1.2 is changed to 10.1.1 to include procedures in both sections 10.1.1.1 and 10.1.1.2.

Q. Method 8 of Appendix A–4 of Part 60

As proposed, Method 8, sections 6.1.1.1 through 6.1.1.4 are renumbered to 6.1.1.2 through 6.1.1.5; a new section 6.1.1.1 is added to clarify the requirements that apply to the probe nozzle; and, in response to comments, Figure 8–1 (Sulfuric Acid Sampling Train) is corrected by: (1) Modifying the impinger graphics to make it consistent with the text in section 6.1.1.4 and (2) revising the proposed label S-Type Pitot Tube to Type S Pitot Tube for consistency. The proposed first sentence in section 6.1.1.1 is revised to ''Borosilicate or quartz glass with a sharp, tapered leading edge and coupled to the probe liner using a polytetrafluoroethylene (PTFE) or glass-lined union (*e.g.,* fused silica, Silico, or equivalent).'' Based on a public comment that recommended adding Silco coated stainless steel unions as an option for Teflon unions, and for consistency with other test methods, we have replaced Teflon with the generic option polytetrafluoroethylene (PTFE).

R. Method 18 of Appendix A–6 of Part 60

In Method 18, in section 13.1, the erroneous paragraph (c) designation is re-designated as (b), as proposed.

S. Method 22 of Appendix A–7 of Part 60

In Method 22, sections 11.2.1 and 11.2.2 are revised as proposed to allow digital photography to be used for a subset of the recordkeeping requirements. As proposed, section 11.2.3 is added to specify the requirements for digital photographic records. In response to comments on the proposal, the next to the last sentence in section 11.2.3 regarding photographs that must be taken within 15 minutes of the observation period is revised from the proposal, and another sentence is added to provide clarity. The revised and new sentences read: ''The photograph(s) representing the environmental conditions including the sky conditions and the position of the sun relative to the observer and the emission point must be taken within a reasonable time of the observation (*i.e.,* 15 minutes). When observations are taken from exactly the same observation point on a routine basis (*e.g.,* daily) and as long as there are no modifications to the units depicted, only a single photograph each day is necessary to document the observer's location relative to the emissions source, the process unit being observed, and the location of potential and actual emission points.'' The agency notes that ALT–109 (see *https://www.epa.gov/emc*) is the associated broadly applicable alternative that allows the use of digital photographs for specific recordkeeping requirements.

T. Method 26 of Appendix A–8 of Part 60

As proposed, Method 26, section 6.2.2 is revised to allow the use of glass sample storage containers as an option to allow flexibility and to be consistent with Method 26A. The proposed title of section 6.2.2, ''Storage Bottles,'' is changed to ''Storage Containers'' to be consistent with the language in section 6.2.2.

U. Method 26A of Appendix A–8 of Part 60

As proposed, in Method 26A, section 6.2.1 is revised to remove the language regarding sample storage containers. In response to comments on our proposal, we have determined that high-density polyethylene is an acceptable material for sample storage containers in addition to the currently allowed glass. Therefore, in a new section 6.2.4., we have specified that both high-density polyethylene and glass are acceptable sample storage containers.

V. Test Method 28WHH of Appendix A–8 of Part 60

In Test Method 28WHH, equation 8 in section 13.5.1 is corrected, as proposed.

W. Performance Specification 1 of Appendix B of Part 60

As proposed, in Performance Specification 1, references to ASTM D6216–98 (in sections 2.1, 3.1, 6.1, 8.1(1), 8.1(3)(ii), 8.2(1), 8.2(2), 8.2(3), 9.0, 12.1, 13.0, 13.1, 13.2, and 16.0 paragraph 8) are replaced with ASTM D6216–12. As noted at proposal, if the initial certification of the continuous opacity monitoring system (COMS) has already occurred using D6216–98, D6216–03, or D6216–07, it will not be necessary to recertify using D6216–12. In response to comments on our decision to add ASTM D6216 to the list of consensus standards, the April 1998 publication date for ASTM D6216 in paragraph 8 in section 16.0 is replaced with October 2012, the ASTM D6216–12 publication date. In response to comments, for consistency with section 2.1, and for purposes of clarification, the note at the end of section 2.1 is added to section 13.0.

X. Performance Specification 2 of Appendix B of Part 60

In Performance Specification 2, section 13.2 is replaced with a table that indicates the relative accuracy performance specifications, as proposed. Given that the equals to (=) signs were erroneously omitted from several of the < and > values during publication of the table in the proposed rule, these values have been corrected.

Y. Performance Specification 3 of Appendix B of Part 60

In Performance Specification 3, the two sentences in section 12.0 that read, ''Calculate the arithmetic difference between the RM and the CEMS output for each run. The average difference of the nine (or more) data sets constitute the RA.'' are deleted, as proposed; these two sentences are no longer necessary since equations 3–1 and 3–2 would be moved from section 13.2 to section 12.0. The sentence, ''Calculate the RA using equations 3–1 and 3–2.'' is added to the beginning of section 12.0.

Z. Performance Specification 11 of Appendix B of Part 60

In Performance Specification 11, section 13.1, the word ''average'' erroneously exists in the second sentence and is deleted, as proposed.

AA. Performance Specification 15 of Appendix B of Part 60

As proposed, in Performance Specification 15, section 13.0 is added as ''Method Performance [Reserved].''

BB. Performance Specification 18 of Appendix B of Part 60

As proposed, in Performance Specification 18, in section 11.8.7, the last sentence is revised to clarify the duration of the drift check. In Table 1, the erroneous acronym ''NO_2'' is replaced with ''NO,'' as proposed. In the appendix of Performance Specification 18, the inadvertently omitted reserved section 12.0 is added, as proposed.

CC. Procedure 1 of Appendix F of Part 60

As proposed, in Procedure 1, in section 5.1.2 (1), the sentence immediately following the table that reads, ''Challenge the CEMS three times at each audit point, and use the average of the three responses in determining accuracy.'' is replaced with, ''Introduce each of the audit gases, three times each for a total of six challenges. Introduce the gases in such a manner that the entire CEMS is challenged. Do not introduce the same gas concentration twice in succession.'' In order to obtain six distinct readings during the cylinder gas audit (CGA), the same gas must not be introduced twice in succession, and this revised language accurately reflects this standard scientific practice. As also proposed, in section 5.1.2 (3), the reference to EPA's traceability protocol for gaseous calibration standards is updated, and the language regarding the use of EPA Method 205 for dilution of audit gases is clarified.

DD. General Provisions (Subpart A) of Part 63

Sections 63.7(g)(2), 63.7(g)(2)(v), and 63.8(e)(5)(i) of the General Provisions (subpart A) of part 63 are revised, as proposed, to require the reporting of specific test data for continuous monitoring system performance evaluation tests and ongoing quality assurance (QA) tests. These data elements are required regardless of the format of the report, *i.e.,* electronic or paper. These modifications will ensure that performance evaluation and QA test reporting include all data necessary for the compliance authority to assess and assure the quality of the reported data and that the reported information describes and identifies the specific unit covered by the evaluation test report. In response to comment, we specified the level of reporting needed for continuous parameter monitoring systems (CPMS) versus other continuous monitoring systems including continuous emission monitoring systems (CEMS), COMS, and predictive emissions monitoring systems (PEMS).

EE. Wool Fiberglass Manufacturing (Subpart NNN) Part 63

In a change from proposal, the allowed filter temperature in § 63.1385(a)(5) is not revised. Based on comments we received on the proposed revisions, we are deferring finalizing proposed revisions of the temperature tolerances of probe and filter holder heating systems as part of this rulemaking. We will continue to review supporting information and data we received on the proposed rule and may propose either revisions or similar requirements as part of future rulemakings.

FF. Major Sources: Industrial, Commercial, and Institutional Boilers and Process Heaters (Subpart DDDDD) Part 63

As proposed, in Table 6 of subpart DDDDD, row 1.f. is revised to allow the use of EPA SW–846–7471B (for liquid samples) in addition to EPA SW–846–7470A for measuring mercury to allow for compliance flexibility.

GG. Coal- and Oil-Fired Electric Utility Steam Generating Units (Subpart UUUUU) Part 63

In a change from proposal, the allowed filter temperature in § 63.10010(h)(7)(i)(1) is not revised. Based on comments we received on the proposed revisions, we are deferring finalizing proposed revisions of the temperature tolerances of probe and filter holder heating systems as part of this rulemaking. We will continue to review supporting information and data we received on the proposed rule and may propose either revisions or similar requirements as part of future rulemakings.

As proposed, in Table 5, Method 5I is specified as a test method option because, as explained at proposal, Method 5I is designed for low particulate matter (PM) application.

HH. Method 303 of Appendix A of Part 63

In Method 303, section 12.4, equation 303–3 is corrected, as proposed, by inserting ''where y = '' in front of the equation.

II. Method 308 of Appendix A of Part 63

As proposed, in Method 308, deionized distilled water replaces the aqueous n-proponal solution; the affected sections are 2.0, 7.2.2, 7.2.3.3, and 11.3.2. Section 7.2.2, which defines the aqueous n-proponal solution, is removed, as proposed. In section 7.2.3.3, the erroneous ''four'' is replaced as proposed, with ''three'' in the sentence that reads ''Pipette 5, 15, and 25 ml of this standard, respectively into four 50-ml volumetric flasks.'' Section 8.1.2 is revised, as proposed, to require a leak check prior to the sampling run (in addition to after the sampling run) for QA purposes; as explained at proposal, requiring a leak check prior to the sampling run would potentially save time and money. In section 9.1, methanol spike recovery check is added as a quality control (QC) measure in Table 9.1, as proposed. In section 12.1, variables used in equations 308–4 and 308–5 are added and section 12.5, which includes equations 308–4 and 308–5, is added, as proposed. In section 13.0, the title ''Reserved'' is replaced with ''Method Performance'' and QA requirements would be added to be consistent with other methods, as proposed. The erroneous proposed paragraph (a) of section 13.0 is replaced, as proposed, with ''Calibration standards must meet the requirements in section 10.2.1 or 10.2.2 as applicable.''

JJ. Method 320 of Appendix A of Part 63

In section 8.2.2.4, the denominator in equation 2 is corrected from P_{SS} to P_S, as proposed. In section 9.2.3, the word ''where'' in the statement, ''Calculate the dilution ratio using the tracer gas as follows: where:'' is deleted, as proposed. Also in section 9.2.3, the inadvertently superscripted ''dir'' on the definition of spike is subscripted, as proposed.

KK. Method 323 of Appendix A of Part 63

In Method 323, section 12.9, the denominator in equation 323–8 is corrected, as proposed.

LL. Method 325A of Appendix A of Part 63

In Method 325A, section 8.2.1.3 is revised, as proposed, to clarify that only one extra sampling site is required near known sources of volatile organic compounds (VOCs) when the source is located both within 50 meters of the boundary and between two monitors. Based on a public comment we received on the proposed regulatory text, wording changes have been made to the language in section 8.2.1.3. As proposed, the label under Figure 8.1 is corrected from ''Refinery (20% angle)'' to ''Refinery (20° angle).'' Section 8.2.3.2 is revised, as proposed, to include facilities with a monitoring perimeter length equal to 7,315 meters (24,000 feet). Section 8.2.3.3 is added, as

proposed, to provide clarification and an equivalent procedure in Option 2 (linear distance between sites) for site locations that parallel section 8.2.2.2.4 in Option 1 (radial distance between sites). In response to comments, section 8.4.3 is added to address worker safety during extenuating circumstances.

MM. Method 325B of Appendix A of Part 63

In Method 325B, section 9.3.2 is revised, as proposed, to correct an error in the number of field blank samples required for a sampling period and to provide consistency with the sample analysis required in Method 325B. In sections 9.13 and 11.3.2.5, the erroneous reference to section 10.6.3 is corrected to 10.0, as proposed. Also in section 11.3.2.5, the erroneous reference to section 10.9.5 is corrected to 9.13, as proposed. Section 12.2.2 is revised, as proposed, to correct the calculation of target compound concentrations at standard conditions, and the erroneous reference to U_{std} in the note in section 12.2.2 is revised to U_{NTP}. Sections 12.2.3 and 12.2.4 are deleted, as proposed, because the equations for target concentrations are incorrect. Table 17–1 is revised, as proposed, to add inadvertently omitted QC criteria from section 9.3.3.

IV. Public Comments on the Proposed Rule

Eighty-three (83) comment letters were received from the public; 23 of the comment letters were relevant, and the other 60 comment letters were considered as beyond the scope of the proposed rule. The public comments and the agency's responses are summarized in the Response to Comments document located in the docket for this rule. See the **ADDRESSES** section of this preamble.

A summary of the relevant portions of significant comments that we received on the proposal and agency responses are presented below.

Comment: Three commenters provided comments on our proposed revisions to the General Provisions (Subpart A) of Part 63. One commenter stated that the proposed revisions impose new requirements on CMS performance evaluations and QA testing for types of monitors not previously subject to such requirements. Another commenter remarked that the proposed revisions to various requirements in Part 63 revisions were vague. Yet another commenter remarked that the proposed revisions to § 63.8(e)(5) would shorten the CMS performance evaluation reporting period for CMS associated with performance tests.

Response: We disagree with the comment that the proposed changes to § 63.8(e)(5)(i) would impose new requirements given that at proposal, the agency had explained that they were intended to clarify and codify data elements and reporting requirements that are already routinely requested by the Administrator's delegated authorities. With regard to § 63.8(e)(5), in a change from proposal, we have retained the existing requirement that allows for the simultaneous submission of the report of a CMS performance evaluation with results of performance testing required under 40 CFR 63.7. We also edited the final rule language for 40 CFR 63.7(g)(2)(v) to improve clarity and to eliminate confusion.

Comment: Fifteen commenters provided comments arguing against the proposal to tighten the filter temperature tolerance in 40 CFR 60.46(b)(2)(i); 60.50Da(b)(1)(ii)(A); 60.45c(a)(5); 60.58a(b)(3); 60.293(f); 60.296(d)(2); 63.1385(a)(5); and sections 2.0, 6.1.1.2, 6.1.1.6, 6.1.1.7 and 8.5 of Method 5, Appendix A–3 of Part 60. They cited issues that included: weather (*e.g.,* ambient temperature fluctuations and windy conditions); costs; lack of justification and data for the revision; inconsistent language (*e.g.,* the use of ''shall'' vs. ''may'' and proposed revisions to temperature tolerance in Methods 5, 5B, and 5I but not in Methods 5D, 5E, and 5F); and safety risks. Nine commenters remarked that ambient conditions (cold climates, wind gusts, etc.) can cause temperature fluctuations that are difficult to manage. More specifically, one commenter stated that the reduced allowable temperature range would be problematic during testing in cold, windy ambient conditions that are persistent in the winter months in northern climates because the time required for temperature recovery after a component change in these conditions could add hours and possibly days to testing programs. One commenter remarked that the proposed ±5 °C is unattainable for sources in cold or windy climates.

Eight commenters stated that alteration or replacement of equipment components would likely be necessary to achieve the proposed temperature tolerances resulting in additional costs. One commenter noted potential equipment improvements, such as increased probe sheath tubing diameter to make room for added insulation around every probe heater; re-design of filter heating ovens; improved sealing and insulation of the openings at the inlet and outlet of filter heating ovens; and/or for sources with high stack temperatures, more frequent use of air-cooled or water-cooled probes. One commenter remarked that this revision would force cold weather stack testers to replace or retrofit equipment with higher power heating devices and possibly more refined control devices which would be costly. One commenter remarked that this revision will most likely require air sampling equipment suppliers to redesign sample probes by either increasing sheath diameter, altering the placement or increasing the number of thermocouples used to control the probe heating system, and/or increasing the insulation around the sample liner. The commenter added that an increase in the diameter of the probe sheath would have a cascading effect either requiring test companies to purchase new sample hot boxes or retrofit existing sample hot boxes to accommodate the increased probe sheath diameter.

Seven commenters stated that neither information nor data was provided to support, justify, or quantify the claimed increased precision of filterable PM measurements, and a few of these commenters noted that the Electric Power Research Institute (EPRI) paper that the EPA used as the basis for tightening the filter temperature tolerance was from a comparison of results measured at four coal-fired power plants.

One commenter requested that the statement in § 60.50Da(b)(1)(ii)(A), ''The probe and filter holder heating system in the sampling train may be set to provide an average gas temperature of no greater than 160 ±5 °C (320 ±9 °F),'' be changed to, ''The probe and filter holder heating system in the sampling train shall be set to provide an average gas temperature of 160 ±5 °C (320 ±9 °F),'' because they believe that this was the agency's intent. Similarly, another commenter requested that the statement in § 60.296(d)(2), ''The probe and filter holder heating system may be set to provide a gas temperature no greater than 177 ±5 °C (320 ±9 °F),'' be changed to, ''The probe and filter holder heating system shall be set to provide an average gas temperature 160 ±5 °C (320 ±9 °F),'' because they believe that this was the agency's intent. One commenter also recommended changing the sentence in Method 5B to, ''The collected sample is then heated in an oven at 160 °C (320 °F) for 6 hours . . . ,'' to, ''The collected sample is then heated in an oven at 160 ±5 °C (320 ±9 °F) for 6 hours . . .,'' to be internally consistent.

Three commenters noted that if the temperature tolerances are changed in Method 5, methods that reference Method 5 (namely Method 5D, section

2.1; Method 5E, section 2.0; and Method 5F, section 2.0) would also need to be revised.

Three commenters remarked that tightening the filter temperature tolerance conflicts with the assertion that the proposed rule will improve the quality of data but will not impose new substantive requirements. Two of the three commenters further remarked that the proposed rule does not meet the requirements of Executive Order 13771 nor the Paperwork Reduction Act (PRA).

Three commenters acknowledged that an improvement in measurement precision could benefit the data quality in limited situations, such as the Mercury and Air Toxics Standards (MATS).

Four commenters remarked that if the proposed revisions to the temperature tolerances lead to a measurable change in reported PM emissions, sources that were previously in compliance with their emission standards may become non-compliant; one commenter added that the opposite situation may occur. One commenter stated that the proposed revision may have the unintended consequence of redefining the filterable PM being measured leading to either higher or lower PM measurements as compared to sampling runs conducted with wider tolerances.

Two commenters mentioned that this revision could result in a potential safety risk. One of the commenters remarked that the added weight and handling difficulties associated with air- or water-cooled probes (if necessary to control the probe temperature) can increase safety risks to testing personnel, and the other commenter remarked that the proposed requirements may require the use of encapsulated probes which are heavy and cumbersome resulting in hazards.

Response: In response to these comments and in a change from proposal, we are deferring finalizing proposed revisions of the temperature tolerances of probe and filter holder heating systems as part of this rulemaking. We will continue to review supporting information and data we received on the proposed rule and may propose either revisions or similar requirements as part of future rulemakings.

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.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 Regulations and Controlling Regulatory Costs

This action is considered an Executive Order 13771 deregulatory action. This final rule provides meaningful burden reduction by allowing regulated facilities the flexibility to use newly-approved alternative procedures for compliance demonstration purposes, which may result in lower labor costs for some facilities (*e.g.,* allowing digital photography in lieu of manual documentation in EPA Method 22); lower compliance testing costs (*e.g.,* additional sample storage container options now allowed by Method 26); reducing the likelihood of re-testing (*e.g.,* revised QA requirements in Method 308); and expediting data processing (*e.g.,* simplified calculations in Method 325B).

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. The revisions do not substantively revise the existing information collection requirements but simply corrects, updates, and clarifies performance testing and continuous monitoring requirements.

D. Regulatory Flexibility Act (RFA)

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. This action will not impose emission measurement requirements beyond those specified in the current regulations, nor does it change any emission standard. We have, therefore, concluded that this action will have no net regulatory burden for all directly regulated small entities.

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. This action simply corrects and updates existing testing regulations. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

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

This action involves technical standards. The EPA used ASTM D6216–12 for continuous opacity monitors in Performance Specification 1. The ASTM D6216–12 standard covers the procedure for certifying continuous opacity monitors and includes design and performance specifications, test procedures, and QA requirements to ensure that continuous opacity monitors meet minimum design and calibration

requirements necessary, in part, for accurate opacity monitoring measurements in regulatory environmental opacity monitoring applications subject to 10 percent or higher opacity standards.

The ASTM D6216–12 standard was developed and adopted by the American Society for Testing and Materials (ASTM). The standard may be obtained from *http://www.astm.org* or from the ASTM at 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959.

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

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This action is a technical correction to previously promulgated regulatory actions and does not have an impact on human health or the environment.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the 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).

List of Subjects

40 CFR Part 51

Environmental protection, Air pollution control, Performance specifications, Test methods and procedures.

40 CFR Part 60

Environmental protection, Air pollution control, Incorporation by reference, Performance specifications, Test methods and procedures.

40 CFR Part 63

Environmental protection, Air pollution control, Incorporation by reference, Performance specifications, Test methods and procedures.

Dated: November 5, 2018.

Andrew R. Wheeler,

Acting Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency amends title 40, chapter I of the Code of Federal Regulations as follows:

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

■ 2. Amend appendix M to part 51 as follows:

■ a. Revise section 12.5, equation 24, in Method 201A.

■ b. Revise the last sentence in section 8.2 in Method 204.

■ c. Revise section 2.1.1 in Method 205.

The revisions read as follows:

Appendix M to Part 51—Recommended Test Methods for State Implementation Plans

* * * * *

Method 201A—Determination of PM_{10} and $PM_{2.5}$ Emissions From Stationary Sources (Constant Sampling Rate Procedure)

* * * * *

12.5 * * *

$$t_n = \left[\frac{C_p \sqrt{\Delta p_n}}{C_p' \left[(\Delta p)^{0.5}\right]_{avg}}\right]\left[\frac{t_r}{N_{tp}}\right] \quad \text{(Eq. 24)}$$

* * * * *

Method 204—Criteria for and Verification of a Permanent or Temporary Total Enclosure

* * * * *

8.2 * * *

The NEAR must be ≤0.05.

* * * * *

Method 205—Verification of Gas Dilution Systems for Field Instrument Calibrations

* * * * *

2.1.1 The gas dilution system shall be recalibrated once per calendar year using NIST-traceable flow standards with an uncertainty ≤0.25 percent. You shall report the results of the calibration by the person or manufacturer who carried out the calibration whenever the dilution system is used, listing the date of the most recent calibration, the due date for the next calibration, calibration point, reference flow device (ID, S/N), and acceptance criteria. Follow the manufacturer's instructions for the operation and use of the gas dilution system. A copy of the manufacturer's instructions for the operation of the instrument, as well as the most recent calibration documentation, shall be made available for inspection at the test site.

* * * * *

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

■ 3. The authority citation for part 60 continues to read as follows:

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

■ 4. In § 60.17, revise paragraph (h)(177) to read as follows:

§ 60.17 Incorporations by reference.

* * * * *

(h) * * *

(177) ASTM D6216–12, Standard Practice for Opacity Monitor Manufacturers to Certify Conformance with Design and Performance Specifications, approved October 1, 2012; IBR approved for appendix B to part 60.

* * * * *

■ 5. In Appendix A–1 to part 60, revise ''$(CO_2)_a$'' in section 12.1 in Method 2B to read as follows:

Appendix A–1 to Part 60—Test Methods 1 through 2F

* * * * *

Method 2B—Determination of Exhaust Gas Volume Flow Rate From Gasoline Vapor Incinerators

* * * * *

12.1 * * *

$(CO_2)_a$ = Ambient carbon dioxide concentration, ppm (if not measured during the test period, may be assumed to equal the global monthly mean CO_2 concentration posted at *http://www.esrl.noaa.gov/gmd/ccgg/trends/global.html#global_data*).

* * * * *

■ 6. In appendix A–3 to part 60:

■ a. Revise sections 6.1.1.9 and 11.2.1 in Method 5.

■ b. Revise section 11.0 in Method 5B.

■ c. Add section 17.0 in Method 5B.

The revisions and addition read as follows:

Appendix A–3 to Part 60—Test Methods 4 through 5I

* * * * *

Method 5—Determination of Particulate Matter Emissions From Stationary Sources

* * * * *

6.1.1.9 Metering System. Vacuum gauge, leak-free pump, calibrated temperature sensors, dry gas meter (DGM) capable of measuring volume to within 2 percent, and related equipment, as shown in Figure 5–1. Other metering systems capable of maintaining sampling rates within 10 percent of isokinetic and of determining sample volumes to within 2 percent may be used, subject to the approval of the Administrator. When the metering system is used in conjunction with a pitot tube, the system shall allow periodic checks of isokinetic rates. The average DGM temperature for use in the calculations of section 12.0 may be obtained by averaging the two temperature sensors located at the inlet and outlet of the DGM as shown in Figure 5–3 or alternatively from a single temperature sensor located at the immediate outlet of the DGM or the plenum of the DGM.

* * * * *

11.2.1 Container No. 1. Leave the contents in the shipping container or transfer the filter and any loose PM from the sample container to a tared weighing container. Desiccate for 24 hours in a desiccator containing anhydrous calcium sulfate. Weigh to a constant weight, and report the results to the nearest 0.1 mg. For the purposes of this section, the term ''constant weight'' means a difference of no more than 0.5 mg or 1 percent of total weight less tare weight, whichever is greater, between two consecutive weighings, with no less than 6 hours of desiccation time between weighings. Alternatively, the sample may be oven dried at 104 °C (220 °F) for 2 to 3 hours, cooled in the desiccator, and weighed to a constant weight, unless otherwise specified by the Administrator. The sample may be oven dried at 104 °C (220 °F) for 2 to 3 hours. Once the sample has cooled, weigh the sample, and use this weight as a final weight.

* * * * *

Method 5B-Determination of Nonsulfuric Acid Particulate Matter Emissions From Stationary Sources

* * * * *

11.0 Analytical Procedure

11.1 Record and report the data required on a sheet such as the one shown in Figure 5B–1.

11.2 Handle each sample container as follows:

11.2.1 Container No. 1. Leave the contents in the shipping container or transfer the filter and any loose PM from the sample container to a tared non-reactive oven-proof container. Oven dry the filter sample at a temperature of 160 ±5 °C (320 ±9 °F) for 6 hours. Cool in a desiccator for 2 hours, and weigh to constant weight. Report the results to the nearest 0.1 mg. For the purposes of this section, the term ''constant weight'' means a difference of no more than 0.5 mg or 1 percent of total weight less tare weight, whichever is greater, between two consecutive weighings, with no less than 6 hours of desiccation time between weighings.

11.2.2 Container No. 2. Note the level of liquid in the container, and confirm on the analysis sheet whether leakage occurred during transport. If a noticeable amount of leakage has occurred, either void the sample or use methods, subject to the approval of the Administrator, to correct the final results. Measure the liquid in this container either volumetrically to ±1 ml or gravimetrically to ±0.5 g. Transfer the contents to a tared 250 ml beaker, and evaporate to dryness at ambient temperature and pressure. Then oven dry the probe sample at a temperature of 160 ±5 °C (320 ±9 °F) for 6 hours. Cool in a desiccator for 2 hours, and weigh to constant weight. Report the results to the nearest 0.1 mg.

11.2.3 Container No. 3. Weigh the spent silica gel (or silica gel plus impinger) to the nearest 0.5 g using a balance. This step may be conducted in the field.

11.2.4 Acetone Blank Container. Measure the acetone in this container either volumetrically or gravimetrically. Transfer the acetone to a tared 250 ml beaker, and evaporate to dryness at ambient temperature and pressure. Desiccate for 24 hours, and weigh to a constant weight. Report the results to the nearest 0.1 mg.

Note: The contents of Container No. 2 as well as the acetone blank container may be evaporated at temperatures higher than ambient. If evaporation is done at an elevated temperature, the temperature must be below the boiling point of the solvent; also, to prevent ''bumping,'' the evaporation process must be closely supervised, and the contents of the beaker must be swirled occasionally to maintain an even temperature. Use extreme care, as acetone is highly flammable and has a low flash point.

* * * * *

17.0 Tables, Diagrams, Flowcharts, and Validation Data

Container number	Weight of particulate collected, mg		
	Final weight	Tare weight	Weight gain
1.			
2.			
Total:			
Less acetone blank			
Weight of particulate matter			

	Volume of liquid water collected	
	Impinger volume, ml	Silica gel weight, g
Final		
Initial		
Liquid collected		
Total volume collected		g* ml

* Convert weight of water to volume by dividing total weight increase by density of water (1 g/ml).

Figure 5B–1. Analytical Data Sheet

* * * * *

■ 7. In appendix A–4 to part 60:

■ a. Revise sections 10.1.2 and 11.3 in Method 7.

■ b. Redesignate sections 6.1.1.1 through 6.1.1.4 as sections 6.1.1.2 through 6.1.1.5 in Method 8.

■ c. Add a new section 6.1.1.1 in Method 8.

■ d. Revise Figure 8–1 in Method 8.

The revisions and addition read as follows:

Appendix A–4 to Part 60—Test Methods 6 Through 10B

* * * * *

Method 7—Determination of Nitrogen Oxide Emissions From Stationary Sources

* * * * *

10.1.2 Determination of Spectrophotometer Calibration Factor K_c. Add 0 ml, 2.0 ml, 4.0 ml, 6.0 ml, and 8.0 ml of the KNO_3 working standard solution (1 ml = 100 µg NO_2) to a series of five 50-ml volumetric flasks. To each flask, add 25 ml of absorbing solution and 10 ml water. Add 1 N NaOH to each flask until the pH is between 9 and 12 (about 25 to 35 drops). Dilute to the mark with water. Mix thoroughly, and pipette a 25-ml aliquot of each solution into a separate porcelain evaporating dish. Beginning with the evaporation step, follow the analysis procedure of section 11.2 until the solution has been transferred to the 100-ml volumetric flask and diluted to the mark. Measure the absorbance of each solution at the optimum wavelength as determined in section 10.1.1. This calibration procedure must be repeated on each day that samples are analyzed. Calculate the spectrophotometer calibration factor as shown in section 12.2.

* * * * *

11.3 Sample Analysis. Mix the contents of the flask thoroughly, and measure the absorbance at the optimum wavelength used for the standards (section 10.1.1), using the blank solution as a zero reference. Dilute the sample and the blank with equal volumes of water if the absorbance exceeds A_4, the absorbance of the 400-µg NO_2 standard (see section 10.1.3).

* * * * *

Method 8—Determination of Sulfuric Acid and Sulfur Dioxide Emissions From Stationary Sources

* * * * *

6.1.1.1 Probe Nozzle. Borosilicate or quartz glass with a sharp, tapered leading edge and coupled to the probe liner using a polytetrafluoroethylene (PTFE) or glass-lined union (*e.g.,* fused silica, Slico, or equivalent). When the stack temperature exceeds 210 °C (410 °F), a leak-free ground glass fitting or other leak free, non-contaminating fitting must be used to couple the nozzle to the probe liner. It is also acceptable to use a one-piece glass nozzle/liner assembly. The angle of the taper shall be ≤30°, and the taper shall be on the outside to preserve a constant internal diameter. The probe nozzle shall be of the button-hook or elbow design, unless otherwise specified by the Administrator. Other materials of construction may be used, subject to the approval of the Administrator. A range of nozzle sizes suitable for isokinetic sampling should be available. Typical nozzle sizes range from 0.32 to 1.27 cm (⅛ to ½ in) inside diameter (ID) in increments of 0.16 cm (1⁄16 in). Larger nozzles sizes are also available if higher volume sampling trains are used.

* * * * *

17.0 * * *

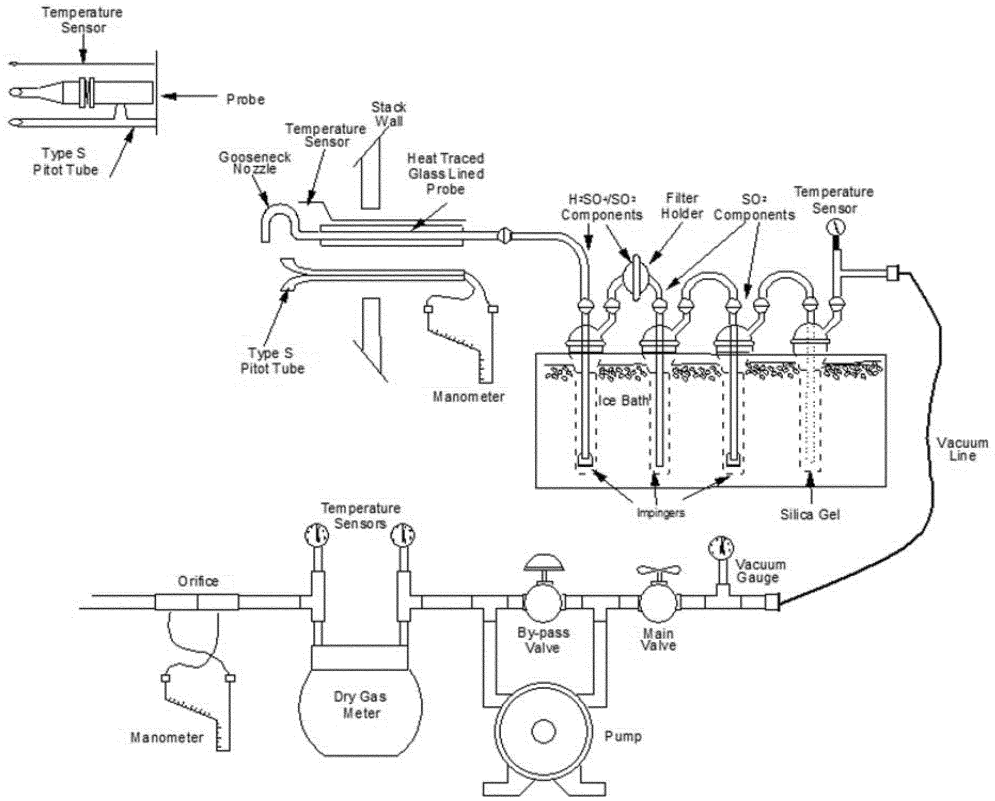

Figure 8-1. Sulfuric Acid Sampling Train

* * * * *

Appendix A–6 to Part 60—[Amended]

■ 8. In Appendix A–6 to part 60, redesignate paragraph (c) as paragraph (b) in section 13.1 in Method 18.

■ 9. In appendix A–7 to part 60:

■ a. Revise sections 11.2.1 and 11.2.2 in Method 22.

■ b. Add section 11.2.3 in Method 22.

The revisions and addition read as follows:

Appendix A–7 to Part 60—Test Methods 19 Through 25E

* * * * *

Method 22—Visual Determination of Fugitive Emissions From Material Sources and Smoke Emissions From Flares

* * * * *

11.2.1 Outdoor Location. Record the following information on the field data sheet (Figure 22–1): Company name, industry, process unit, observer's name, observer's affiliation, and date. Record also the estimated wind speed, wind direction, and sky condition. Sketch the process unit being observed, and note the observer location relative to the source and the sun. Indicate the potential and actual emission points on the sketch. Alternatively, digital photography as described in section 11.2.3 may be used for a subset of the recordkeeping requirements of this section.

11.2.2 Indoor Location. Record the following information on the field data sheet (Figure 22–2): Company name, industry, process unit, observer's name, observer's affiliation, and date. Record as appropriate the type, location, and intensity of lighting on the data sheet. Sketch the process unit being observed, and note the observer location relative to the source. Indicate the potential and actual fugitive emission points on the sketch. Alternatively, digital photography as described in section 11.2.3 may be used for a subset of the recordkeeping requirements of this section.

11.2.3 Digital Photographic Records. Digital photographs, annotated or unaltered, may be used to record and report sky conditions, observer's location relative to the source, observer's location relative to the sun, process unit being observed, potential emission points and actual emission points for the requirements in sections 11.2.1 and 11.2.2. The image must have the proper lighting, field of view and depth of field to properly distinguish the sky condition (if applicable), process unit, potential emission point and actual emission point. At least one digital photograph must be from the point of the view of the observer. The photograph(s) representing the environmental conditions including the sky conditions and the position of the sun relative to the observer and the emission point must be taken within a reasonable time of the observation (*i.e.,* 15 minutes). When observations are taken from exactly the same observation point on a routine basis (*i.e.,* daily) and as long as there are no modifications to the units depicted, only a single photograph each is necessary to document the observer's location relative to the emissions source, the process unit being observed, and the location of potential and actual emission points. Any photographs altered or annotated must be retained in an unaltered format for recordkeeping purposes.

* * * * *

■ 10. In appendix A–8 to part 60:

■ a. Revise section 6.2.2 in Method 26.

■ b. Revise section 6.2.1 in Method 26A.

■ c. Add section 6.2.4 in Method 26A.

■ d. Revise equation 8 in section 13.5.1 in Test Method 28WHH.

The revisions and additions read as follows:

Appendix A–8 to Part 60—Test Methods 26 Through 30B

* * * * *

Method 26—Determination of Hydrogen Halide and Halogen Emissions From Stationary Sources Non-Isokinetic Method

* * * * *

6.2.2 Storage Containers. 100- or 250-ml, high-density polyethylene or glass sample storage containers with Teflon screw cap liners to store impinger samples.

* * * * *

Method 26A—Determination of Hydrogen Halide and Halogen Emissions From Stationary Sources Isokinetic Method

* * * * *

6.2.1 Probe-Liner and Probe-Nozzle Brushes, Wash Bottles, Petri Dishes, Graduated Cylinder and/or Balance, and Rubber Policeman. Same as Method 5, sections 6.2.1, 6.2.2, 6.2.4, 6.2.5, and 6.2.7.

* * * * *

6.2.4 Sample Storage Containers. High-density polyethylene or glass sample storage containers with Teflon screw cap liners to store impinger samples.

* * * * *

Test Method 28WHH for Measurement of Particulate Emissions and Heating Efficiency of Wood-Fired Hydronic Heating Appliances

* * * * *

13.5.1 * * *

$$\sigma_i = (62.56 + (-.0003413 \times T3_i) + (-.00006225 \times T3_i^2)) 0.1337, \text{ lbs/gal} \quad \text{Eq. 8}$$

* * * * *

■ 11. In appendix B to part 60:

■ a. Add the following entries to the list of Performance Specifications in numeric order:

■ i. Performance Specification 12B—Specifications and Test Procedures for Monitoring Total Vapor Phase Mercury Emissions From Stationary Sources Using A Sorbent Trap Monitoring System

■ ii. Performance Specification 17 [Reserved]

■ iii. Performance Specification 18—Performance Specifications and Test Procedures for Gaseous Hydrogen Chloride (HCl) Continuous Emission Monitoring Systems at Stationary Sources

■ iv. PS–18—Appendix A Standard Addition Procedures

■ b. In Performance Specification 1, remove ''D 6216–98'' wherever it appears and add in its place ''D6216–12'', and revise section 2.1, the introductory text of section 13.0, sections 13.1 and 13.2, and paragraph 8. of section 16.0.

■ c. In Performance Specification 2, revise section 13.2.

■ d. In Performance Specification 3, revise sections 12.0 and 13.2.

■ e. In Performance Specification 11, revise section 13.1.

■ f. In Performance Specification 15, add reserved section 13.0.

■ g. In Performance Specification 18, revise section 11.8.7 and table 1 in section 17.0, and add reserved section 12.0 to PS–18.

The revisions and additions read as follows:

Appendix B to Part 60—Performance Specifications

* * * * *

Performance Specification 1—Specifications and Test Procedures for Continuous Opacity Monitoring Systems in Stationary Sources

* * * * *

2.1 ASTM D6216–12 (incorporated by reference, see § 60.17) is the reference for design specifications, manufacturer's performance specifications, and test procedures. The opacity monitor manufacturer must periodically select and test an opacity monitor, that is representative of a group of monitors produced during a specified period or lot, for conformance with the design specifications in ASTM D6216–12. The opacity monitor manufacturer must test each opacity monitor for conformance with the manufacturer's performance specifications in ASTM D6216–12. Note: If the initial certification of the opacity monitor occurred before November 14, 2018 using D6216–98, D6216–03, or D6216–07, it is not necessary to recertify using D6216–12.

* * * * *

13.0 What Specifications Does a COMS Have to Meet for Certification?

A COMS must meet the following design, manufacturer's performance, and field audit performance specifications:

Note: If the initial certification of the opacity monitor occurred before November 14, 2018 using D6216–98, D6216–03, or D6216–07, it is not necessary to recertify using D6216–12.A. COMS must meet the following design, manufacturer's performance, and field audit performance specifications.

13.1 Design Specifications. The opacity monitoring equipment must comply with the design specifications of ASTM D6216–12.

13.2 Manufacturer's Performance Specifications. The opacity monitor must comply with the manufacturer's performance specifications of ASTM D6216–12.

* * * * *

16.0 * * *

8. ASTM D6216–12: Standard Practice for Opacity Monitor Manufacturers to Certify Conformance with Design and Performance Specifications. ASTM. October 2012.

* * * * *

Performance Specification 2—Specifications and Test Procedures for SO_2 and NO_X Continuous Emission Monitoring Systems in Stationary Sources

* * * * *

13.2 Relative Accuracy Performance Specification.

	Calculate . . .	RA criteria (%)
If average emissions during the RATA are ≥50% of emission standard.	Use Eq. 2–6, with RM in the denominator	≤20.0
If average emissions during the RATA are <50% of emission standard.	Use Eq. 2–6, emission standard in the denominator	≤10.0
For SO_2 emission standards ≤130 but ≥86 ng/J (0.30 and 0.20 lb/million Btu).	Use Eq. 2–6, emission standard in the denominator	≤15.0
For SO_2 emission standards <86 ng/J (0.20 lb/million Btu)	Use Eq. 2–6, emission standard in the denominator	≤20.0

* * * * *

Performance Specification 3—Specifications and Test Procedures for O_2 and CO_2 Continuous Emission Monitoring Systems in Stationary Sources

* * * * *

12.0 Calculations and Data Analysis

Calculate the RA using equations 3–1 and 3–2. Summarize the results on a data sheet similar to that shown in Figure 2.2 of PS2.

$$RA = \frac{\left[\left|\bar{d}\right| + \left|CC\right|\right]}{\overline{RM}} \times 100 \qquad \text{Eq. 3-1}$$

Where:

$\left|\bar{d}\right|$ = Absolute value of the mean of the differences (from Equation 2-3 of Performance Specification 2).

|CC| = Absolute value of the confidence coefficient (from Equation 2-5 of Performance Specification 2).

$\overline{RM}$ = Average Reference Method Value

$$RA = \left|\overline{RM} - \overline{CEMS}\right| \qquad \text{Eq. } 3-2$$

$\overline{RM}$ = Average Reference Method Value

$\overline{CEMS}$ = Average CEMS Value

* * * * *

13.2 CEMS Relative Accuracy Performance Specification. The RA of the CEMS must be no greater than 20.0 percent of the mean value of the reference method (RM) data when calculated using equation 3–1. The results are also acceptable if the result of Equation 3–2 is less than or equal to 1.0 percent O_2 (or CO_2).

* * * * *

Performance Specification 11—Specifications and Test Procedures for Particulate Matter Continuous Emission Monitoring Systems at Stationary Sources

* * * * *

13.1 What is the 7-day drift check performance specification? Your daily PM CEMS internal drift checks must demonstrate that the daily drift of your PM CEMS does not deviate from the value of the reference light, optical filter, Beta attenuation signal, or other technology-suitable reference standard by more than 2 percent of the response range. If your CEMS includes diluent and/or auxiliary monitors (for temperature, pressure, and/or moisture) that are employed as a necessary part of this performance specification, you must determine the calibration drift separately for each ancillary monitor in terms of its respective output (see the appropriate performance specification for the diluent CEMS specification). None of the calibration drifts may exceed their individual specification.

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Performance Specification 15—Performance Specification for Extractive FTIR Continuous Emissions Monitor Systems in Stationary Sources

* * * * *

13.0 Method Performance [Reserved]

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Performance Specification 18—Performance Specifications and Test Procedures for Gaseous Hydrogen Chloride (HCl) Continuous Emission Monitoring Systems at Stationary Sources

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11.8.7 The zero-level and mid-level CD for each day must be less than 5.0 percent of the span value as specified in section 13.2 of this PS. You must meet this criterion for 7 consecutive operating days.

* * * * *

17.0 * * *

TABLE 1—INTERFERENCE TEST GAS CONCENTRATIONS

Potential interferent gas [1]	Approximate concentration (balance N_2)
CO_2	15% ± 1% CO_2.[2]
CO	100 ± 20 ppm.
CH_2O	20 ± 5 ppm.
CH_4	100 ± 20 ppm.
NH_3	10 ± 5 ppm (extractive CEMS only).
NO	250 ± 50 ppm.
SO_2	200 ± 20 ppm.
O_2	3% ± 1% O_2.[2]
H_2O	10% ± 1% H_2O.[2]
N_2	Balance.[2]

[1] Any of these specific gases can be tested at a lower level if the manufacturer has provided reliable means for limiting or scrubbing that gas to a specified level in CEMS field installations.

[2] Gases for short path IP cell interference tests cannot be added above 100 percent stack equivalent concentration. Add these gases at the indicated percentages to make up the remaining cell volume.

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PS–18 Appendix A Standard Addition Procedures

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12.0 [Reserved]

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■ 12. Revise sections 5.1.2(1) and (3) in Procedure 1 of appendix F to part 60 to read as follows:

Appendix F to Part 60—Quality Assurance Procedures

Procedure 1—Quality Assurance Requirements for Gas Continuous Emission Monitoring Systems Used For Compliance Determination

* * * * *

5.1.2 * * *

(1) Challenge the CEMS (both pollutant and diluent portions of the CEMS, if applicable) with an audit gas of known concentration at two points within the following ranges:

Audit point	Audit range		
	Pollutant monitors	Diluent monitors for—	
		CO_2	O_2
1	20 to 30% of span value	5 to 8% by volume	4 to 6% by volume.
2	50 to 60% of span value	10 to 14% by volume	8 to 12% by volume.

Introduce each of the audit gases, three times each for a total of six challenges. Introduce the gases in such a manner that the entire CEMS is challenged. Do not introduce the same gas concentration twice in succession.

Use of separate audit gas cylinder for audit points 1 and 2. Do not dilute gas from audit cylinder when challenging the CEMS.

The monitor should be challenged at each audit point for a sufficient period of time to assure adsorption-desorption of the CEMS sample transport surfaces has stabilized.

* * * * *

(3) Use Certified Reference Materials (CRM's) (See Citation 1) audit gases that have been certified by comparison to National Institute of Standards and Technology (NIST) Standard Reference Materials (SRM's) or EPA Protocol Gases following the most recent edition of the EPA Traceability Protocol for Assay and Certification of Gaseous Calibration Standards (See Citation 2). Procedures for preparation of CRM's are described in Citation 1. Procedures for preparation of EPA Protocol Gases are described in Citation 2. In the case that a suitable audit gas level is not commercially available, Method 205 (See Citation 3) may be used to dilute CRM's or EPA Protocol Gases to the needed level. The difference between the actual concentration of the audit gas and the concentration indicated by the monitor is used to assess the accuracy of the CEMS.

* * * * *

PART 63—NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR SOURCE CATEGORIES

■ 13. The authority citation for part 63 continues to read as follows:

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

■ 14. In § 63.7, revise paragraphs (g)(2) introductory text and (g)(2)(v) to read as follows:

§ 63.7 Performance testing requirements.

* * * * *

(g) * * *

(2) Contents of a performance test, CMS performance evaluation, or CMS quality assurance test report (electronic or paper submitted copy). Unless otherwise specified in a relevant standard, test method, CMS performance specification, or quality assurance requirement for a CMS, or as otherwise approved by the Administrator in writing, the report shall include the elements identified in paragraphs (g)(2)(i) through (vi) of this section.

* * * * *

(v) Where a test method, CEMS, PEMS, or COMS performance specification, or on-going quality assurance requirement for a CEMS, PEMS, or COMS requires you record or report, the following shall be included in your report: Record of preparation of standards, record of calibrations, raw data sheets for field sampling, raw data sheets for field and laboratory analyses, chain-of-custody documentation, and example calculations for reported results.

* * * * *

■ 15. In § 63.8, revise paragraph (e)(5)(i) to read as follows:

§ 63.8 Monitoring requirements.

* * * * *

(e) * * *

(5) * * * (i) The owner or operator shall furnish the Administrator a copy of a written report of the results of the performance evaluation containing the information specified in § 63.7(g)(2)(i) through (vi) simultaneously with the results of the performance test required under § 63.7 or within 60 days of completion of the performance evaluation, unless otherwise specified in a relevant standard.

* * * * *

■ 16. Revise Table 6 to Subpart DDDDD of part 63 to read as follows:

Table 6 to Subpart DDDDD of Part 63—Fuel Analysis Requirements

As stated in § 63.7521, you must comply with the following requirements

for fuel analysis testing for existing, new or reconstructed affected sources. However, equivalent methods (as defined in § 63.7575) may be used in lieu of the prescribed methods at the discretion of the source owner or operator:

To conduct a fuel analysis for the following pollutant . . .	You must . . .	Using . . .
1. Mercury	a. Collect fuel samples	Procedure in § 63.7521(c) or ASTM D5192[a], or ASTM D7430[a], or ASTM D6883[a], or ASTM D2234/D2234M[a] (for coal) or EPA 1631 or EPA 1631E or ASTM D6323[a] (for solid), or EPA 821–R–01–013 (for liquid or solid), or ASTM D4177[a] (for liquid), or ASTM D4057[a] (for liquid), or equivalent.
	b. Composite fuel samples	Procedure in § 63.7521(d) or equivalent.
	c. Prepare composited fuel samples.	EPA SW–846–3050B[a] (for solid samples), ASTM D2013/D2013M[a] (for coal), ASTM D5198[a] (for biomass), or EPA 3050[a] (for solid fuel), or EPA 821–R–01–013[a] (for liquid or solid), or equivalent.
	d. Determine heat content of the fuel type.	ASTM D5865[a] (for coal) or ASTM E711[a] (for biomass), or ASTM D5864[a] for liquids and other solids, or ASTM D240[a] or equivalent.
	e. Determine moisture content of the fuel type.	ASTM D3173[a], ASTM E871[a], or ASTM D5864[a], or ASTM D240[a], or ASTM D95[a] (for liquid fuels), or ASTM D4006[a] (for liquid fuels), or equivalent.
	f. Measure mercury concentration in fuel sample.	ASTM D6722[a] (for coal), EPA SW–846–7471B[a] or EPA 1631 or EPA 1631E[a] (for solid samples), or EPA SW–846–7470A[a] or EPA SW–846–7471B[a] (for liquid samples), or EPA 821–R–01–013[a] (for liquid or solid), or equivalent.
	g. Convert concentration into units of pounds of mercury per MMBtu of heat content.	For fuel mixtures use Equation 8 in § 63.7530.
2. HCl	a. Collect fuel samples	Procedure in § 63.7521(c) or ASTM D5192[a], or ASTM D7430[a], or ASTM D6883[a], or ASTM D2234/D2234M[a] (for coal) or ASTM D6323[a] (for coal or biomass), ASTM D4177[a] (for liquid fuels) or ASTM D4057[a] (for liquid fuels), or equivalent.
	b. Composite fuel samples	Procedure in § 63.7521(d) or equivalent.
	c. Prepare composited fuel samples.	EPA SW–846–3050B[a] (for solid samples), ASTM D2013/D2013M[a] (for coal), or ASTM D5198[a] (for biomass), or EPA 3050[a] or equivalent.
	d. Determine heat content of the fuel type.	ASTM D5865[a] (for coal) or ASTM E711[a] (for biomass), ASTM D5864[a], ASTM D240[a] or equivalent.
	e. Determine moisture content of the fuel type.	ASTM D3173[a] or ASTM E871[a], or D5864[a], or ASTM D240[a], or ASTM D95[a] (for liquid fuels), or ASTM D4006[a] (for liquid fuels), or equivalent.
	f. Measure chlorine concentration in fuel sample.	EPA SW–846–9250[a], ASTM D6721[a], ASTM D4208[a] (for coal), or EPA SW–846–5050[a] or ASTM E776[a] (for solid fuel), or EPA SW–846–9056[a] or SW–846–9076[a] (for solids or liquids) or equivalent.
	g. Convert concentrations into units of pounds of HCl per MMBtu of heat content.	For fuel mixtures use Equation 7 in § 63.7530 and convert from chlorine to HCl by multiplying by 1.028.
3. Mercury Fuel Specification for other gas 1 fuels.	a. Measure mercury concentration in the fuel sample and convert to units of micrograms per cubic meter, or.	Method 30B (M30B) at 40 CFR part 60, appendix A–8 of this chapter or ASTM D5954[a], ASTM D6350[a], ISO 6978–1:2003(E)[a], or ISO 6978–2:2003(E)[a], or EPA–1631[a] or equivalent.
	b. Measure mercury concentration in the exhaust gas when firing only the other gas 1 fuel is fired in the boiler or process heater.	Method 29, 30A, or 30B (M29, M30A, or M30B) at 40 CFR part 60, appendix A–8 of this chapter or Method 101A or Method 102 at 40 CFR part 61, appendix B of this chapter, or ASTM Method D6784[a] or equivalent.
4. TSM	a. Collect fuel samples	Procedure in § 63.7521(c) or ASTM D5192[a], or ASTM D7430[a], or ASTM D6883[a], or ASTM D2234/D2234M[a] (for coal) or ASTM D6323[a] (for coal or biomass), or ASTM D4177[a], (for liquid fuels), or ASTM D4057[a] (for liquid fuels), or equivalent.
	b. Composite fuel samples	Procedure in § 63.7521(d) or equivalent.
	c. Prepare composited fuel samples.	EPA SW–846–3050B[a] (for solid samples), ASTM D2013/D2013M[a] (for coal), ASTM D5198[a] or TAPPI T266[a] (for biomass), or EPA 3050[a] or equivalent.
	d. Determine heat content of the fuel type.	ASTM D5865[a] (for coal) or ASTM E711[a] (for biomass), or ASTM D5864[a] for liquids and other solids, or ASTM D240[a] or equivalent.
	e. Determine moisture content of the fuel type.	ASTM D3173[a] or ASTM E871[a], or D5864[a], or ASTM D240[a], or ASTM D95[a] (for liquid fuels), or ASTM D4006[a] (for liquid fuels), or ASTM D4177[a] (for liquid fuels) or ASTM D4057[a] (for liquid fuels), or equivalent.
	f. Measure TSM concentration in fuel sample.	ASTM D3683[a], or ASTM D4606[a], or ASTM D6357[a] or EPA 200.8[a] or EPA SW–846–6020[a], or EPA SW–846–6020A[a], or EPA SW–846–6010C[a], EPA 7060[a] or EPA 7060A[a] (for arsenic only), or EPA SW–846–7740[a] (for selenium only).

To conduct a fuel analysis for the following pollutant . . .	You must . . .	Using . . .
	g. Convert concentrations into units of pounds of TSM per MMBtu of heat content.	For fuel mixtures use Equation 9 in § 63.7530.

[a] Incorporated by reference, see § 63.14.

* * * * *

■ 17. Revise Table 5 to Subpart UUUUU of part 63 to read as follows:

Table 5 to Subpart UUUUU of Part 63—Performance Testing Requirements

As stated in § 63.10007, you must comply with the following requirements for performance testing for existing, new or reconstructed affected sources: [1]

To conduct a performance test for the following pollutant . . .	Using . . .	You must perform the following activities, as applicable to your input- or output-based emission limit . . .	Using . . .[2]
1. Filterable Particulate matter (PM).	Emissions Testing ...	a. Select sampling ports location and the number of traverse points.	Method 1 at appendix A–1 to part 60 of this chapter.
		b. Determine velocity and volumetric flow-rate of the stack gas.	Method 2, 2A, 2C, 2F, 2G or 2H at appendix A–1 or A–2 to part 60 of this chapter.
		c. Determine oxygen and carbon dioxide concentrations of the stack gas.	Method 3A or 3B at appendix A–2 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981.[3]
		d. Measure the moisture content of the stack gas.	Method 4 at appendix A–3 to part 60 of this chapter.
		e. Measure the filterable PM concentration	Methods 5 and 5I at appendix A–3 to part 60 of this chapter. For positive pressure fabric filters, Method 5D at appendix A–3 to part 60 of this chapter for filterable PM emissions. Note that the Method 5 or 5I front half temperature shall be 160° ±14 °C (320° ±25 °F).
		f. Convert emissions concentration to lb/MMBtu or lb/MWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
	OR	OR	
	PM CEMS	a. Install, certify, operate, and maintain the PM CEMS.	Performance Specification 11 at appendix B to part 60 of this chapter and Procedure 2 at appendix F to part 60 of this chapter.
		b. Install, certify, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems.	Part 75 of this chapter and § 63.10010(a), (b), (c), and (d).
		c. Convert hourly emissions concentrations to 30 boiler operating day rolling average lb/MMBtu or lb/MWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
2. Total or individual non-Hg HAP metals.	Emissions Testing ...	a. Select sampling ports location and the number of traverse points.	Method 1 at appendix A–1 to part 60 of this chapter.
		b. Determine velocity and volumetric flow-rate of the stack gas.	Method 2, 2A, 2C, 2F, 2G or 2H at appendix A–1 or A–2 to part 60 of this chapter.
		c. Determine oxygen and carbon dioxide concentrations of the stack gas.	Method 3A or 3B at appendix A–2 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981.[3]
		d. Measure the moisture content of the stack gas.	Method 4 at appendix A–3 to part 60 of this chapter.

[1] Regarding emissions data collected during periods of startup or shutdown, see §§ 63.10020(b) and (c) and 63.10021(h).

To conduct a performance test for the following pollutant . . .	Using . . .	You must perform the following activities, as applicable to your input- or output-based emission limit . . .	Using . . .[2]
		e. Measure the HAP metals emissions concentrations and determine each individual HAP metals emissions concentration, as well as the total filterable HAP metals emissions concentration and total HAP metals emissions concentration.	Method 29 at appendix A–8 to part 60 of this chapter. For liquid oil-fired units, Hg is included in HAP metals and you may use Method 29, Method 30B at appendix A–8 to part 60 of this chapter; for Method 29, you must report the front half and back half results separately. When using Method 29, report metals matrix spike and recovery levels.
		f. Convert emissions concentrations (individual HAP metals, total filterable HAP metals, and total HAP metals) to lb/MMBtu or lb/MWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
3. Hydrogen chloride (HCl) and hydrogen fluoride (HF).	Emissions Testing ...	a. Select sampling ports location and the number of traverse points.	Method 1 at appendix A–1 to part 60 of this chapter.
		b. Determine velocity and volumetric flowrate of the stack gas.	Method 2, 2A, 2C, 2F, 2G or 2H at appendix A–1 or A–2 to part 60 of this chapter.
		c. Determine oxygen and carbon dioxide concentrations of the stack gas.	Method 3A or 3B at appendix A–2 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981.[3]
		d. Measure the moisture content of the stack gas.	Method 4 at appendix A–3 to part 60 of this chapter.
		e. Measure the HCl and HF emissions concentrations.	Method 26 or Method 26A at appendix A–8 to part 60 of this chapter or Method 320 at appendix A to part 63 of this chapter or ASTM D6348–03[3] with (1) the following conditions when using ASTM D6348–03: (A) The test plan preparation and implementation in the Annexes to ASTM D6348–03, Sections A1 through A8 are mandatory; (B) For ASTM D6348–03 Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (see Equation A5.5); (C) For the ASTM D6348–03 test data to be acceptable for a target analyte, %R must be 70% ≥R ≤130%; and

3.e.1(D) The %R value for each compound must be reported in the test report and all field measurements corrected with the calculated %R value for that compound using the following equation:

$$\text{Reported Result} = \frac{(\text{Measured Concentration in Stack})}{\%R} \, x \, 100$$

and

To conduct a performance test for the following pollutant . . . (cont'd)	Using . . . (cont'd)	You must perform the following activities, as applicable to your input- or output-based emission limit . . . (cont'd)	Using . . .[2] (cont'd)
			(2) spiking levels nominally no greater than two times the level corresponding to the applicable emission limit. Method 26A must be used if there are entrained water droplets in the exhaust stream.

To conduct a performance test for the following pollutant . . . (cont'd)	Using . . . (cont'd)	You must perform the following activities, as applicable to your input- or output-based emission limit . . . (cont'd)	Using . . .[2] (cont'd)
		f. Convert emissions concentration to lb/MMBtu or lb/MWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
	OR	OR	
	HCl and/or HF CEMS.	a. Install, certify, operate, and maintain the HCl or HF CEMS.	Appendix B of this subpart.
		b. Install, certify, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems.	Part 75 of this chapter and § 63.10010(a), (b), (c), and (d).
		c. Convert hourly emissions concentrations to 30 boiler operating day rolling average lb/MMBtu or lb/MWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
4. Mercury (Hg)	Emissions Testing	a. Select sampling ports location and the number of traverse points.	Method 1 at appendix A–1 to part 60 of this chapter or Method 30B at Appendix A–8 for Method 30B point selection.
		b. Determine velocity and volumetric flowrate of the stack gas.	Method 2, 2A, 2C, 2F, 2G or 2H at appendix A–1 or A–2 to part 60 of this chapter.
		c. Determine oxygen and carbon dioxide concentrations of the stack gas.	Method 3A or 3B at appendix A–1 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981.[3]
		d. Measure the moisture content of the stack gas.	Method 4 at appendix A–3 to part 60 of this chapter.
		e. Measure the Hg emission concentration	Method 30B at appendix A–8 to part 60 of this chapter, ASTM D6784,[3] or Method 29 at appendix A–8 to part 60 of this chapter; for Method 29, you must report the front half and back half results separately.
		f. Convert emissions concentration to lb/TBtu or lb/GWh emission rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
	OR	OR	
	Hg CEMS	a. Install, certify, operate, and maintain the CEMS.	Sections 3.2.1 and 5.1 of appendix A of this subpart.
		b. Install, certify, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems.	Part 75 of this chapter and § 63.10010(a), (b), (c), and (d).
		c. Convert hourly emissions concentrations to 30 boiler operating day rolling average lb/TBtu or lb/GWh emissions rates.	Section 6 of appendix A to this subpart.
	OR	OR	
	Sorbent trap monitoring system.	a. Install, certify, operate, and maintain the sorbent trap monitoring system.	Sections 3.2.2 and 5.2 of appendix A to this subpart.
		b. Install, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems.	Part 75 of this chapter and § 63.10010(a), (b), (c), and (d).
		c. Convert emissions concentrations to 30 boiler operating day rolling average lb/TBtu or lb/GWh emissions rates.	Section 6 of appendix A to this subpart.
	OR	OR	
	LEE testing	a. Select sampling ports location and the number of traverse points.	Single point located at the 10% centroidal area of the duct at a port location per Method 1 at appendix A–1 to part 60 of this chapter or Method 30B at Appendix A–8 for Method 30B point selection.
		b. Determine velocity and volumetric flowrate of the stack gas.	Method 2, 2A, 2C, 2F, 2G, or 2H at appendix A–1 or A–2 to part 60 of this chapter or flow monitoring system certified per appendix A of this subpart.
		c. Determine oxygen and carbon dioxide concentrations of the stack gas.	Method 3A or 3B at appendix A–1 to part 60 of this chapter, or ANSI/ASME PTC 19.10–1981,[3] or diluent gas monitoring systems certified according to part 75 of this chapter.

To conduct a performance test for the following pollutant . . . (cont'd)	Using . . . (cont'd)	You must perform the following activities, as applicable to your input- or output-based emission limit . . . (cont'd)	Using . . .[2] (cont'd)
		d. Measure the moisture content of the stack gas.	Method 4 at appendix A–3 to part 60 of this chapter, or moisture monitoring systems certified according to part 75 of this chapter.
		e. Measure the Hg emission concentration	Method 30B at appendix A–8 to part 60 of this chapter; perform a 30 operating day test, with a maximum of 10 operating days per run (*i.e.,* per pair of sorbent traps) or sorbent trap monitoring system or Hg CEMS certified per appendix A of this subpart.
		f. Convert emissions concentrations from the LEE test to lb/TBtu or lb/GWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).
		g. Convert average lb/TBtu or lb/GWh Hg emission rate to lb/year, if you are attempting to meet the 29.0 lb/year threshold.	Potential maximum annual heat input in TBtu or potential maximum electricity generated in GWh.
5. Sulfur dioxide (SO_2)	SO_2 CEMS	a. Install, certify, operate, and maintain the CEMS.	Part 75 of this chapter and § 63.10010(a) and (f).
		b. Install, operate, and maintain the diluent gas, flow rate, and/or moisture monitoring systems.	Part 75 of this chapter and § 63.10010(a), (b), (c), and (d).
		c. Convert hourly emissions concentrations to 30 boiler operating day rolling average lb/MMBtu or lb/MWh emissions rates.	Method 19 F-factor methodology at appendix A–7 to part 60 of this chapter, or calculate using mass emissions rate and gross output data (see § 63.10007(e)).

■ 18. In appendix A to Part 63:

■ a. Revise section 12.4 in Method 303.

■ b. Revise section 2.0 in Method 308.

■ c. Remove and reserve section 7.2.2 in Method 308.

■ d. Revise sections 7.2.3.3, 8.1.2, 9.1, 11.3.2, and 12.1 in Method 308.

■ e. Add sections 12.5 and 13.0 in Method 308.

■ f. Revise sections 8.2.2.4 and 9.2.3 in Method 320.

■ g. Revise section 12.9 in Method 323.

■ h. Revise section 8.2.1.3, Figure 8.1. and section 8.2.3.2 in Method 325A.

■ i. Add sections 8.2.3.3 and 8.4.3 in Method 325A.

■ j. Revise sections 9.3.2, 9.13, 11.3.2.5, and 12.2.2 in Method 325B.

■ k. Remove sections 12.2.3 and 12.2.4 in Method 325B.

■ l. Revise table 17.1 in Method 325B.

The revisions and additions read as follows:

Appendix A to Part 63—Test Methods

* * * * *

Method 303—Determination of Visible Emissions From By-Product Coke Oven Batteries

* * * * *

12.4 Average Duration of VE from Charging Operations. Use Equation 303–3 to calculate the daily 30-day rolling log average of seconds of visible emissions from the charging operation for each battery using these current day's observations and the 29 previous valid daily sets of observations.

$$\text{logarithmic average} = e^{y} - 1 \qquad \text{(Eq. 303-3)}$$

$$\text{where } y = \frac{\ln(X_1 + 1) + \ln(X_2 + 1) + \ldots \ln(X_i + 1)}{A}$$

* * * * *

Method 308—Procedure for Determination of Methanol Emission From Stationary Sources

* * * * *

2.0 Summary of Method

A gas sample is extracted from the sampling point in the stack. The methanol is collected in deionized distilled water and adsorbed on silica gel. The sample is returned to the laboratory where the methanol in the water fraction is separated from other organic compounds with a gas chromatograph (GC) and is then measured by a flame ionization detector (FID). The fraction adsorbed on silica gel is extracted with deionized distilled water and is then separated and measured by GC/FID.

* * * * *

7.2.2 [Reserved]

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7.2.3.3 Methanol Standards for Adsorbent Tube Samples. Prepare a series of methanol standards by first pipetting 10 ml of the methanol working standard into a 100-ml volumetric flask and diluting the contents to exactly 100 ml with deionized distilled water. This standard will contain 10 µg/ml of methanol. Pipette 5, 15, and 25 ml of this

[2] See Tables 1 and 2 to this subpart for required sample volumes and/or sampling run times.

[3] Incorporated by reference, see § 63.14.

standard, respectively, into three 50-ml volumetric flasks. Dilute each solution to 50 ml with deionized distilled water. These standards will have 1, 3, and 5 µg/ml of methanol, respectively. Transfer all four standards into 40-ml glass vials capped with Teflon®-lined septa and store under refrigeration. Discard any excess solution.

* * * * *

8.1.2 Leak Check. A leak check before and after the sampling run is mandatory. The leak-check procedure is as follows:

Temporarily attach a suitable (*e.g.,* 0- to 40-ml/min) rotameter to the outlet of the DGM, and place a vacuum gauge at or near the probe inlet. Plug the probe inlet, pull a vacuum of at least 250 mm (10 inch) Hg or the highest vacuum experienced during the sampling run, and note the flow rate as indicated by the rotameter. A leakage rate in excess of 2 percent of the average sampling rate is acceptable.

Note: Carefully release the probe inlet plug before turning off the pump.

* * * * *

9.1 Miscellaneous Quality Control Measures. The following quality control measures are required:

Section	Quality control measure	Effect
8.1.2, 8.1.3, 10.1	Sampling equipment leak check and calibration	Ensures accurate measurement of sample volume.
10.2	GC calibration	Ensures precision of GC analysis.
13.0	Methanol spike recovery check	Verifies all methanol in stack gas is being captured in impinge/adsorbent tube setup.

* * * * *

11.3.2 Desorption of Samples. Add 3 ml of deionized distilled water to each of the stoppered vials and shake or vibrate the vials for 30 minutes.

* * * * *

12.1 Nomenclature.

C_{af} = Concentration of methanol in the front of the adsorbent tube, µg/ml.

C_{ab} = Concentration of methanol in the back of the adsorbent tube, µg/ml.

C_i = Concentration of methanol in the impinger portion of the sample train, µg/ml.

E = Mass emission rate of methanol, µg/hr (lb/hr).

m_s = Total mass of compound measured in impinger and on adsorbent with spiked train (mg).

m_u = Total mass of compound measured in impinger and on adsorbent with unspiked train (mg).

m_v = Mass per volume of spiked compound measured (mg/L).

M_{tot} = Total mass of methanol collected in the sample train, µg.

P_{bar} = Barometric pressure at the exit orifice of the DGM, mm Hg (in. Hg).

P_{std} = Standard absolute pressure, 760 mm Hg (29.92 in. Hg).

Q_{std} = Dry volumetric stack gas flow rate corrected to standard conditions, dscm/hr (dscf/hr).

R = fraction of spiked compound recovered

s = theoretical concentration (ppm) of spiked target compound

T_m = Average DGM absolute temperature, degrees K (°R).

T_{std} = Standard absolute temperature, 293 degrees K (528 °R).

V_{af} = Volume of front half adsorbent sample, ml.

V_{ab} = Volume of back half adsorbent sample, ml.

V_i = Volume of impinger sample, ml.

V_m = Dry gas volume as measured by the DGM, dry cubic meters (dcm), dry cubic feet (dcf).

$V_{m(std)}$ = Dry gas volume measured by the DGM, corrected to standard conditions, dry standard cubic meters (dscm), dry standard cubic feet (dscf).

* * * * *

12.5 Recovery Fraction (R)

$$m_v = \frac{m_s}{V_s} - \frac{m_u}{V_u} \qquad \text{Equation 308-4}$$

$$R = \frac{m_v \, x \, v_s}{s} \qquad \text{Equation 308-5}$$

13.0 Method Performance

Since a potential sample may contain a variety of compounds from various sources, a specific precision limit for the analysis of field samples is impractical. Precision in the range of 5 to 10 percent relative standard deviation (RSD) is typical for gas chromatographic techniques, but an experienced GC operator with a reliable instrument can readily achieve 5 percent RSD. For this method, the following combined GC/operator values are required.

(a) Precision. Calibration standards must meet the requirements in section 10.2.1 or 10.2.2 as applicable.

(b) Recovery. After developing an appropriate sampling and analytical system for the pollutants of interest, conduct the following spike recovery procedure at each sampling point where the method is being applied.

i. Methanol Spike. Set up two identical sampling trains. Collocate the two sampling probes in the stack. The probes shall be placed in the same horizontal plane, where the first probe tip is 2.5 cm from the outside edge of the other. One of the sampling trains shall be designated the spiked train and the other the unspiked train. Spike methanol into the impinger, and onto the adsorbent tube in the spiked train prior to sampling. The total mass of methanol shall be 40 to 60 percent of the mass expected to be collected with the unspiked train. Sample the stack gas into the two trains simultaneously. Analyze the impingers and adsorbents from the two trains utilizing identical analytical procedures and instrumentation. Determine the fraction of spiked methanol recovered (R) by combining the amount recovered in the impinger and in the adsorbent tube, using the equations in section 12.5. Recovery values must fall in the range: $0.70 \leq R \leq 1.30$. Report the R value in the test report.

ii. [Reserved]

* * * * *

Method 320—Measurement of Vapor Phase Organic and Inorganic Emissions By Extractive Fourier Transform Infrared (FTIR) Spectroscopy

* * * * *

8.2.2.4 Determine the percent leak volume $\%V_L$ for the signal integration time t_{SS} and for ΔP_{max}, *i.e.,* the larger of ΔP_v or ΔP_p, as follows:

$$\%V_L = 50 t_{ss} \frac{\Delta P_{max}}{P_s} \qquad (2)$$

Where:

50 = 100% divided by the leak-check time of 2 minutes.

* * * * *

9.2.3 Calculate the dilution ratio using the tracer gas as follows:

$$DF = \frac{SF_{6(spk)}}{SF_{6(dir)}} \quad (3)$$

Where:

$$CS = DF * Spike_{dir} + Unspike\ (1 - DF) \quad (4)$$

DF = Dilution factor of the spike gas; this value shall be ≥10.

$SF_{6(dir)}$ = SF_6 (or tracer gas) concentration measured directly in undiluted spike gas.

$SF_{6(spk)}$ = Diluted SF_6 (or tracer gas) concentration measured in a spiked sample.

$Spike_{dir}$ = Concentration of the analyte in the spike standard measured by filling the FTIR cell directly.

CS = Expected concentration of the spiked samples.

Unspike = Native concentration of analytes in unspiked samples.

* * * * *

Method 323—Measurment of Formaldehyde Emissions From Natural Gas-Fired Stationary Sources-Acetyl Acetone Derivitization Method

* * * * *

12.9 Formaldehyde Concentration Corrected to 15% Oxygen

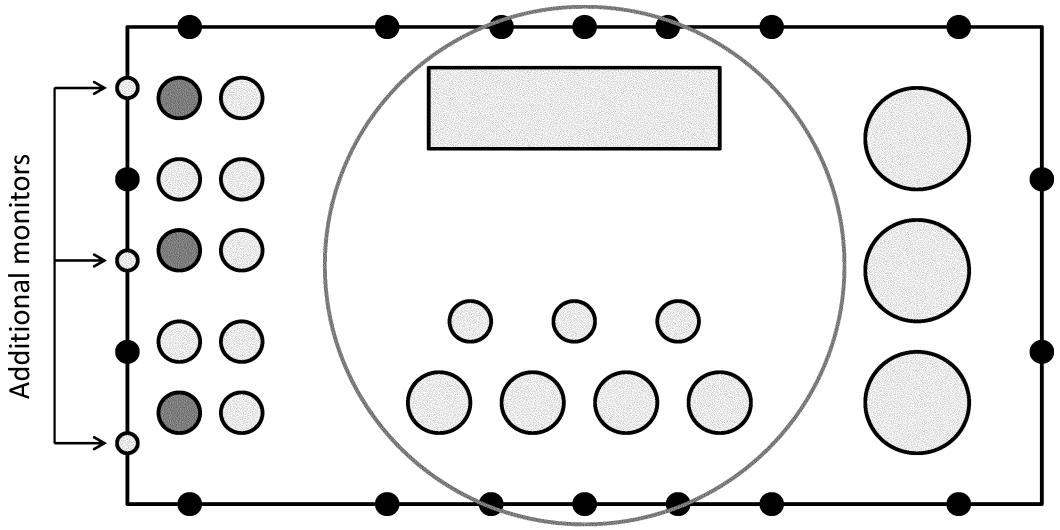
* * * * *

$$C_{form@15\%O_2} = C_{form}\ \frac{(20.9-15)}{(20.9-O_{2d})} \quad \text{Eq. 323-8}$$

Method 325A—Volatile Organic Compounds From Fugitive and Area Sources: Sampler Deployment and VOC Sample Collection

* * * * *

8.2.1.3 An extra sampler must be placed near known sources of VOCs if potential emission sources are within 50 meters (162 feet) of the boundary and the source or sources are located between two monitors. Measure the distance (x) between the two monitors and place another monitor approximately halfway between (x/2 ±10 percent) the two monitors. Only one extra sampler is required between two monitors to account for known sources of VOCs. For example, in Figure 8.1, the facility added three additional monitors (*i.e.,* light shaded sampler locations), and in Figure 8.2, the facility added two additional monitors to provide sufficient coverage of all area sources.



Refinery (20° Angle)

Note: Shaded sources are within 50 meters of the property boundary and are located between two monitors. Additional coverage required by this method was accomplished by placing the monitors halfway between two existing monitors.

Figure 8.1. Facility with a Regular Shape Between 750 and 1,500 Acres in Area

* * * * *

8.2.3.2 For facilities with a monitoring perimeter length greater than or equal to 7,315 meters (24,000 feet), sampling locations are spaced 610 ± 76 meters (2,000 ± 250 feet) apart.

8.2.3.3 Unless otherwise specified in an applicable regulation, permit or other requirement, for small disconnected subareas with known sources within 50 meters (162 feet) of the monitoring perimeter, sampling points need not be placed closer than 152 meters (500 feet) apart as long as a minimum of 3 monitoring locations are used for each subarea.

* * * * *

8.4.3 When extenuating circumstances do not permit safe deployment or retrieval of passive samplers (*e.g.,* extreme weather, power failure), sampler placement or retrieval earlier or later than the prescribed schedule is allowed but must occur as soon as safe access to sampling sites is possible.

* * * * *

Method 325B—Volatile Organic Compounds From Fugitive and Area Sources: Sampler Preparation and Analysis

* * * * *

9.3.2 Field blanks must be shipped to the monitoring site with the sampling tubes and must be stored at the sampling location throughout the monitoring exercise. The field blanks must be installed under a protective hood/cover at the sampling location, but the long-term storage caps must remain in place throughout the monitoring period (see Method 325A). The field blanks are then shipped back to the laboratory in the same container as the sampled tubes. Collect at least two field blank samples per sampling period to ensure sample integrity associated with shipment, collection, and storage.

* * * * *

9.13 Routine CCV at the Start of a Sequence. Run CCV before each sequence of analyses and after every tenth sample to ensure that the previous multi-level calibration (see section 10.0) is still valid.

* * * * *

11.3.2.5 Whenever the thermal desorption—GC/MS analytical method is changed or major equipment maintenance is performed, you must conduct a new five-level calibration (see section 10.0). System calibration remains valid as long as results from subsequent CCV are within 30 percent of the most recent 5-point calibration (see section 9.13). Include relevant CCV data in the supporting information in the data report for each set of samples.

* * * * *

12.2.2 Determine the equivalent concentrations of compounds in atmospheres as follows. Correct target compound concentrations determined at the sampling site temperature and atmospheric pressure to standard conditions (25 °C and 760 mm mercury) using Equation 12.5.

$$C_c = \frac{(m_{meas}) * 10^6}{U_{NTP} * \left[\frac{t_{ss}}{298.15}\right]^{\frac{1}{2}} * t} \qquad \text{Eq. 12.5}$$

Where:

m_{meas} = The mass of the compound as measured in the sorbent tube (µg).

t = The exposure time (minutes).

t_{ss} = The average temperature during the collection period at the sampling site (K).

U_{NTP} = The method defined diffusive uptake rate (sampling rate) (mL/min).

Note: Diffusive uptake rates (U_{NTP}) for common VOCs, using carbon sorbents packed into sorbent tubes of the dimensions specified in section 6.1, are listed in Table 12.1. Adjust analytical conditions to keep expected sampled masses within range (see sections 11.3.1.3 to 11.3.1.5). Best possible method detection limits are typically in the order of 0.1 ppb for 1,3-butadiene and 0.05 ppb for volatile aromatics such as benzene for 14-day monitoring. However, actual detection limits will depend upon the analytical conditions selected.

* * * * *

TABLE 17.1—SUMMARY OF GC/MS ANALYSIS QUALITY CONTROL PROCEDURES

Parameter	Frequency	Acceptance criteria	Corrective action
Bromofluorobenzene Instrument Tune Performance Check.	Daily [a] prior to sample analysis	Evaluation criteria presented in Section 9.5 and Table 9.2.	(1) Retune and or (2) Perform Maintenance.
Five point calibration bracketing the expected sample concentration.	Following any major change, repair or maintenance or if daily CCV does not meet method requirements. Recalibration not to exceed three months.	(1) Percent Deviation (%DEV) of response factors ±30%. (2) Relative Retention Times (RRTs) for target peaks ±0.06 units from mean RRT.	(1) Repeat calibration sample analysis. (2) Repeat linearity check. (3) Prepare new calibration standards as necessary and repeat analysis.
Calibration Verification (CCV Second source calibration verification check).	Following the calibration curve	The response factor ±30% DEV from calibration curve average response factor.	(1) Repeat calibration check. (2) Repeat calibration curve.
Laboratory Blank Analysis	Daily [a] following bromofluoro benzene and calibration check; prior to sample analysis.	(1) ≤0.2 ppbv per analyte or ≤3 times the LOD, whichever is greater. (2) Internal Standard (IS) area response ±40% and IS Retention Time (RT) ±0.33 min. of most recent calibration check.	(1) Repeat analysis with new blank tube. (2) Check system for leaks, contamination. (3) Analyze additional blank.
Blank Sorbent Tube Certification ...	One tube analyzed for each batch of tubes cleaned or 10 percent of tubes whichever is greater.	<0.2 ppbv per VOC targeted compound or 3 times the LOD, whichever is greater.	Re-clean all tubes in batch and reanalyze.
Samples—Internal Standards	All samples	IS area response ±40% and IS RT ±0.33 min. of most recent calibration validation.	Flag Data for possible invalidation.

TABLE 17.1—SUMMARY OF GC/MS ANALYSIS QUALITY CONTROL PROCEDURES—Continued

Parameter	Frequency	Acceptance criteria	Corrective action
Field Blanks	Two per sampling period	No greater than one-third of the measured target analyte or compliance limit.	Flag Data for possible invalidation due to high blank bias.

[a] Every 24 hours.

* * * * *

[FR Doc. 2018–24747 Filed 11–13–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2018–0222; FRL–9986–31–Region 9]

Approval of Arizona Air Plan; Hayden Lead Nonattainment Area Plan for the 2008 Lead Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a state implementation plan (SIP) revision submitted by the State of Arizona to meet Clean Air Act (CAA or ''Act'') requirements applicable to the Hayden lead nonattainment area (''Hayden Lead NAA''). The EPA is approving the base year emissions inventory, the attainment demonstration, the control strategy, including reasonably available control technology and reasonably available control measures demonstrations, the reasonable further progress demonstration, and the contingency measure as meeting the requirements of the CAA and the EPA's implementing regulations for the 2008 lead national ambient air quality standard (NAAQS). We also find that the State has demonstrated that the Arizona SIP meets the new source review (NSR) requirements of CAA section 172(c)(5) for the Hayden Lead NAA.

DATES: This final rule is effective on December 14, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2018–0222. 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 through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Ginger Vagenas, EPA Region IX, 415–972–3964, *Vagenas.Ginger@epa.gov.*

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

Table of Contents

I. Background

Lead is generally emitted in the form of particles that are deposited in water, soil, and dust. People may be exposed to lead by inhaling it or by ingesting lead-contaminated food, water, soil, or dust. Once in the body, lead is quickly absorbed into the bloodstream and can result in a broad range of adverse health effects including damage to the central nervous system, cardiovascular function, kidneys, immune system, and red blood cells. Children are particularly vulnerable to lead exposure, in part because they are more likely to ingest lead and in part because their still-developing bodies are more sensitive to the effects of lead. The harmful effects to children's developing nervous systems (including their brains) arising from lead exposure may include IQ[1] loss, poor academic achievement, long-term learning disabilities, and an increased risk of delinquent behavior.

The EPA first established a lead standard in 1978 at 1.5 micrograms per meter cubed (μg/m^3) as a quarterly average.[2] Based on new health and scientific data, the EPA revised the federal lead standard to 0.15 μg/m^3 and revised the averaging time for the standard on October 15, 2008.[3] A violation of the standard occurs when ambient lead concentrations exceed 0.15 μg/m^3 averaged over a 3-month rolling period.

Following the promulgation of a new or revised NAAQS, the EPA is required by the CAA to designate areas throughout the United States as attaining or not attaining the NAAQS. This process is set forth in section 107(d)(1) of the Act. After initially being designated unclassifiable due to insufficient monitoring data, the Hayden area was redesignated nonattainment on September 3, 2014, effective October 3, 2014.[4] [5] The designation of the Hayden area as nonattainment for the 2008 lead NAAQS triggered requirements under section 191(a) of the CAA requiring Arizona to submit a SIP revision with a plan to attain the standard as expeditiously as practicable, but no later than October 3, 2019.

The Arizona Department of Environmental Quality (ADEQ) is the air quality agency that develops SIP revisions for the Hayden area. The SIP revision for the Hayden Lead NAA, entitled ''SIP Revision: Hayden Lead Nonattainment Area'' (''2017 Hayden Lead Plan'' or ''Plan'') was adopted by ADEQ on March 3, 2017, and submitted to the EPA on the same day.[6] The Plan includes a 2012 base year emissions inventory, a demonstration that controls required under the Plan are sufficient to bring the area into attainment of the 2008 lead NAAQS, an analysis that demonstrates reasonably available control measures/reasonably available control technology (RACM/RACT) levels of control are required to be implemented, a demonstration that the Plan provides for reasonable further progress (RFP) towards attainment, and a contingency measure that will be implemented if the area fails to make

[1] IQ (intelligence quotient) is a score created by dividing a person's mental age score, obtained by administering an intelligence test, by the person's chronological age, both expressed in terms of years and months. ''Glossary of Important Assessment and Measurement Terms,'' Philadelphia, PA: National Council on Measurement in Education. 2016.

[2] 43 FR 46246 (October 5, 1978).

[3] 73 FR 66964 (November 12, 2008) (''lead NAAQS rule'').

[4] 79 FR 52205.

[5] For an exact description of the Hayden Lead NAA, see 40 CFR 81.303.

[6] Letter dated March 3, 2017, from Timothy S. Franquist, Director, Air Quality Division, ADEQ, to Alexis Strauss, Acting Regional Administrator, EPA Region IX.

RFP or to attain the NAAQS by the applicable deadlines. The Plan also describes ADEQ's NSR program and its intention to submit revisions to its NSR rules to address deficiencies identified by the EPA.[7]

II. Proposed Action and Public Comment

On July 3, 2018, the EPA published a notice of proposed rulemaking in which we proposed to approve the Plan as a revision to the Arizona SIP.[8] [9] The rationale for our proposed action is included in the proposal, and will not be restated here.

The EPA's proposed action provided a 30-day public comment period. During this period, we received six anonymous comments. After reviewing the comments, we determined that two were ''test comments'' that did not include any text and therefore do not necessitate a response. Three comments were outside the scope of our proposed action and failed to identify any material issue necessitating a response.

The sixth comment included the observation that the EPA had used the term ''off-road'' when describing a portion of mobile source inventory, but the term ''non-road'' was used in the table summarizing ADEQ's base year emissions inventory. The commenter asked if, to make it consistent, would ''off-road'' be used throughout the proposal?

In the proposal, we explained that emissions can be grouped into two general categories: Stationary and mobile. We further noted that stationary source category can be subdivided into point and area sources and that the mobile source category can be subdivided into on-road and off-road categories.[10] In tables 1 and 3, which immediately follow that discussion, we listed emissions for point, area, mobile source (non-road) and mobile source (on-road) categories.[11] In our proposed action, we used the terms interchangeably and believe their equivalent meaning is apparent from the context.

The comments have been added to the docket for this action and are accessible at *https://www.regulations.gov/docket?D=EPA-R09-OAR-2018-0222.*

III. Final Action

For the reasons discussed in the proposal, the EPA is approving under CAA section 110(k)(3) the 2017 Hayden Lead Plan as a revision to the Arizona SIP. Specifically, we are approving:

(1) The SIP's base year emissions inventory as meeting the requirements of CAA section 172(c)(3) and 40 CFR 51.117(e)(1);

(2) the attainment demonstration, including air quality modeling, as meeting the requirements of CAA section 172(c)(1);

(3) the RACM/RACT demonstration as meeting the requirements of CAA section 172(c)(1);

(4) the RFP demonstration as meeting the requirements of CAA section 172(c)(2); and

(5) the contingency measure as meeting the requirements of the CAA section 172(c)(9);

We also find that the State has demonstrated that the Arizona SIP meets the NSR requirements of CAA section 172(c)(5) for the Hayden Lead NAA.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely 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 (Public Law 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 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). We offered to consult with San Carlos Apache Tribe, which has lands adjacent to the Hayden lead nonattainment area. The tribe did not respond to the EPA's offer to consult.

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 action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to

[7] ADEQ subsequently submitted the changes and, on May 4, 2018, the EPA approved the revision into the SIP (83 FR 19631). The SIP revision ensures that ADEQ's rules provide for appropriate NSR for lead sources undergoing construction or major modification in the Hayden Lead NAA.

[8] 83 FR 31087.

[9] ADEQ has determined that the cause of the nonattainment status in the Hayden area is the primary copper smelter owned and operated by ASARCO, which accounts for over 99 percent of lead emissions, and that the emissions generally come from the hot-metal smelting process and lead-bearing fugitive dust. Plan, 38. ADEQ's control strategy for the Hayden Lead NAA relies on the implementation of two source-specific regulations in the Arizona Administrative Code: Rule R18–2–B1301 (limits on Lead Emissions from the Hayden Smelter) and Rule R–18–2–B1301.01 (Limits on Lead-Bearing Fugitive Dust from the Hayden Smelter), and two associated appendices. We approved Rule R–18–B1301.01 and Appendix 15 into the Arizona SIP on February 22, 2018 (83 FR 7614) and, in a notice signed on October 30, 2018, we approved Rule R18–2–B1301 and Appendix 14.

[10] 83 FR 31087, 31090.

[11] Id. Note that the terms off-road and non-road do not appear elsewhere in the notice.

publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 14, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

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

Dated: October 31, 2018.

Deborah Jordan,

Acting Regional Administrator, Region IX.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart D—Arizona

■ 2. Section 52.120 in paragraph (e), Table 1 is amended by adding, under the table heading ''Part D Elements and Plans (Other than for the Metropolitan Phoenix and Tucson Areas),'' an entry for ''SIP Revision: Hayden Lead Nonattainment Area, excluding Appendix C.'' after the entry for ''Maintenance Plan Renewal, 1971 Sulfur Dioxide National Ambient Air Quality Standards, Douglas Maintenance Area.'' The addition reads as follows:

§ 52.120 Identification of plan.

* * * * *

(e) * * *

TABLE 1—EPA-APPROVED NON-REGULATORY AND QUASI-REGULATORY MEASURES

[Excluding certain resolutions and statutes, which are listed in tables 2 and 3, respectively] [1]

Name of SIP provision	Applicable geographic or non-attainment area or title/subject	State submittal date	EPA approval date	Explanation
The State of Arizona Air Pollution Control Implementation Plan				
*	*	*	*	*
SIP Revision: Hayden Lead Nonattainment Area, excluding Appendix C.	Hayden, AZ Lead Nonattainment Area.	March 3, 2017	[INSERT **Federal Register** CITATION], November 14, 2018.	Adopted by the Arizona Department of Environmental Quality on March 3, 2017.
*	*	*	*	*

[1] Table 1 is divided into three parts: Clean Air Act Section 110(a)(2) State Implementation Plan Elements (excluding Part D Elements and Plans), Part D Elements and Plans (other than for the Metropolitan Phoenix or Tucson Areas), and Part D Elements and Plans for the Metropolitan Phoenix and Tucson Areas.

* * * * *

[FR Doc. 2018–24740 Filed 11–13–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2017–0661; FRL–9986–32–Region 9]

Air Plan Approval; Arizona; Hayden and Miami Areas; Lead and Sulfur Dioxide Control Measures—Copper Smelters

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Arizona State Implementation Plan (SIP). These revisions concern emissions of lead and sulfur dioxide (SO_2) from the copper smelter at Hayden, AZ and SO_2 from the copper smelter at Miami, AZ. We are approving local rules that regulate these emission sources under the Clean Air Act (CAA or the Act).

DATES: This rule will be effective on December 14, 2018.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2017–0661. 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 through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Kevin Gong, EPA Region IX, (415) 972–3073, *gong.kevin@epa.gov.*

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

Table of Contents

I. Proposed Action

On March 30, 2018 (83 FR 13716), the EPA proposed to approve the following rules into the Arizona SIP.[1]

[1] In addition to the rules addressed in this action, ADEQ's April 6, 2017 submittal also included R18–2–B1301.01—Limits on Lead-Bearing Fugitive Dust from the Hayden Smelter; R18–2–B1302—Limits on SO_2 Emissions from the Hayden Smelter; R18–2–715—Standards of Performance for Existing Primary Copper Smelters: Site-Specific Requirements; and R18–2–715.01—Standards of Performance for Existing Primary Copper Smelters; Compliance and Monitoring. The EPA has already approved R18–2–B1301.01 into the SIP, 83 FR 7614 (February 22, 2018) and intends to take action on the remaining rules in a separate rulemaking.

Rule citation	Rule title	Effective	Submitted
R18–2–B1301	Limits on Lead Emissions from the Hayden Smelter.	7/1/2018 or 180 calendar days after completion of all Converter Retrofit Project improvements authorized by Significant Permit Revision No. 60647.	4/6/2017
R18–2–C1302	Limits on SO_2 Emissions from the Miami Smelter	On the later of the effective date of the EPA Administrator's action approving it as part of the state implementation plan or January 1, 2018.	4/6/2017
Appendix 14	Procedures for Sulfur Dioxide and Lead Fugitive Emissions Studies for the Hayden Smelter.	5/7/2017	4/6/2017
R18–2–715.02	Standards of Performance for Existing Primary Copper Smelters; Fugitive Emissions.	5/7/2017	4/6/2017

We proposed to approve these rules because we determined that they comply with the relevant CAA requirements. Our proposed action contains more information on the rules and our evaluation.

II. Public Comments and EPA Responses

The EPA's notice of proposed rulemaking provided a 30-day public comment period. During this period, we received 15 comments. Nine of these comments address issues not related to the subject of this rulemaking, including: Environmental quality issues in Asia, climate change policy, and other federal requirements not related to SO_2 or lead pollution in Arizona. Six comments are germane to this rulemaking, and are supportive of the EPA's proposal to approve these regulations. One of these commenters raised a concern about the State and the EPA's statement that controlling emissions from the 1,000-foot stack would result in improved air quality at the ground level monitors at Hillcrest and Globe Highway in the Hayden Area. This commenter also suggested that the EPA should pay additional attention to fugitive lead emissions that may result from other smelter processes, including furnace dust and from residue from converter bed cleaning. We thank the commenter for the questions and suggestion and address the issues raised below.

The Arizona Department of Environmental Quality (ADEQ) and the EPA believe that the prime contributors to lead nonattainment are fugitive emissions from smelter operations and leaded dust surrounding the smelter. Rule R18–2–B1301.01, approved into the Arizona SIP in 83 FR 7614, addresses leaded dust control measures for non-smelting process sources, which includes sources such as the bedding plant and reverts piles. Dust and material generated from smelter process sources, such as furnace and converter dust, are collected and deposited in these non-smelting process sources for disposal or reintroduction into the smelter process. Rule R18–2–B1301 addresses fugitive emissions from smelter operations by establishing operational standards for process equipment and control devices, requirements for the process gas capture system and control devices operations and maintenance plan (O&M plan), performance testing and compliance demonstration requirements, and recordkeeping and reporting requirements. However, Rule R18–2–B1301 does not include a numeric fugitive lead emissions limit. The EPA recognized this issue during the rule development process and requested that ADEQ provide supplementary analysis to address this concern. ADEQ responded on October 11, 2018, stating that continuous monitoring of fugitive lead emissions is technically infeasible, and that parametric monitoring of capture and control device efficiency (which would minimize uncontrolled fugitive emissions, and increase the volume of process gas directed to control devices and ultimately the 1,000-foot stack) was a suitable proxy for a numeric fugitive lead limit. ADEQ also reiterated that the fugitive emissions analyses required by Appendix 14 would be used to validate this approach.[2] The EPA generally agrees with this reasoning.

The EPA also requested that ADEQ address an issue regarding the allowance for alternative sampling points for SO_2 at the Miami Smelter. Specifically, we requested that ADEQ eliminate a provision that allowed for the owner or operator of the Miami Smelter to petition for an alternative sampling point if the current locations proved infeasible. Such flexibility might have been necessary at the time of rule development, as capture and control upgrades were still being installed; however, now that the upgrades are complete, we do not believe this flexibility is still necessary. ADEQ agreed to withdraw subsection (E)(6) of Rule R18–2–C1302 allowing for alternative sampling point since none are needed at the Miami Smelter.[3]

The comments and additional analysis from ADEQ have been added to the docket for this action and are accessible at *https://www.regulations.gov/docket?D=EPA-R09-OAR-2017-0661.*

III. EPA Action

No comments were submitted that change our assessment of the rules as described in our proposed action. Therefore, as authorized in section 110(k)(3) of the Act, the EPA is approving these rules into the Arizona SIP, with the exception of subsection (E)(6) in Rule R18–2–C1302, which was withdrawn by ADEQ. The EPA is also approving Appendix 14 and revised R18–2–715.02.

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 ADEQ rules described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents 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). Therefore, these materials have been approved by the EPA for inclusion in the SIP, have been incorporated by

[2] Letter from Timothy S. Franquist, Director, Air Quality Division, Arizona Department of Environmental Quality, to Michael Stoker, Regional Administrator, U.S. Environmental Protection Agency, Region 9, ''Re: Justification and Clarification on Arizona Administrative Code R18–2–B1301, *Limits on Lead Emissions from the Hayden Smelter,*'' dated October 11, 2018.

[3] Letter from Timothy S. Franquist, Director, Air Quality Division, Arizona Department of Environmental Quality, to Michael Stoker, Regional Administrator, U.S. Environmental Protection Agency, Region 9, ''Re: Request to Withdraw from EPA Consideration, Arizona Administrative Code R18–2–C1302, Subsection (E)(6),'' dated August 27, 2018.

reference by the 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 the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[4]

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 the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

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. Section 804, however, exempts from section 801 the following types of rules: Rules of particular applicability; rules relating to agency management or personnel; and rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties. 5 U.S.C. 804(3). Because this is a rule of particular applicability, the EPA is not required to submit a rule report regarding this action under section 801.

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 14, 2019. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

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

Dated: October 30, 2018.

Michael Stoker,

Regional Administrator, Region IX.

Part 52, Chapter I, Title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart D—Arizona

■ 2. In § 52.120, table 2 in paragraph (c) is amended by:

■ a. Revising the entry ''R18–2–715.02'';

■ b. Adding the entry ''R18–2–B1301'' after the subheading ''Article 13 (State Implementation Plan Rules for Specific Locations)''; and

■ c. Adding the entries ''R18–2–C1302, excluding subsection (E)(6)'' and ''Appendix 14'' after the entry ''R18–2–B1301.01''.

The revision and additions read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

TABLE 2—EPA-APPROVED ARIZONA REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Article 7 (Existing Stationary Source Performance Standards)				

[4] 62 FR 27968 (May 22, 1997).

TABLE 2—EPA-APPROVED ARIZONA REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Additional explanation
*	* *	*	*	* *
R18–2–715.02	Standards of Performance for Existing Primary Copper Smelters; Fugitive Emissions.	5/7/2017	11/14/2018, [insert **Federal Register** citation].	Submitted by the Governor's designee on April 6, 2017.
*	* *	*	*	* *
Article 13 (State Implementation Plan Rules for Specific Locations)				
R18–2–B1301	Limits on Lead Emissions from the Hayden Smelter.	7/1/2018	11/14/2018, [insert **Federal Register** citation].	Submitted by the Governor's designee on April 6, 2017.
*	* *	*	*	* *
R18–2–C1302, excluding subsection (E)(6).	Limits on SO_2 Emissions from the Miami Smelter.	12/14/2018	11/14/2018, [insert **Federal Register** citation].	Submitted by the Governor's designee on April 6, 2017. Subsection (E)(6) was withdrawn by the Arizona Department of Environmental Quality.
Appendix 14	Procedures for Sulfur Dioxide and Lead Fugitive Emissions Studies for the Hayden Smelter.	5/7/2017	11/14/2018, [insert **Federal Register** citation].	Submitted by the Governor's designee on April 6, 2017.
*	* *	*	*	* *

* * * * *

[FR Doc. 2018–24743 Filed 11–13–18; 8:45 am]

BILLING CODE 6560–50–P

GENERAL SERVICES ADMINISTRATION

48 CFR Part 509

[GSAR Change 96; GSAR Case 2017–G503; Docket No. 2018–0012; Sequence No. 1]

RIN 3090–AJ87

General Services Administration Acquisition Regulation; Removing Duplicative Responsibility Determination Guidance

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Direct final rule.

SUMMARY: GSA is amending the General Services Administration Acquisition Regulation (GSAR) to remove duplicative text already contained in the Federal Acquisition Regulation.

DATES: *Effective date:* This rule is effective January 14, 2019 unless GSA receives adverse comments during the comment period. If GSA receives adverse comments, we will publish a timely withdrawal in the **Federal Register** informing the public that the rule will not take effect.

Comment date: Comments are due December 14, 2018 by any of the methods listed in the Addresses section of this rule.

ADDRESSES: Submit comments in response to GSAR Case 2017–G503 by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for ''GSAR Case 2017–G503''. Select the link ''Comment Now'' that corresponds with ''GSAR Case 2017–G503.'' Follow the instructions provided on the screen. Please include your name, company name (if any), and ''GSAR Case 2017–G503'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), ATTN: Lois Mandell, 1800 F Street NW, 2nd floor, Washington, DC 20405.

Instructions: Please submit comments only and cite ''GSAR Case 2017–G503'' in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Johnnie McDowell, Procurement Analyst, at 202–718–6112 or *johnnie.mcdowell@gsa.gov,* for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755. Please cite GSAR Case 2017–G503.

SUPPLEMENTARY INFORMATION:

I. Background

FAR 1.304(b) states that agency regulations shall not ''unnecessarily repeat, paraphrase, or otherwise restate material contained in the FAR.'' Here, both GSAR 509.105–1(b) and FAR 9.105(b) provide guidance to obtaining information from Government sources for a responsibility determination of potential Government contractors.

II. Discussion and Analysis

Both GSAR 509.105–1(b) and FAR 9.105–1(b) pertain to how contracting officers obtain information regarding a contractor's responsibility. GSAR 509.105–1(b) states ''[t]he contracting officer may solicit and consider information from any appropriate activities[.]'' FAR 9.105–1(b) states ''[g]enerally, the contracting officer shall obtain information regarding the responsibility of prospective contractors, including requesting pre-award surveys when necessary (see 9.106) promptly after bid opening or receipt of offers . . .'' GSAR 509.105–1(b) simply paraphrases FAR 9.105–1(b) as it restates that a contracting officer should obtain information regarding a contractor's responsibility through ''any appropriate activities'' which is implied through FAR 9.105–1(b)'s language. Further, FAR 9.105 includes that standards and procedures for requesting and obtaining information sufficient to determine the responsibility of a

prospective contractor, *i.e.,* that an offeror meets the standards at FAR 9.104. Therefore, GSAR 509.105–1(b) will be removed from the GSAR because it violates FAR 1.304(b) by unnecessarily paraphrasing FAR 9.105–1(b).

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Executive Order 13771

This final rule is not subject to E.O. 13771, because this rule is not a significant regulatory action under E.O. 12866.

V. Regulatory Flexibility Act

This rule will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* because the rule merely removes unnecessarily duplicative regulatory language. The rule imposes no new reporting, recordkeeping, or other information collection requirements. Therefore, a Regulatory Flexibility Analysis has not been performed.

VI. Paperwork Reduction Act

This rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Part 509

Government procurement.

Dated: November 7, 2018.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy, General Services Administration.

Therefore, GSA is amending 48 CFR part 509 as set forth below:

PART 509—CONTRACTOR QUALIFICATIONS

■ 1. The authority citation for part 509 continues to read as follows:

Authority: 40 U.S.C. 121(c).

■ 2. Revise section 509.105–1 to read as follows:

509.105–1 Obtaining information.

FAR 9.105–1 lists a number of sources of information that a contracting officer may utilize before making a determination of responsibility. The contracting officer may request information directly from a prospective contractor using GSA Form 527, Contractor's Qualifications and Financial Information, but only after exhausting other available sources of information.

[FR Doc. 2018–24755 Filed 11–13–18; 8:45 am]

BILLING CODE 6820–61–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 170817779–8161–02]

RIN 0648–XG591

Fisheries of the Exclusive Economic Zone Off Alaska; Reallocation of Pacific Cod in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; reallocation.

SUMMARY: NMFS is reallocating the projected unused amount of Pacific cod total allowable catch (TAC) from vessels using jig gear, trawl catcher vessels, and American Fisheries Act (AFA) catcher/processors to catcher vessels less than 60 feet (18.3 m) length overall (LOA) using hook-and-line or pot gear in the Bering Sea and Aleutian Islands management area. This action is necessary to allow the 2018 TAC of Pacific cod to be harvested.

DATES: Effective November 13, 2018, through 2400 hours, Alaska local time (A.l.t.), December 31, 2018.

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

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

The 2018 Pacific cod TAC specified for vessels using jig gear in the BSAI is 249 metric tons (mt) as established by the final 2018 and 2019 harvest specifications for groundfish in the BSAI (83 FR 8365, February 27, 2018) and reallocation (83 FR 42227, August 21, 2018).

The 2018 Pacific cod TAC specified for trawl catcher vessels in the BSAI is 40,227 mt as established by the final 2018 and 2019 harvest specifications for groundfish in the BSAI (83 FR 8365, February 27, 2018).

The 2018 Pacific cod TAC specified for AFA catcher/processors in the BSAI is 4,186 mt as established by the final 2018 and 2019 harvest specifications for groundfish in the BSAI (83 FR 8365, February 27, 2018).

The 2018 Pacific cod TAC allocated to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear in the BSAI is 6,290 mt as established by final 2018 and 2019 harvest specifications for groundfish in the BSAI (83 FR 8365, February 27, 2018) and reallocation (83 FR 42227, August 21, 2018).

The Administrator, Alaska Region, NMFS, (Regional Administrator) has determined that jig vessels will not be able to harvest 100 mt of the 2018 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*1*), the trawl catcher vessels will not be able to harvest 2,200 mt of the 2018 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*9*), and the AFA catcher/processors will not be able to harvest 158 mt of the 2018 Pacific cod TAC allocated to those vessels under § 679.20(a)(7)(ii)(A)(*7*). Therefore, in accordance with § 679.20(a)(7)(iii)(A), NMFS apportions 100 mt of Pacific cod from the jig vessel apportionment, 2,200 mt of Pacific cod from the trawl catcher vessel apportionment, and 158 mt of Pacific cod from the AFA catcher/processor apportionment to the annual amount specified for catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear. The harvest specifications for Pacific cod included in final 2018 and 2019 harvest specifications for groundfish in the BSAI (83 FR 8365, February 27, 2018) and reallocations (83 FR 42227, August 21, 2018) are revised as follows: 149 mt to the annual amount for vessels using

jig gear, 38,027 mt to trawl catcher vessels, 4,028 mt to AFA catcher/processors, and 8,748 mt to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the reallocations of Pacific cod to catcher vessels less than 60 feet (18.3 m) LOA using hook-and-line or pot gear. Since the fishery is currently open, it is important to immediately inform the industry as to the revised allocations. Immediate notification is necessary to allow for the orderly conduct and efficient operation of this fishery, to allow the industry to plan for the fishing season, and to avoid potential disruption to the fishing fleet as well as processors. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 7, 2018.

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

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

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

Dated: November 8, 2018.

Karen H. Abrams,

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

[FR Doc. 2018–24824 Filed 11–13–18; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 83, No. 220
Wednesday, November 14, 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 AGRICULTURE

Agricultural Marketing Service

7 CFR Part 981

[AMS–SC–18–0018; SC18–981–3]

Almonds Grown in California; Proposed Amendments to Marketing Order 981 and Referendum Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule and referendum order.

SUMMARY: This rulemaking proposes amendments to Marketing Order No. 981, which regulates the handling of almonds in California. The Almond Board of California (Board) recommended changing the dates associated with the process to nominate members to the Board as well as the start of the term of office of members of the Board. The Board also recommended adding authority to allow future revisions of the nomination methods and term of office start date through the development of regulations using informal rulemaking.

DATES: The referendum will be conducted from March 25, 2019, through April 5, 2019. The representative period for the referendum is August 1, 2017, through July 31, 2018.

FOR FURTHER INFORMATION CONTACT: Debbie Wray, Senior Marketing Specialist, or Michelle Sharrow, Deputy Director, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Stop 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Debbie.Wray@usda.gov* or *Michelle.Sharrow@usda.gov*.

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

SUPPLEMENTARY INFORMATION: This proposal, pursuant to 5 U.S.C. 553, proposes amendments to regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This proposal is issued under Marketing Order No. 981, as amended (7 CFR part 981), regulating the handling of almonds grown in California. Part 981 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' Section 608c(17) of the Act and the applicable rules of practice and procedure governing the formulation of marketing agreements and orders (7 CFR part 900) authorizes amendment of the Order through this informal rulemaking action.

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

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

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed no later than 20 days after the date of entry of the ruling.

Section 1504 of the Food, Conservation, and Energy Act of 2008 (2008 Farm Bill)(Pub. L. 110–246) amended section 608c(17) of the Act, which in turn required the addition of supplemental rules of practice to 7 CFR part 900 (73 FR 49307; August 21, 2008). The amendment of section 608c(17) of the Act and additional supplemental rules of practice authorize the use of informal rulemaking (5 U.S.C. 553) to amend Federal fruit, vegetable, and nut marketing agreements and orders. USDA may use informal rulemaking to amend marketing orders based on the nature and complexity of the proposed amendments, the potential regulatory and economic impacts on affected entities, and any other relevant matters.

AMS has considered these factors and has determined that the amendments proposed are not unduly complex and the nature of the proposed amendments is appropriate for utilizing the informal rulemaking process to amend the Order.

The proposed amendments were unanimously recommended by the Board following deliberations at a public meeting held on December 4, 2017. The proposal would amend the Order by: (1) Changing the nomination deadline for Board nominees from January 20 to April 1, the deadline for presenting nominees to USDA for selection from February 20 to June 1, and the start of the term of office from March 1 to August 1; (2) adding the ability to propose future revisions to Board nomination methods by developing regulations through informal rulemaking; and (3) adding the ability to propose future revisions to the start date of the Board's term of office by developing regulations through informal rulemaking. In addition to these proposals, AMS proposes to make any additional changes to the Order as may be necessary to conform to any amendment that may result from this rulemaking action.

A proposed rule soliciting comments on the proposed amendments was issued on July 2, 2018, and published in the **Federal Register** on July 6, 2018 (83 FR 31473). One comment was received,

but it did not pertain to this proposal; therefore, no changes were made to the proposed amendments. AMS will conduct a grower referendum to determine support for the proposed amendments. If appropriate, a final rule will then be issued to effectuate the amendments favored by growers in the referendum.

The Board's proposed amendments would amend the Order by changing the dates associated with the process to nominate members to the Board, changing the start date for the term of office of members of the Board, and adding authority to the Order to allow future revisions of the nomination methods and term of office start date through the development of regulations using informal rulemaking.

Proposal 1—Nomination and Term of Office Dates

Section 981.32 provides that, each year, nominees for open Board member and alternate member positions shall be chosen by ballot delivered to the Board. In support of this nomination process, § 981.32 further provides that on or before January 20 of each year, the Board shall mail to all handlers and growers, other than the cooperative(s) of record, the required ballots with all necessary voting information; and that nominees chosen shall be submitted by the Board to the USDA Secretary of Agriculture (Secretary) on or before February 20 of each year. If a nomination for any Board member or alternate is not received by the Secretary on or before February 20, the Secretary may select, without nomination, such member or alternate from persons belonging to the group to be represented.

Section 981.33 provides that the term of office of Board members and alternate members selected by the Secretary pursuant to § 981.32 shall begin on March 1.

This proposal would amend § 981.32 by changing the nomination deadline for Board nominees from January 20 to April 1 and the deadline for presenting nominees for selection to the Secretary from February 20 to June 1. It would also amend § 981.33 by changing the start of the term of office from March 1 to August 1. A clarifying change would also be made to § 981.33 to remove language related to a previous amendment to the Order that is no longer needed.

Changing the two nomination process dates from January 20 and February 20 to April 1 and June 1, respectively, could provide several benefits. First, preparing ballots to mail in January is very challenging for the Board because it prepares for and hosts major industry activities in December, including a Board meeting and a large, multi-day almond conference that is held at an off-site location. The Board office is also closed the last week of December every year. Because of these year-end activities, it is difficult for the Board to prepare for a nomination mailing in January. Changing the nomination dates would allow the Board enough time to prepare nominations for mailing.

In addition, the Board believes that more industry members might participate in the nomination process if it occurred later in the calendar year. This is because many industry members are busy with or returning from winter holiday season activities in December and January and, therefore, may be less likely to participate in nomination proceedings that are occurring at that time.

In addition to the challenges the Board faces in meeting the January nomination deadline, there is currently only one month between the deadline for mailing ballots (January 20) and the date that the Board must process returned ballots and prepare a nomination package to submit to USDA (February 20). In addition to this short timeframe, there are only 9 or 10 days between the February 20 deadline by which the Board must submit nominations to USDA and the March 1 term of office start date. This short timeframe does not provide adequate time for the nominations to be processed and new member selections to be made prior to the new term of office. The proposed changes would provide 60 days between the April 1 and June 1 nomination process deadline dates, compared to the existing 30 days between the current dates of January 20 and February 20. The proposed changes would also provide 60 days between the June 1 deadline for the Board to submit the nominations to USDA and the new August 1 term of office start date, compared to the existing 10 days between the current dates of February 20 and March 1. Extending the times between these dates would improve the overall preparation and processing of nominations.

The proposal to change the term of office start date would improve Board cohesiveness because the Board would then operate on the same timeline as the crop year and the Board's committees. The Order's crop year is defined in § 981.19 as August 1 through July 31. The Board is responsible for all program planning and budgeting for each crop year. However, with the current term of office beginning on March 1, Board members responsible for annual program planning and budget recommendations leave office prior to the end of the crop year; conversely, new Board members also begin serving in the middle of a crop year. Starting the term of office on August 1 would allow Board members to administer activities for an entire crop year as well as provide valuable insight related to the next crop year's activities. Changing the start of the term of office to August 1 would align with the appointment of individuals to various committees that operate under the Board, which occurs at the beginning of each crop year.

Changing the term of office start date from March 1 to August 1 would require current members and alternates to serve a few additional months, beyond the original March 1 start date, until their respective successors were selected and qualified pursuant to § 981.33(a).

These changes to the nomination and term of office dates that appear in two sections of the Order (§§ 981.32 and 981.33) are being proposed as a single amendment because of the relation of the nomination process to the start date of the term of office; that is, if the nomination process dates are changed to occur later in the calendar year (on April 1 and June 1, respectively, as described above), then the start date of the term of office would also need to change from March 1 to a date that would follow the new nomination process dates. As noted above, the Board recommended the term of office start date be changed to August 1.

For the reasons stated above, it is proposed that § 981.32, Nominations, be amended by changing the nomination deadline for Board nominees from January 20 to April 1 and the deadline for presenting nominees for selection to the Secretary from February 20 to June 1. Further, it is proposed that § 981.33, Selection and term of office, be amended by changing the start of the term of office from March 1 to August 1 and by making a clarifying change to remove language related to a previous amendment to the Order that is no longer needed.

Proposal 2—Regulation Authority for Nomination Methods

Section 981.32 provides the methods by which nominations for open Board member and alternate member positions shall be chosen, including the dates by which (1) ballots and voting information shall be mailed by the Board to all handlers and growers, other than cooperative(s) of record, and (2) nominations shall be submitted by the Board to the Secretary. Changes to these dates are included in Proposal 1 above.

This proposal would change § 981.32 by adding authority to modify the nomination methods described in paragraph (a) through the future development of regulations using the informal rulemaking process. Currently, changes to the nomination methods require formal rulemaking. The Board would still be required to discuss future proposed changes at its meetings and to vote on whether to recommend changes to USDA. If amended, future changes would still require notice be given to the public with an opportunity for the public to comment on the proposed changes. However, it is anticipated that this proposed amendment would streamline future changes to the Order by allowing such changes to be proposed and finalized using informal rulemaking.

For the reasons stated above, it is proposed that § 981.32, Nominations, be amended by adding a new paragraph that would provide the Board with authority to modify its nomination methods by developing regulations using the informal rulemaking process.

Proposal 3—Regulation Authority for Term of Office Start Date

Section 981.33 provides that the term of office of Board members and alternate members selected by the Secretary pursuant to § 981.32 shall begin on March 1. A change to this term of office start date is included in Proposal 1.

This proposal would change § 981.33 by adding authority to modify the term of office start date through the future development of regulations using the informal rulemaking process. Currently, changes to the term of office start date require formal rulemaking. The Board would still be required to discuss a future proposed change at its meetings and to vote on whether to recommend a change to USDA. If amended, a future change to the term of office start date would still require notice be given to the public with an opportunity for the public to comment on the proposed change. However, it is anticipated that this proposed amendment would streamline future changes to the Order by allowing such changes to be proposed and finalized using informal rulemaking.

For the reasons stated above, it is proposed that § 981.33, Selection and term of office, be amended by adding a new paragraph that would provide the Board with authority to modify the term of office start date by developing regulations using the informal rulemaking process.

Final Regulatory Flexibility Analysis

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

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

There are approximately 6,800 almond growers in the production area and approximately 100 almond handlers subject to regulation under the Order. Small agricultural service firms are defined by the Small Business Administration (SBA) as those having annual receipts of less than $7,500,000, and small agricultural producers are defined as those having annual receipts of less than $750,000 (13 CFR 121.201).

The National Agricultural Statistics Service (NASS) reported in its 2012 Agricultural Census that there were 6,841 almond farms in the production area (California), of which 6,204 had bearing acres. The following computation provides an estimate of the proportion of agricultural producers (farms) and agricultural service firms (handlers) that would be considered small under the SBA definitions.

The NASS Census data indicates that out of the 6,204 California farms with bearing acres of almonds, 4,471 (72 percent) have fewer than 100 bearing acres.

For the almond industry's most recently reported crop year (2016), NASS reported an average yield of 2,280 pounds per acre and a season average grower price of $2.44 per pound. A 100-acre farm with an average yield of 2,280 pounds per acre would produce about 228,000 pounds of almonds. At $2.44 per pound, that farm's production would be valued at $556,320. The Census of Agriculture indicates that the majority of California's almond farms are smaller than 100 acres; therefore, it could be concluded that the majority of growers had annual receipts from the sale of almonds in 2016–17 of less than $556,320, which is below the SBA threshold of $750,000. Thus, over 70 percent of California's almond growers would be classified as small entities according to SBA's definition.

To estimate the proportion of almond handlers that would be considered small businesses, it was assumed that the unit value per shelled pound of almonds exported in a particular year could serve as a representative almond price at the handler level. A unit value for a commodity is the value of exports divided by the quantity. Data from USDA's Foreign Agricultural Service showed that the value of almond exports from August 2016 to July 2017 (combining shelled and inshell almonds) was $4.072 billion. The quantity of almond exports over that period was 1.406 billion pounds, combining shelled exports and the shelled equivalent of inshell exports. Dividing the export value by the quantity yields a unit value of $2.90 per pound. Subtracting this figure from the NASS 2016 estimate of season average grower price per pound ($2.44) yields $0.46 per pound as a representative grower-handler margin. Applying the $2.90 representative handler price per pound to 2016–17 handler shipment quantities provided by the Board showed that approximately 40 percent of California's almond handlers shipped almonds valued under $7,500,000 during the 2016–17 crop year and would therefore be considered small entities according to the SBA definition.

The proposed amendments would change the dates associated with the process to nominate Board members and alternates as well as the start of the term of office of Board members. The proposed amendments would also add authority to allow future revisions of the nomination methods and term of office dates through the development of regulations using informal rulemaking. These amendments would improve the nomination process, align the term of office with the crop year and appointment of Board committees, and streamline the process for making similar changes in the future.

The Board's proposed amendments were unanimously recommended at a public meeting of the Board on December 4, 2017. The proposed amendments are administrative in nature; therefore, if any or all the proposals are approved in referendum, there should be no economic impact on growers or handlers. Changing the nomination dates could encourage greater industry participation on the Board because the timing of the current nominations occurs immediately after the winter holiday season, when many industry members are just returning to their operations and may be less inclined to participate. The changes to the nomination process dates and the term of office start date are expected to

streamline and improve operations of the Board. Adding authority to allow the development of regulations through informal rulemaking for making future changes to the nomination methods and term of office start date could reduce the time it takes to implement the changes, thereby allowing the Board to function more effectively.

Alternatives to the proposals, including recommending no changes, were considered. However, the Board believes that changing the nomination process dates and term of office start date, as well as adding authority to make similar changes in the future by creating regulations through informal rulemaking, will be beneficial to the industry by enhancing Board operations and effectiveness.

Paperwork Reduction Act

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

As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. In addition, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

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

The Board's meeting was widely publicized throughout the almond industry. All interested persons were invited to attend the meeting and encouraged to participate in Board deliberations on all issues. Like all Board meetings, the December 4, 2017, meeting was public, and all entities, both large and small, were encouraged to express their views on these proposals.

A proposed rule concerning this action was published in the **Federal Register** on July 6, 2018 (83 FR 31473). Copies of the proposed rule were sent via email to all Board members and almond handlers. Finally, the rule was made available through the internet by USDA and the Office of the Federal Register. A 60-day comment period ending September 4, 2018, was provided to allow interested persons to respond to the proposal. One comment was received, but it did not pertain to this proposal; therefore, no changes were made to the proposed amendments.

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

Findings and Conclusions

The findings and conclusions and general findings and determinations included in the proposed rule set forth in the July 6, 2018, issue of the **Federal Register** are hereby approved and adopted.

Marketing Order

Annexed hereto and made a part hereof is the document entitled ''Order Amending the Order Regulating the Handling of Almonds Grown in California.'' This document has been decided upon as the detailed and appropriate means of effectuating the foregoing findings and conclusions. It is hereby ordered that this entire rule be published in the **Federal Register**.

Referendum Order

It is hereby directed that a grower referendum be conducted in accordance with the procedure for the conduct of referenda (7 CFR 900.400–407) to determine whether the annexed order amending the Order regulating the handling of almonds grown in California is approved by growers who have engaged in the production of almonds within the production area during the representative period. The representative period for the conduct of such referendum is hereby determined to be August 1, 2017, to July 31, 2018.

The agents of the Secretary to conduct such referendum are designated to be Peter Sommers and Terry Vawter, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *PeterR.Sommers@usda.gov* or *Terry.Vawter@usda.gov.,* respectively.

Order Amending the Order Regulating the Handling of Almonds Grown in California [1]

Findings and Determinations

The findings hereinafter set forth are supplementary to the findings and determinations which were previously made in connection with the issuance of the marketing order; and all said previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

1. The Order, as amended, and as hereby proposed to be further amended, and all of the terms and conditions thereof, would tend to effectuate the declared policy of the Act;

2. The Order, as amended, and as hereby proposed to be further amended, regulates the handling of almonds grown in California in the same manner as, and are applicable only to, persons in the respective classes of commercial and industrial activity specified in the Order;

3. The Order, as amended, and as hereby proposed to be further amended, is limited in application to the smallest regional production area which is practicable, consistent with carrying out the declared policy of the Act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the Act;

4. The Order, as amended, and as hereby proposed to be further amended, prescribe, insofar as practicable, such different terms applicable to different parts of the production area as are necessary to give due recognition to the differences in the production and marketing of almonds produced in the production area; and

5. All handling of almonds produced in the production area as defined in the Order is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

Order Relative to Handling

It is therefore ordered, that on and after the effective date hereof, all handling of almonds grown in California shall be in conformity to, and in compliance with, the terms and conditions of the said order as hereby proposed to be amended as follows:

The provisions of the proposed marketing order amending the Order

[1] This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

contained in the proposed rule issued by the Administrator on July 2, 2018, and published in the **Federal Register** (83 FR 31473) on July 6, 2018, will be and are the terms and provisions of this order amending the Order and are set forth in full herein.

List of Subjects in 7 CFR Part 981

Almonds, Marketing agreements, Nuts, Reporting and recordkeeping requirements.

Dated: November 7, 2018.

Bruce Summers,

Administrator, Agricultural Marketing Service.

For the reasons discussed in the Preamble, 7 CFR part 981 is proposed to be amended as follows.

PART 981—ALMONDS GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 981 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Amend § 981.32 by revising paragraph (a)(1) and adding paragraph (a)(3) to read as follows:

§ 981.32 Nominations.

(a) *Method.* (1) Each year the terms of office of three of the members elected pursuant to § 981.31(a) and (b) shall expire, except every third year when the term of office for two of those members shall expire. Nominees for each respective member and alternate member shall be chosen by ballot delivered to the Board. Nominees chosen by the Board in this manner shall be submitted by the Board to the Secretary on or before June 1 of each year together with such information as the Secretary may require. If a nomination for any Board member or alternate is not received by the Secretary on or before June 1, the Secretary may select such member or alternate from persons belonging to the group to be represented without nomination. The Board shall mail to all handlers and growers, other than the cooperative(s) of record, the required ballots with all necessary voting information including the names of incumbents willing to accept renomination, and, to such growers, the name of any person proposed for nomination in a petition signed by at least 15 such growers and filed with the Board on or before April 1. Distribution of ballots shall be announced by press release, furnishing pertinent information on balloting, issued by the Board through newspapers and other publications having general circulation in the almond producing areas.

* * * * *

(3) The Board may recommend, subject to the approval of the Secretary, a change to the nomination method, should the Board determine that a revision is necessary.

* * * * *

■ 3. Amend § 981.33 by revising the first sentence of paragraphs (a) and (b), revising the last sentence of paragraph (c), and adding paragraph (d) to read as follows:

§ 981.33 Selection and term of office.

(a) Members and their respective alternates for positions open on the Board shall be selected by the Secretary from persons nominated pursuant to § 981.32, or, at the discretion of the Secretary, from other qualified persons, for a term of office beginning August 1. * * *

(b) The term of office of members of the Board shall be for a period of three years beginning on August 1 of the years selected except where otherwise provided. * * *

(c) * * * This limitation on tenure shall not apply to alternate members.

(d) The Board may recommend, subject to approval of the Secretary, revisions to the start date for the term of office of members of the Board.

[FR Doc. 2018–24727 Filed 11–13–18; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF ENERGY

10 CFR Part 430

Energy Conservation Program: Test Procedures for Consumer Warm Air Furnaces, Notice of Petition for Rulemaking

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of petition for rulemaking; request for comment.

SUMMARY: On October 12, 2018, the Department of Energy (DOE) received a petition from the Air-Conditioning, Heating, and Refrigeration Institute (AHRI) asking DOE to initiate notice-and-comment rulemaking to develop a new, unified test procedure for residential furnaces which would replace the three currently required performance metrics (*i.e.,* annual fuel utilization efficiency (AFUE), fan efficiency ratio (FER), and standby mode/off mode energy consumption ($P_{W,SB}$ and $P_{W,OFF}$)) with a single new metric (AFUE2). As the petition acknowledges, a combined metric would necessitate a translation of the existing energy conservation standards applicable to residential furnaces using an appropriate crosswalk. Through this announcement, DOE seeks comment on the petition, as well as any data or information that could be used in DOE's determination whether to proceed with the petition.

DATES: Written comments and information are requested on or before January 14, 2019.

ADDRESSES: Interested persons are encouraged to submit comments, identified by ''Test Procedure for Consumer Warm Air Furnaces Petition,'' by any of the following methods:

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

Email: ResFurnPet2018PET0017@ee.doe.gov. Include Docket No. EERE–2018–BT–PET–0017 in the subject line of the message.

Postal Mail: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

Hand Delivery/Courier: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, Suite 600, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

Docket: For access to the docket to read background documents, or comments received, go to the Federal eRulemaking Portal at: *http://www.regulations.gov/docket?D=EERE-2018-BT-PET-0017.*

FOR FURTHER INFORMATION CONTACT: Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, 1000 Independence Avenue SW, Washington, DC 20585. Telephone: (202) 586–9507. Email: *Eric.Stas@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.,* provides among other things, that ''[e]ach agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.'' (5 U.S.C. 553(e)) DOE received a petition from AHRI, as described in this notice and set forth verbatim below,[1] requesting that DOE

[1] Attachments and data submitted by AHRI with its petition for rulemaking are available in the

develop a new test procedure for residential furnaces with a combined metric (annual fuel utilization efficiency 2 (AFUE2)), which would encompass the three existing metrics currently required (*i.e.,* AFUE, FER, and $P_{W,SB}$/$P_{W,OFF}$). In promulgating this petition for public comment, DOE is seeking views on whether it should grant the petition and undertake a rulemaking to consider the proposal contained in the petition. By seeking comment on whether to grant this petition, DOE takes no position at this time regarding the merits of the suggested rulemaking or the assertions in AHRI's petition.

In its petition, AHRI requests that DOE undertake notice-and-comment rulemaking to develop a new test procedure for residential warm air furnaces that would consolidate all aspects of the regulation of such furnaces using a single metric (AFUE2) and yield a unified timeline for rulemaking and compliance. Currently, residential furnaces are subject to separate requirements for heating (AFUE), air circulation (FER), and standby mode and off mode energy consumptions (power in watts for standby mode and off mode ($P_{W,SB}$ and $P_{W,OFF}$)). The petitioner asserts that its recommended single metric would reduce regulatory burden on manufacturers by streamlining test requirements and aligning regulatory review schedules, thereby promoting design flexibility and product innovation. The petitioner further asserts that consumers would also benefit by having a single, combined metric for product comparison purposes and by receiving some portion of anticipated cost savings, all of which could be achieved without sacrificing energy savings. As the petition acknowledges, a combined metric would necessitate a translation of the existing energy conservation standards applicable to residential furnaces using an appropriate crosswalk.

DOE welcomes comments and views of interested parties on any aspect of the petition for rulemaking.

In conjunction with its petition, AHRI requested that DOE not enforce the reporting, certification and compliance obligations related to the furnace fan energy conservation standards (for which compliance is required on July 3, 2019) pending consideration of this petition for rulemaking.[2] In response to AHRI's request, DOE is issuing an enforcement policy regarding enforcement of the furnace fan standards. Further details will be provided on the DOE website.[3]

Submission of Comments

DOE invites all interested parties to submit in writing by January 14, 2019 comments and information regarding this petition.

Submitting comments via http://www.regulations.gov. The *http://www.regulations.gov* webpage will require you to provide your name and contact information prior to submitting comments. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *http://www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through *http://www.regulations.gov* cannot be claimed as CBI. Comments received through the website will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *http://www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *http://www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery, or postal mail. Comments and documents via email, hand delivery, or postal mail will also be posted to *http://www.regulations.gov*. If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments.

Include contact information in your cover letter each time you submit comments, data, documents, and other information to DOE. If you submit via postal mail or hand delivery, please provide all items on a CD, if feasible, in which case it is not necessary to submit printed copies. No telefacsimiles (faxes) will be accepted.

Comments, data, and other information submitted electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English, and free of any defects or viruses. Documents should not include any special characters or any form of encryption, and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. Pursuant to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: One copy of the document marked ''Confidential'' including all the information believed to be confidential, and one copy of the document marked ''Non-confidential'' with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

docket at *http://www.regulations.gov/docket?D=EERE-2018-BT-PET-0017*.

[2] AHRI's request is available in the docket at *http://www.regulations.gov/docket?D=EERE-2018-BT-PET-0017*.

[3] *See http://www.energy.gov/gc/enforcement/*.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include: (1) A description of the items; (2) whether and why such items are customarily treated as confidential within the industry; (3) whether the information is generally known by or available from other sources; (4) whether the information has previously been made available to others without obligation concerning its confidentiality; (5) an explanation of the competitive injury to the submitting person which would result from public disclosure; (6) when such information might lose its confidential character due to the passage of time, and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

DOE considers public participation to be a very important part of its process for considering rulemaking petitions. DOE actively encourages the participation and interaction of the public during the comment period. Interactions with and between members of the public provide a balanced discussion of the issues and assist DOE in determining how to proceed with a petition. Anyone who wishes to be added to DOE mailing list to receive future notices and information about this petition should contact Appliance and Equipment Standards Program staff at (202) 287–1445 or via email at *ApplianceStandardsQuestions@ee.doe.gov*.

Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this notice of petition for rulemaking.

Signed in Washington, DC, on November 2, 2018.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

Before the

UNITED STATES DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Energy Conservation Program:

Test Procedures for Consumer Warm Air Furnaces

PETITION FOR A RULEMAKING

The Air-Conditioning, Heating, and Refrigeration Institute (AHRI) submits this Petition for a Rulemaking to formally request that the Department of Energy (DOE or the Department) promulgate a new test procedure for residential furnaces pursuant to its authority under the Energy Policy and Conservation Act (EPCA), 42 U.S.C. § 6293. Currently, three separate Federal test procedures measure three different performance characteristics of consumer warm-air furnaces: fuel efficiency (AFUE), air-movement efficiency (FER), and stand-by/off-mode energy consumption. AHRI petitions DOE to establish a new test procedure that will designate a single efficiency metric for the entire product and replace the existing test procedures for all three performance characteristics. A whole-product test procedure and single performance metric will reduce regulatory burden and increase opportunity for innovation.

AHRI Petitions DOE to Conduct a Notice-and-Comment Rulemaking to Adopt the AFUE2 Test Procedure and Metric for Residential Furnaces

AHRI is the trade association representing air conditioning, heating, commercial refrigeration, and ventilation equipment manufacturers. AHRI advocates for the HVACR industry, administers a third-party certification program that verifies the performance of HVACR equipment, and publishes global industry standards. Many of AHRI's 315 members design, develop, and manufacture residential furnaces. Any AHRI member that manufactures a furnace for sale in the United States or Canada is eligible to participate in AHRI's Furnace Product Section. The Furnace Engineering Committee is a subcommittee of the Furnace Product Section and is comprised of furnace product engineers with decades of experience. Over a year ago, the Furnace Engineering Committee identified challenges with the existing residential furnace Federal test procedures and has dedicated its time and resources to developing a more functional and facile test procedure. The goal of the new test procedure is to combine the three existing furnace test procedures into a single test using a single metric: AFUE2.[4]

I. Description of the Test Method and Metric

The AFUE2 test procedure is based upon the methods established by the ASHRAE 103–2017 AFUE test procedure;[5] the Federal FER test procedure (10 CFR § 430 Appx AA); and the Federal stand-by loss/off-mode test procedure (10 CFR § 430 Appx N). The AFUE2 metric accounts for furnace fuel, fan power, and stand-by and off-mode power consumption. The measured value represents the sum of usable heat and fan benefit, divided by the total fuel and electricity consumed. A draft of the test procedure is attached.[6] For the benefit of the Department and the public, a description of the notable features of the test procedure and metric are provided below.

The first step in the process is to measure the fuel consumption. The furnace is set up and measurements are taken in accordance with the most current industry test standard, ASHRAE 103–2017.[7] The AFUE2 test procedure differs most significantly from the ASHRAE 103–2017 test procedure by including only steady-state testing and excluding cyclic testing for fuel and oil furnace models currently available in the U.S. market.[8] Cyclic testing is time consuming and requires the execution of complex calculations, and the value of the cyclic testing is limited at best. AHRI's data indicates that for the vast majority of modern products, the steady-state efficiency accurately represents the AFUE efficiency, and cyclic testing and calculations are unnecessary. Based on an analysis of over 100 models, only a handful demonstrated greater than a 1% difference between measured AFUE and steady-state efficiencies (less jacket loss).[9] The average difference between actual AFUE and steady-state efficiencies is close to zero. The elimination of cyclic testing for currently compliant products is warranted and reduces testing burden without sacrificing accuracy. Notably, to close any loopholes that might permit technology backsliding, the test procedure specifies that products that incorporate draft hoods and draft diverter technologies must complete the cyclic testing procedures published in ASHRAE 103–2017. AHRI is not aware of any furnaces on the market today that incorporate these technologies.

After the fuel consumption is measured, the next step in the procedure is to turn off the equipment and measure the electrical consumption of the furnace when not in heating mode. The procedure for measuring and calculating stand-by and off-mode energy use is identical to the Federal method.

Finally, the ventilation energy consumption is measured. The AFUE2 test method for measuring and calculating ventilation energy consumption is based on the FER test procedure, with some significant changes. First, the AFUE2 test procedure describes set-up and settings for the ventilation test in greater detail than the FER test procedure. For example, the AFUE2 test procedure specifically identifies the location of the external static pressure taps. These set-up descriptions are intended to reduce test-to-test variability.

The AFUE2 test procedure also clarifies the hierarchy of speed taps settings for the

[4] During previous discussions with DOE about unrelated performance metric changes, DOE staff indicated that the name of a metric is mandated by statute, and therefore any metric change must retain the codified nomenclature. If upon further review, DOE determines that the nomenclature, like the test procedure, is mutable, then AHRI encourages DOE to adopt a fitting identifier for the metric. AHRI is not bound to ''AFUE2.''

[5] AFUE2 fuel efficiency measures are based primarily on ASHRAE 103–2017. DOE has codified ASHRAE 103–1993 in 10 CFR § 430 Appx N. The relevant portions of the ASHRAE 103–2017 that are referenced in the AFUE2 test procedure are similar to the equivalent provisions in ASHRAE 103–1993/10 CFR 430 Appendix N. Other provisions, related to cyclic testing, are only applicable to products with draft hoods and draft diverter technologies.

[6] Exhibit 1 AFUE2 Draft Test Procedure.

[7] Per Note 2, DOE regulations currently refer to the ASHRAE 103–1993, but the test set-up is the same with some clarifications.

[8] These are models with power burners as defined by the DOE test procedures.

[9] Exhibit 2: Calculations reflecting steady-state efficiency and measured AFUE efficiency.

various modes of ventilation testing. The FER procedure directs manufacturers to test using the ''maximum airflow settings,'' but this description is ambiguous and can lead to absurd results depending on its interpretation. The AFUE2 test procedure specifies that the airflow be set according to the installation and operations manual, and the test procedure prescribes which airflow setting should be selected if there is overlap between operating modes. If the manual identifies the maximum airflow during the heating mode, and the second highest airflow during cooling mode, then the speed taps should be set accordingly: first heating, then cooling. If the heating and cooling mode airflows are the same, then the cooling mode speed tap is set first, which reflects how the furnace would operate in the field.

Finally, manufacturers have been challenged with the repeatability of the FER test. Testing has demonstrated more than a 5% difference among tests on the same unit. The poor repeatability of the FER measurements is resolved in AFUE2 due to the relatively small proportion of the electrical consumption. The AFUE fuel efficiency test is well established and repeatable, so overall AFUE2 will be much more repeatable than FER.

II. The AFUE2 Metric Prevents Double Regulation

AFUE2 efficiency is the sum of the fan benefit and usable heat, divided by electric and fuel consumption, all weighted by operating hours. The calculations for AFUE2 and FER are based on different operating hours. The hours differ in two meaningful ways: (1) The cooling hours are derived directly from AHRI Standard 210/240, which is incorporated by reference into the Federal standard for central air conditioners; and (2) package equipment is ascribed zero fan operating hours in the cooling mode. The AFUE2 test procedure relies on cooling mode operating hours from AHRI Standard 210/240 based on the simple logic that air conditioners conduct the cooling during furnace-ventilation cooling mode and air conditioner operating hours are already defined in AHRI 210/240. Harmonizing the two standards is preferable and logical, and assigning different operating hours in two different regulations for what is essentially the same product is arbitrary. Packaged equipment is assigned zero operating hours because the ventilation electricity consumption is already directly regulated by DOE's air conditioning standard. DOE is strictly prohibited from regulating the same product twice. Two separate regulations (SEER and FER) imposed on the same component of a single type of equipment is contrary to DOE's statutory authority. Eliminating operating hours for packaged equipment permits the furnace to be measured by AFUE2 without double-regulating the ventilation energy use.

Aside from the above distinctions, most of the methods and measurements from the currently applicable test procedures and metrics are reflected in the AFUE2 test procedure and metric. The ultimate goal of combining the AFUE, FER, and stand-by/off-mode test procedures is to streamline the testing requirements, align regulatory review schedules, and reduce regulatory burden.

III. Establishing the AFUE2 as the Federal Test Procedure and Metric Is in the Public Interest

A. A Combined Test Procedure and Metric Reduces Burden

The AFUE2 test procedure and metric will decrease the regulatory burden. At least six different regulations apply to consumer furnace efficiency: (1) AFUE test procedure (2) AFUE energy conservation standard (3) FER test procedure (4) FER energy conservation standard (5) stand-by loss/off-mode test procedure (6) stand-by loss/off-mode energy conservation standard. Each of these regulations is subject to mandatory review—every six years for energy conservation standards and every seven years for test procedures. Each of the six applicable regulations follows a different schedule, which places the equipment manufacturers, distributors, contractors and DOE in a constant state of change and adjustment. The AFUE test procedure was most recently finalized in 2016. DOE is required to review it again by 2023. The FER test procedure was finalized in 2014; it will be reviewed by 2021. The stand-by loss test procedure was finalized in 2013; it will be reviewed by 2020. Stand-by and off-mode test procedures were amended in 2012 and are due for review in 2019. Energy conservation standards for stand-by and FER were published in 2013 and 2014, respectively, while the AFUE standard has been under review since 2011. Industry expects that energy conservation standards will be reviewed again in 2019 and 2020. The Department is perennially reviewing and amending furnace regulations, while manufacturers pour time and resources into public comments, testing, redesign, and ever-shifting compliance requirements. The total reduction in regulatory burden resulting from implementation of AFUE2 will save manufacturers more than $250 million over thirty years.[10]

If DOE adopts the AFUE2 test procedure that assesses all three performance characteristics simultaneously, then the Department would only have to conduct a test procedure rulemaking process once every seven years. Similarly, combining the performance measurements into a single metric will obviate the need for three separate energy conservation standards, and DOE will only have to review energy conservation standards once every six years.

Resource savings to the Department are relevant, but pale in comparison to the significant savings afforded manufacturers, and consequently consumers, if DOE were to combine the test metric and eliminate four of six rulemaking review cycles. Multiple discordant regulatory requirements generate unnecessary costs. For example, manufacturers must run an FER test, and a separate AFUE test, and stand-by loss testing. The incremental costs of the equipment, the set-up, mounting on the test stand, the laboratory time, and technician costs can be drastically reduced by conducting one test instead of three. The alignment of review cycles and redesign cycles further reduces repetitive testing required for design development and safety certifications. The AFUE2 test procedure mimics many of the existing test methods, but the merging of the instances of active testing cuts superfluous costs.[11]

Every time DOE makes an amendment to any of the applicable regulations, manufacturers must redesign equipment, make capital investments to update manufacturing facilities, republish all marketing literature, and educate distributors, contractors, and consumers about the change. Merging six rulemaking cycles into two dramatically reduces the compliance burden associated with regulatory changes because changes will occur two-thirds less frequently. Manufacturers can pass on significant savings to consumers by making all required changes to their furnaces within a single design-cycle rather than spending resources on unnecessary tooling, design, testing, production introduction, training and other related costs.[12] Less frequent regulatory changes offer greater certainty to manufacturers, which promotes investment in innovation and product improvements.

Crucially, reduced costs for manufacturers and consumers does not translate to lost energy savings. Fewer regulatory review cycles does not mean regulatory roll-back or less oversight. AHRI is confident that DOE will take no less interest in the representativeness and effectiveness of the applicable test procedure as a result of this change. And each energy conservation standard review remains targeted at achieving the ''maximum energy savings'' that are economically justified. Ultimately, DOE will be able to look at the furnace as a whole and make necessary adjustments to testing and energy conservation during a single rulemaking review instead of executing its mandate piecemeal.

B. The AFUE2 Test Procedure and Metric Will Increase Innovation

As discussed above, the AFUE2 test metric combines three performance characteristics into a single measure. The current approach fragments furnace efficiency into three separate minimum requirements: stand-by/off mode, ventilation, and fuel efficiency. The practice of setting minimums for discrete characteristics of a single product is overly prescriptive; this approach drives product development in only one direction. Component level regulation restricts design choices between manufacturers. AFUE2 gives manufacturers more design flexibility on how they achieve overall energy savings. The AFUE2 test method and metric requires manufacturers to account for all three performance characteristics, but it promotes innovation by allowing for internal efficiency trade-offs at the product level. Product designers must be given license to develop better ways to save fuel and electricity while improving the quality and performance of the equipment. A combined metric saves energy

[10] Exhibit 3, ''Estimated Benefits of AFUE2''

[11] *Id.*

[12] *Id.*

without prescribing multiple engineering requirements.

C. The Combined Metric Is Easier for Consumers To Use and Understand

AFUE2 is easier for consumers to understand. It is difficult for the average consumer to distinguish between the fuel efficiency of a furnace, the electric efficiency of the furnace fans and the watts saved or lost during stand-by or off-mode. The average consumer considers three separate measures for a single product unnecessarily complex and unhelpful. A single metric will serve as an easy basis of comparison between all fuel furnace types. A simple label can concisely represent the single efficiency metric and provide approximate costs of operation, which is a chief concern of consumers.

The AFUE2 test method and metric improves consumer utility of the efficiency information. Furnace manufacturers question the technical viability of the FER test procedure and metric. A separate regulation for ventilation energy disproportionately emphasizes the electrical consumption of a furnace, when the fuel consumption is much more significant to consumers. A representative proportion of energy use by both parts is described by AFUE2.

IV. Metric Changes Require a Crosswalk

AHRI requests that DOE adopt the AFUE2 test procedure pursuant to a notice-and-comment rulemaking. The Department has statutory authority to amend test procedures under 42 U.S.C. 6293(e) of EPCA. The statute prescribes steps to establish a crosswalk from the previous metric to the new metric. Specifically, EPCA states that DOE ''shall determine, in the rulemaking carried out with respect to prescribing such procedure, to what extent, if any, the proposed test procedure would alter the measured energy efficiency . . . of a covered product as determined under the existing test procedure.''

The transition from three independent metrics to one integrated product metric will demonstrably ''alter the measured efficiency.'' As such, DOE ''shall amend the applicable energy conservation standard during the rulemaking carried out with respect to such test procedure. In determining the amended energy conservation standard, the Secretary shall measure, pursuant to the amended test procedure, the energy efficiency . . . of a representative sample of covered products that minimally comply with the existing standard. The average of such energy efficiency . . . determined under the amended test procedure shall constitute the amended conservation standard for the applicable covered products.''

AHRI has begun analyzing testing data to assist in the development of the required crosswalk. A representative sample of furnaces that are ''minimally compliant'' with energy conservation minimums at each furnace product class will be tested, rated, and averaged. This average will provide a degradation factor that can be applied to all furnaces within that product class to ensure equivalence across product lines with the current AFUE metric. Uniquely, this particular crosswalk requires translation from three performance characteristics to one product efficiency measure, and each of those performance characteristic standards are currently further divided into separate product classes. It will likely be necessary to adjust the calculated baseline efficiencies to ensure that the maximum permissible energy use of the furnace reflects minimally compliant furnaces at each product class for each metric.

For example, minimally compliant non-weatherized natural gas furnaces are currently rated with an AFUE of 80%. Based on preliminary estimates, after the application of the degradation factor, the baseline efficiencies for the AFUE2 rating is 77%.[13] The FER and stand-by loss regulations also specify different product classes for which the minimally compliant product will also have to be measured and averaged. Using this data, the baseline minimum efficiencies can be adjusted upward to ensure all current energy use is appropriately captured. More testing is required to assign values to this methodology.

Crosswalks can create havoc in the market if not carefully executed. AHRI urges DOE to work with stakeholders to ensure a precise and simple transition from ''AFUE + FER + Stand-by/off-mode'' to ''AFUE2.'' For clarity, AHRI recommends that the baseline efficiency for translation is the AFUE minimum for each residential furnace product class. Maintaining the established product class structure for residential furnaces will have the least disruptive impact on the market. As described above, these baseline efficiencies can be adjusted to ensure that maximum energy use and minimum efficiencies remain steady, but the decades-old definitions and classifications remain constant for ease of market adoption.

V. AHRI Requests a Prompt Response

Finally, AHRI requests that DOE act promptly to initiate a notice-and-comment rulemaking to adopt the proffered test procedure and metric as soon as possible. The FER minimum efficiency standards go into effect in July of 2019, and DOE will have to expedite the release of a notice of proposed rulemaking to ensure that manufacturers do not have to comply with one metric and test procedure while preparing to comply with another. AHRI appreciates the consideration that DOE will give this petition and thanks the Department in advance for its attention to this petition.

Signed,

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[13] The 3% degradation factor is based on preliminary findings. AHRI will provide more substantial testing to support a degradation factor as more tests are conducted. The preliminary value will likely change with more data.

[FR Doc. 2018–24697 Filed 11–13–18; 8:45 am]
BILLING CODE 6450–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 175, 176, 177, and 178

[Docket No. FDA–2018–F–3757]

Flexible Vinyl Alliance; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by the Flexible Vinyl Alliance (FVA), requesting that we amend our food additive regulations to no longer provide for the use of 26 ortho-phthalates in various food-contact applications because these uses have been permanently abandoned.

DATES: The food additive petition was filed on July 3, 2018. Submit either electronic or written comments by January 14, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 14, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 14, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such

as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–F–3757 for ''Flexible Vinyl Alliance; Filing of Food Additive Petition.'' 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.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

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

FOR FURTHER INFORMATION CONTACT: Stephen DiFranco, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2710.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(b)(5)), we are giving notice that we have filed a food additive petition (FAP 8B4820), submitted by FVA, c/o Keller and Heckman, LLP., 1001 G St. NW, Suite 500 West, Washington, DC 20001. The petition requests that we amend our food additive regulations in parts 175, 176, 177, and 178 (21 CFR parts 175, 176, 177, and 178) to revoke the approvals for 26 substances that the petition identifies as ortho-phthalates. The petition requests that we revoke the approvals because the food additive uses have been permanently abandoned. The substances affected by this petition and their corresponding Chemical Abstracts Service (CAS) numbers (when available) are listed in table 1. Some of the substances are the subject of approvals in multiple food additive regulations for different uses, and the petition identifies the regulations that authorize the food additive use of the substances. Therefore, we are also listing the regulations that would be affected by this FAP (see tables 2–19). For each regulation that would be affected, we list the specific ortho-phthalates that the regulation authorizes. The petition asserts that the uses of the ortho-phthalates identified in tables 2–19 have been abandoned. If the FAP is granted in full, none of the ortho-phthalates listed in table 1 would be authorized for food additive use in FDA's food additive regulations. Some of the substances are the subject of prior sanction authorizations. The FAP does not pertain to those prior sanction uses.

TABLE 1—ORTHO-PHTHALATES THAT WOULD BE AFFECTED BY THIS FAP

Food Additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131–11–3
Diphenyl phthalate	84–62–8
Methyl phthalyl ethyl glycolate (1,2-Benzenedicarboxylicacid, 1-(2-ethoxy-2-oxoethyl) 2-methyl ester)	85–71–2
Diethyl phthalate	84–66–2
Diphenylguanidine phthalate [1]	17573–13–6
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84–72–0
Diallyl phthalate	131–17–9
Diisobutyl phthalate	84–69–5
Butyl benzyl phthalate	85–68–7
Di-n-butyl phthalate	84–74–2
Butyl phthalyl butyl glycolate [2] (Butyl carbobutoxymethyl phthalate)	85–70–1
Dihexyl phthalate (Di-n-hexyl phthalate)	84–75–3
Di(butoxyethyl) phthalate (Bis(2-n-butoxyethyl) phthalate)	117–83–9
Dimethylcyclohexyl phthalate	1322–94–7
Diisooctyl phthalate	27554–26–3
Dioctyl phthalate (Di-n-octyl phthalate)	117–84–0
Butyloctyl phthalate (n-butyl n-octyl phthalate)	84–78–6
Di(2-ethylhexyl) hexahydrophthalate [1]	84–71–9
Amyl decyl phthalate (n-amyl n-decyl phthalate)	7493–81–4
Butyl decyl phthalate (n-butyl n-decyl phthalate)	89–19–0

TABLE 1—ORTHO-PHTHALATES THAT WOULD BE AFFECTED BY THIS FAP—Continued

Food Additive	CAS No.
Decyl octyl phthalate (Octyldecyl phthalate/n-octyl n-decyl phthalate)	119–07–3
Didecyl phthalate (Di-n-decyl phthalate)	84–77–5
Dodecyl phthalate	21577–80–0
Dihydroabietyl phthalate	26760–71–4
Castor oil phthalate, hydrogenated	N/A
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol	68650–73–7

[1] We note that while these substances are not chemically classified as ortho-phthalates, they are included in FAP 8B4820. The FAP describes all of the substances as ortho-phthalates, although for these substances that characterization is incorrect.
[2] Substance is named Butyl phthalate butyl glycolate in 21 CFR 175.105. We believe this is a typographical error, and it should be named butyl phthalyl butyl glycolate or butyl carbobutoxymethyl phthalate.

The petition identifies § 175.105, ''Adhesives'' (21 CFR 175.105) as being impacted by the FAP. Specifically, the petition identifies the use of the substances listed in table 2 as being impacted.

TABLE 2—ORTHO-PHTHALATES AUTHORIZED BY § 175.105 THAT WOULD BE AFFECTED BY THIS FAP

[''Adhesives'']

Food additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131–11–3
Diphenyl phthalate	84–62–8
Methyl phthalyl ethyl glycolate (1,2Benzenedicarboxylicacid, 1-(2-ethoxy-2-oxoethyl) 2-methyl ester)	85–71–2
Diethyl phthalate	84–66–2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84–72–0
Diallyl phthalate	131–17–9
Diisobutyl phthalate	84–69–5
Butyl benzyl phthalate	85–68–7
Di-n-butyl phthalate [1]	84–74–2
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate) [2]	85–70–1
Dihexyl phthalate (Di-n-hexyl phthalate)	84–75–3
Di(butoxyethyl) phthalate (Bis(2-n-butoxyethyl) phthalate)	117–83–9
Diisooctyl phthalate	27554–26–3
Dioctyl phthalate (Di-n-octyl phthalate)	117–84–0
Butyloctyl phthalate (n-butyl n-octyl phthalate)	84–78–6
Di(2-ethylhexyl) hexahydrophthalate	84–71–9
Butyl decyl phthalate (n-butyl n-decyl phthalate) [3]	89–19–0
Decyl octyl phthalate (Octyldecyl phthalate/n-octyl n-decyl phthalate)	119–07–3
Dihydroabietyl phthalate	26760–71–4

[1] Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 175.105 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.
[2] Although the petitioner refers to this substance as Butyl phthalyl butyl glycolate phthalate in the petition, it is listed in § 175.105 as Butyl phthalate butyl glycolate. These terms are synonymous, referring to the same chemical substance.
[3] Although the petitioner refers to this substance as Butyl decyl phthalate in the petition, it is listed in § 175.105 as Butyldecyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 175.300, ''Resinous and polymeric coatings'' (21 CFR 175.300), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 3 as being impacted.

TABLE 3—ORTHO-PHTHALATES AUTHORIZED BY § 175.300 THAT WOULD BE AFFECTED BY THIS FAP

[''Resinous and polymeric coatings'']

Food additive	CAS No.
Diethyl phthalate	84–66–2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84–72–0
Di-n-butyl phthalate [1]	84–74–2
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate)	85–70–1
Diisooctyl phthalate	27554–26–3

[1] Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 175.300 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 175.320, ''Resinous and polymeric coating for polyolefin films'' (21 CFR 175.320), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 4 as being impacted.

TABLE 4—ORTHO-PHTHALATES AUTHORIZED BY § 175.320 THAT WOULD BE AFFECTED BY THIS FAP

["Resinous and polymeric coatings for polyolefin films"]

Food additive	CAS No.
Diethyl phthalate	84–66–2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84–72–0
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate)	85–70–1

The petition identifies § 175.380, ''Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins'' (21 CFR 175.380), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 5 as being impacted. Although the regulation in § 175.380 does not directly refer to these ortho-phthalates, the regulation authorizes their use by cross-referencing § 175.300(b)(3). Although use of ortho-phthalates authorized by § 175.380 would be affected by the FAP, the FAP would not require the regulatory text in § 175.380 to be amended.

TABLE 5—ORTHO-PHTHALATES AUTHORIZED BY § 175.380 THAT WOULD BE AFFECTED BY THIS FAP

["Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins"]

Food additive	CAS No.
Diethyl phthalate	84–66–2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84–72–0
Di-n-butyl phthalate [1]	84–74–2
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate) [2]	85–70–1
Diisooctyl phthalate	27554–26–3

[1] Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 175.300(b)(3) as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 175.390, ''Zinc-silicon dioxide matrix coatings'' (21 CFR 175.390) as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 6 as being impacted by the FAP. Although the regulation in § 175.390 does not directly refer to these ortho-phthalates, the regulation authorizes their use by cross-referencing § 175.300. Although use of ortho-phthalates authorized by § 175.390 would be affected by the FAP, the FAP would not require the regulatory text in § 175.390 to be amended.

TABLE 6—ORTHO-PHTHALATES AUTHORIZED BY § 175.390 THAT WOULD BE AFFECTED BY THIS FAP

["Zinc-silicon dioxide matrix coatings"]

Food additive	CAS No.
Diethyl phthalate	84–66–2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84–72–0
Di-n-butyl phthalate [1]	84–74–2
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate)	85–70–1
Diisooctyl phthalate	27554–26–3

[1] Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 175.300 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 176.170, ''Components of paper and paperboard in contact with aqueous and fatty foods'' (21 CFR 176.170) as being affected by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 7 as being impacted.

TABLE 7—ORTHO-PHTHALATES AUTHORIZED BY § 176.170 THAT WOULD BE AFFECTED BY THIS FAP

["Components of paper and paperboard in contact with aqueous and fatty foods"]

Food additive	CAS No.
Butyl benzyl phthalate [1]	85–68–7
Di-n-butyl phthalate [2]	84–74–2

[1] Although the petitioner refers to this substance as Butyl benzyl phthalate in the petition, it is listed in § 176.170 as Butylbenzyl phthalate. These terms are synonymous, referring to the same chemical substance.

[2] Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 176.170 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 176.180, ''Components of paper and paperboard in contact with dry food'' (21 CFR 176.180) as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in

table 8 as being impacted. Although the regulation in § 176.180 does not directly refer to all of these ortho-phthalates, the regulation authorizes the use of all of them either directly or by cross-referencing § 176.170.

TABLE 8—ORTHO-PHTHALATES AUTHORIZED BY § 176.180 THAT WOULD BE AFFECTED BY THIS FAP

["Components of paper and paperboard in contact with dry food"]

Food additive	CAS No.
Diallyl phthalate	131–17–9
Butyl benzyl phthalate	85–68–7
Di-n-butyl phthalate [1]	84–74–2
Didecyl phthalate (Di-n-decyl phthalate)	84–77–5
Dodecyl phthalate	21577–80–0

[1] Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 176.170 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 176.300, ''Slimicides'' (21 CFR 176.300), as being impacted by the FAP. Specifically, the petition identifies the ortho-phthalates listed in table 9 as being impacted, some of which are permitted as a result of being listed in §§ 176.170 and 176.180.

TABLE 9—ORTHO-PHTHALATES AUTHORIZED BY § 176.300 THAT WOULD BE AFFECTED BY THIS FAP

["Slimicides"]

Food additive	CAS No.
Diallyl phthalate	131–17–9
Butyl benzyl phthalate	85–68–7
Di-n-butyl phthalate	84–74–2
Didecyl phthalate (Di-n-decyl phthalate)	84–77–5
Dodecyl phthalate	21577–80–0

The petition identifies § 177.1010, ''Acrylic and modified acrylic plastics, semirigid and rigid'' (21 CFR 177.1010) as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalate listed in table 10 as being impacted.

TABLE 10—ORTHO-PHTHALATES AUTHORIZED BY § 177.1010 THAT WOULD BE AFFECTED BY THIS FAP

["Acrylic and modified acrylic plastics, semirigid and rigid"]

Food additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131–11–3

The petition identifies § 177.1200, ''Cellophane'' (21 CFR 177.1200) as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 11 as being impacted.

TABLE 11—ORTHO-PHTHALATES AUTHORIZED BY § 177.1200 THAT WOULD BE AFFECTED BY THIS FAP

["Cellophane"]

Food additive	CAS No.
Diisobutyl phthalate	84–69–5
Di-n-butyl phthalate [1]	84–74–2
Dimethylcyclohexyl phthalate	1322–94–7
Castor oil phthalate, hydrogenated	N/A
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol	68650–73–7

[1] Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 177.1200 as dibutylphthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 177.1210, ''Closures with sealing gaskets for food containers'' (21 CFR 177.1210), as being impacted by the FAP. Specifically, the petition identifies the first five ortho-phthalates listed in table 12 as being impacted based on the authorization of their use in § 177.1210. Although the regulation in § 177.1210 does not directly refer to these ortho-phthalates, the regulation authorizes their use by cross-referencing authorizations in 21 CFR parts 174–178 and § 179.45 (21 CFR 179.45). In addition to the first five ortho-phthalates in table 12 that the petition identifies as being authorized under § 177.1210, § 177.1210 also authorizes the use of the remaining substances that are listed in table 12. We have listed these remaining substances in table 12 because the petition seeks to revoke the food additive approvals for these substances, and § 177.1210 authorizes their food additive use by

cross-referencing authorizations in parts 174–178 and § 179.45. Although use of the substances authorized by § 177.1210 that are listed in table 12 would be affected by the FAP, the FAP would not require the regulatory text in § 177.1210 to be amended.

TABLE 12—ORTHO-PHTHALATES AUTHORIZED BY § 177.1210 THAT WOULD BE AFFECTED BY THIS FAP

["Closures with sealing gaskets for food containers"]

Food additive	CAS No.
Diethyl phthalate	84–66–2
Ethyl phthalyl ethyl glycolate (Ethyl carbethoxymethyl phthalate)	84–72–0
Di-n-butyl phthalate	84–74–2
Butyl phthalyl butyl glycolate (Butyl carbobutoxymethyl phthalate)	85–70–1
Diisooctyl phthalate	27554–26–3
Dimethyl phthalate (dimethyl orthophthalate)	131–11–3
Diphenyl phthalate	84–62–8
Methyl phthalyl ethyl glycolate (1,2-Benzenedicarboxylicacid, 1-(2-ethoxy-2-oxoethyl) 2-methyl ester)	85–71–2
Diphenylguanidine phthalate	17573–13–6
Diallyl phthalate	131–17–9
Diisobutyl phthalate	84–69–5
Butyl benzyl phthalate	85–68–7
Dihexyl phthalate (Di-n-hexyl phthalate)	84–75–3
Di(butoxyethyl) phthalate (Bis(2-n-butoxyethyl) phthalate)	117–83–9
Dimethylcyclohexyl phthalate	1322–94–7
Dioctyl phthalate (Di-n-octyl phthalate)	117–84–0
Butyloctyl phthalate (n-butyl n-octyl phthalate)	84–78–6
Di(2-ethylhexyl) hexahydrophthalate	84–71–9
Amyl decyl phthalate (n-amyl n-decyl phthalate)	7493–81–4
Butyl decyl phthalate (n-butyl n-decyl phthalate)	89–19–0
Decyl octyl phthalate (Octyldecyl phthalate/n-octyl n-decyl phthalate)	119–07–3
Didecyl phthalate (Di-n-decyl phthalate)	84–77–5
Dodecyl phthalate	21577–80–0
Dihydroabietyl phthalate	26760–71–4
Castor oil phthalate, hydrogenated	N/A
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol	68650–73–7

The petition identifies § 177.1400, ''Hydoxyethyl cellulose film, water-insoluble'' (21 CFR 177.1400), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 13 as being impacted. Although the regulation in § 177.1400 does not directly refer to these ortho-phthalates, the regulation authorizes their use by cross-referencing § 177.1200(c). Although use of the ortho-phthalates authorized by § 177.1400 would be affected by the FAP, the FAP would not require the regulatory text in § 175.1400 to be amended.

TABLE 13—ORTHO-PHTHALATES AUTHORIZED BY § 177.1400 THAT WOULD BE AFFECTED BY THIS FAP

["Hydroxyethyl cellulose film, water-insoluble"]

Food additive	CAS No.
Diisobutyl phthalate	84–69–5
Di-n-butyl phthalate [1]	84–74–2
Dimethylcyclohexyl phthalate	1322–94–7
Castor oil phthalate, hydrogenated	N/A
Castor oil phthalate with adipic acid and fumaric acid-diethylene glycol	68650–73–7

[1] Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 177.1200 as dibutylphthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 177.1460, ''Melamine-formaldehyde resins in molded articles'' (21 CFR 177.1460), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalate listed in table 14 as being impacted.

TABLE 14—ORTHO-PHTHALATES AUTHORIZED BY § 177.1460 THAT WOULD BE AFFECTED BY THIS FAP

["Melamine-formaldehyde resins in molded articles"]

Food additive	CAS No.
Dioctyl phthalate (Di-n-octyl phthalate)	117–84–0

The petition identifies § 177.1590, ''Polyester elastomers'' (21 CFR 177.1590), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalate listed in table 15 as being impacted.

TABLE 15—ORTHO-PHTHALATES AUTHORIZED BY § 177.1590 THAT WOULD BE AFFECTED BY THIS FAP

[''Polyester elastomers'']

Food additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131–11–3

The petition identifies § 177.2420, ''Polyester resins, cross-linked'' (21 CFR 177.2420), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 16 as being impacted.

TABLE 16—ORTHO-PHTHALATES AUTHORIZED BY § 177.2420 THAT WOULD BE AFFECTED BY THIS FAP

[''Polyester resins, cross-linked'']

Food additive	CAS No.
Dimethyl phthalate (dimethyl orthophthalate)	131–11–3
Butyl benzyl phthalate	85–68–7
Di-n-butyl phthalate	84–74–2

[1] Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 177.2420 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 177.2600, ''Rubber articles for repeated use'' (21 CFR 177.2600), as being impacted by the FAP. Specifically, the petition identifies the use of the substances listed in table 17 as being impacted.

TABLE 17—ORTHO-PHTHALATES AUTHORIZED BY § 177.2600 THAT WOULD BE AFFECTED BY THIS FAP

[''Rubber articles intended for repeated use'']

Food additive	CAS No.
Diphenylguanidine phthalate	17573–13–6
Di-n-butyl phthalate [1]	84–74–2
Dioctyl phthalate (Di-n-octyl phthalate)	117–84–0
Amyl decyl phthalate (n-amyl n-decyl phthalate)	7493–81–4
Decyl octyl phthalate (Octyldecyl phthalate/n-octyl n-decyl phthalate)	119–07–3
Didecyl phthalate (Di-n-decyl phthalate)	84–77–5

[1] Although the petitioner refers to this substance as di-n-butyl phthalate in the petition, it is listed in § 177.1200 as dibutyl phthalate. These terms are synonymous, referring to the same chemical substance.

The petition identifies § 178.3740, ''Plasticizers in polymeric substances'' (21 CFR 178.3740), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalates listed in table 18 as being impacted.

TABLE 18—ORTHO-PHTHALATES AUTHORIZED BY § 178.3740 THAT WOULD BE AFFECTED BY THIS FAP

[''Plasticizers in polymeric substances'']

Food additive	CAS No.
Diphenyl phthalate	84–62–8
Butyl benzyl phthalate	85–68–7
Dihexyl phthalate (Di-n-hexyl phthalate)	84–75–3

The petition identifies § 178.3910, ''Surface lubricants used in the manufacture of metallic articles'' (21 CFR 178.3910), as being impacted by the FAP. Specifically, the petition identifies the use of the ortho-phthalate listed in table 19 as being impacted.

TABLE 19—ORTHO-PHTHALATES AUTHORIZED BY § 178.3910 THAT WOULD BE AFFECTED BY THIS FAP

[''Surface lubricants used in the manufacture of metallic articles'']

Food additive	CAS No.
Diethyl phthalate	84–66–2

II. Abandonment

Under section 409(i) of the FD&C Act, we shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations. Our regulations specific to administrative actions for food additives provide that the Commissioner of Food and Drugs, on his own initiative or on the petition of any interested person, under 21 CFR part 10, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive (§ 171.130(a) (21 CFR 171.130(a))). These regulations further provide that any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or appeal (§ 171.130(b)). New data must be furnished in the form specified in 21 CFR 171.1 and 171.100 for submitting petitions (id.). Under these regulations, a petitioner may propose that we amend a food additive regulation if the petitioner can demonstrate that there are ''old uses abandoned'' for the relevant food additive (id.). Such abandonment must be complete for any intended uses in the U.S. market. While section 409 of the FD&C Act and § 171.130 also provide for amending or revoking a food additive regulation based on safety, an amendment or revocation based on abandonment is not based on safety but is based on the fact that regulatory authorization is no longer necessary because the use of that food additive has been abandoned.

Abandonment may be based on the abandonment of certain authorized food additive uses for a substance (*e.g.,* if a substance is no longer used in certain product categories), or on the abandonment of all authorized food additive uses of a substance (*e.g.,* if a substance is no longer being manufactured). If a FAP seeks an amendment to a food additive regulation based on the abandonment of certain uses of the food additive, such uses must be adequately defined so that both the scope of the abandonment and any amendment to the food additive regulation are clear.

As support for the assertion that the food-contact use of the ortho-phthalates listed in the petition has been abandoned, the FAP includes the results of a survey petitioner sent to its members and other firms. The petitioner asked the recipients to verify that they do not:

- Currently manufacture the ortho-phthalates listed in table 1 for use in food contact applications in the United States;
- Currently import the ortho-phthalates listed in table 1 for use in food contact applications in the United States;
- Intend to manufacture or import the ortho-phthalates listed in table 1 for use in food contact applications in the United States in the future;
- Currently maintain any inventory of the ortho-phthalates listed in table 1 for sale or distribution into commerce that is intended to be marketed for use in food contact applications in the United States; or
- Possess any knowledge that the ortho-phthalates listed in table 1 are used in food contact applications in the United States.

The FAP describes the petitioner's members as including plasticizer manufacturers, compounders, formulators, molders and fabricators of polyvinyl chloride (PVC). The petition states that the surveys collected include the substantial majority of phthalate and PVC manufacturers, as well as the downstream compounders and users of the materials.

In addition, the FAP states that petitioner has confirmed with other industry stakeholders that no entities appear to be using or marketing the ortho-phthalates listed in table 1 in the food-contact applications referenced in tables 2–19. The petition states that other industry stakeholders include members of: (1) The Plastics Industry Association's (PIA's) Food, Drug and Cosmetic Packaging Materials Committee, (2) the Adhesives and Sealants Council, (3) the American Beverage Association, (4) the American Forest and Paper Association, (5) the Grocery Manufacturers Association, and (6) the High Phthalates Panel of the American Chemistry Council. The petition states that no member companies from the organizations indicated that they had any knowledge that the regulatory clearances in tables 2–19 are relied upon for use of the ortho-phthalates listed in table 1. With regard to PIA, the petition states that PIA asked its member companies to advise whether they have any knowledge that the subject ortho-phthalates are being used in food-contact applications.

The FAP states that the petition captures the substantial majority of domestic and international phthalate manufacturers and users.

We expressly request comments on FVA's request that we amend §§ 175.105, 175.300, 175.320, 176.170, 176.180, 176.300, 177.1010, 177.1200, 177.1460, 177.1590, 177.2420, 177.2600, 178.3740, and 178.3910 of the food additive regulations to no longer permit the food additive use of the substances listed in table 1 because these uses have been abandoned. Although the regulatory text in §§ 175.380, 175.390, 177.1210, and 179.1400 would not be amended, these regulations would be affected because they authorize certain uses of substances listed in table 1 by cross-referencing other regulations. Accordingly, we request comments that address whether the use of the substances in table 1 (as authorized in the regulations identified in tables 2–19) have been completely abandoned. For example, we request information on whether food contact materials containing these substances are currently being introduced or delivered for introduction into the U.S. market. Any comments indicating that the specified uses of one or more of the 26 substances have not been abandoned should specify the ortho-phthalate(s) (or substances identified in the petition as ortho-phthalates). We also recommend including information about the use, any relevant regulation(s) authorizing the use, and a description of the product that contains the substance(s).

We are currently unaware of information demonstrating the continued use of these substances in the food contact applications listed. We are providing the public 60 days to submit comments. We anticipate that some interested persons may wish to provide us with certain information they consider to be trade secret or confidential commercial information (CCI) under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552). Interested persons may claim information that is submitted to us as CCI or trade secret by clearly marking both the document and the specific information as ''confidential.'' Information so marked will not be disclosed except in accordance with the Freedom of Information Act and our disclosure regulations (21 CFR part 20). For electronic submissions to *https://www.regulations.gov,* indicate in the ''comments'' box of the appropriate docket that your submission contains confidential information. Interested persons must also submit a copy of the comment that does not contain the information claimed as confidential for

inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice.

We are not requesting comments on the safety of these uses of the substances in table 1 because such information is not relevant to abandonment, which is the basis of the proposed action. We will not consider any comments addressing safety in our evaluation of this FAP. In addition to our consideration of this petition, we are considering information on the safety of many of the ortho-phthalates listed in table 1 as part of our consideration of a petition designated for reference as FAP 6B4815 (see 81 FR 31877, May 20, 2016).

The petitioner has claimed that this action is categorically excluded under 21 CFR 25.32(m) because the petition requests an action that would prohibit or otherwise restrict or reduce the use of a substance in food, food packaging, or cosmetics. In addition, the petitioner has stated that, to petitioner's knowledge, no extraordinary circumstances exist. If FDA determines a categorical exclusion applies, neither an environmental assessment nor an environmental impact statement is required. If FDA determines a categorical exclusion does not apply, we will request an environmental assessment and make it available for public inspection.

Dated: November 6, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24657 Filed 11–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Parts 630 and 635

[FHWA Docket No. FHWA–2018–0036]

RIN 2125–AF84

Construction and Maintenance—Promoting Innovation in Use of Patented and Proprietary Products

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: This rulemaking would provide greater flexibility to States to use proprietary or patented materials in Federal-aid projects. The FHWA is seeking comment on two alternate co-proposals to help advance this objective: First, FHWA proposes to amend and replace the requirements relating to patented and proprietary product approvals with a more flexible general requirement that enhances fairness, open competition, and transparency in the product selection process. Alternatively, the agency proposes rescinding the requirements, thereby encouraging further innovation in the development of new highway transportation technology and methods, as well as potentially reducing costs.

DATES: Comments must be received on or before January 14, 2019. Late-filed comments will be considered to the extent practicable.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and 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;
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. 5 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.
- *Instructions:* You must include the agency name and docket number or the Regulatory Identification Number (RIN) for the rulemaking at the beginning of your comments. All comments received will be posted without change to *www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mr. John Huyer, Office of Preconstruction, Construction and Pavements, (651) 291–6111 or, Mr. William Winne, Office of the Chief Counsel, (202) 366–1397, Federal Highway Administration, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 8 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access and Filing

This document and all comments received may be viewed online through the Federal eRulemaking portal at *http://www.regulations.gov.* Electronic submission and retrieval help and guidelines are available on the website. It is available 24 hours each day, 365 days a year. Please follow the instructions. An electronic copy of this document may also be downloaded from the Office of the Federal Register's home page at: *http://www.archives.gov/federal-register* and the Government Publishing Office's web page at: *http://www.gpo.gov/fdsys.*

Background

There are differing practices across the United States on whether government entities may specify a patented material, article, or process in the letting of public works contracts through competitive bidding.[1] Some jurisdictions prohibit the practice altogether on the grounds that it would inhibit competition, particularly where only one contractor can provide the specified material.[2] Other jurisdictions allow the specification as long as the use of any other article equally as suitable is also allowed.[3] The Federal government's regulations on direct procurement and the uniform regulations on Federal financial assistance take the latter approach.[4] In the majority of States, however, the practice of specifying a patented product in government contracts is allowed.[5]

The Federal-aid Road Act of 1916 (1916 Act)[6] was silent about patented and proprietary products but provided that Federal-aid funded State highway construction was ''subject to the inspection and approval of the Secretary of Agriculture, and in accordance with the rules and regulation made pursuant to this Act.''[7]

Accordingly, regulations implementing the 1916 Act were issued on September 1, 1916. Regulation 8, Section 4 of those rules provided, ''No part of the money apportioned under the act shall be used, directly or indirectly, to pay, or to reimburse a State, county, or local subdivision for the payment of any premium or royalty on any patented or proprietary material, specification, process, or type of construction, unless purchased or obtained on open actual competitive bidding at the same or a less cost than

[1] See generally 10 McQuillin Mun. Corp. § 29.42 (3d ed.).

[2] Examples include Illinois, Indiana, Kentucky, Louisiana, Massachusetts, and Wisconsin.

[3] Examples include California, Iowa, New Jersey, and New York.

[4] See 48 CFR 52.211–6 and 2 CFR 200.319(a)(6).

[5] Examples include Arizona, Colorado, Connecticut, Florida, Idaho, Kansas, Maryland, Michigan, Montana, Nebraska, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Texas, and Washington.

[6] 1916 Act, ch. 241, 39 Stat. 355.

[7] The Office of Public Roads was the predecessor agency of FHWA and was part of the Department of Agriculture in 1916.

unpatented articles or methods equally suitable for the same purpose.'' This regulation connected competitive bidding and lower cost to the restriction on the specification of proprietary products in Federal-aid contracts and has been a requirement of the Federal-aid highway program since its issuance.

In the Federal Highway Act of 1938 (1938 Act), Congress established in statute a competition standard by requiring the Secretary to approve, in connection with federally aided State highway construction projects, ''only such methods of bidding and such plans and specifications of highway construction . . . as will be effective in securing competition and conducive to safety, durability, and economy of maintenance.'' [8] This legislation preceded the current statute codified at 23 U.S.C. 112(a).

During the debate related to the enactment of Section 13 of the 1938 Act, Congressman Whittington expressly tied the rule on proprietary products to the newly enacted statutory requirement for competitive bidding. ''It says there shall be competitive bidding. This means that all types of roads conducive to safety, durability, and economy will be considered. This means that only plans, specifications, and methods that provide for competition will be approved. All will be given a square deal. No special method, no special material will be selected to the exclusion of other materials.'' [9]

In 1954, Congress explicitly required competitive bidding, while also providing a public interest exception, when it mandated that federally funded State highway construction work be ''performed by contract awarded by competitive bidding under such procedures as may by regulations be prescribed by the Secretary . . . unless the Secretary . . . shall affirmatively find that, under the circumstances related to a given project, some other method is in the public interest.'' [10] This legislation preceded the current statute codified at 23 U.S.C. 112(b)(1).

Over the years, the regulation was clarified through various policy and guidance memoranda, and subsequent **Federal Register** Notices, including 25 FR 4162 published on May 11, 1960. The regulatory language has received only relatively minor changes since that time.

The current regulation at 23 CFR 635.411 seeks to promote competitive bidding by prohibiting FHWA participation in the cost of patented or proprietary products or materials except when: (1) Such patented or proprietary item is purchased or obtained through competitive bidding with equally suitable unpatented items; (2) a State Department of Transportation (State DOT) certifies either that such patented or proprietary item is essential for synchronization with existing highway facilities, or that no equally suitable alternate exists; or (3) a patented or proprietary item is used for research or for a distinctive type of construction on relatively short sections of road for experimental purposes. In addition, and also under the current regulation, States may specify a material or product based on a showing of public interest. Without using one of the exceptions described above, the State DOT may choose to use a particular patented or proprietary product, but FHWA funds may not participate in its cost. Patented and proprietary products are used widely on Federal-aid projects, through competition and where State DOTs apply one of the exceptions provided in 23 CFR 635.411.

Many States have been delegated authority under 23 U.S.C. 106 to approve public interest findings without the direct involvement of FHWA. States retain the ability to apply the other exceptions (certification, research) provided under 23 CFR 635.411.

Following its promulgation shortly after the inception of the Federal-aid road program in 1916, and even with the availability of exceptions, various stakeholders have criticized the regulation in 23 CFR 635.411 and its predecessors. Since 2005, FHWA has received inquiries and some expressions of concern from public agencies and industry about the perceived negative impact of the patented and proprietary products requirements in 23 CFR 635.411 on the development and use of new materials, equipment, or methods. Some claim the regulation has resulted in the unintended consequence of prohibiting the specification of innovative products on Federal-aid projects because the products were patented or proprietary. Others claim the requirements of 23 CFR 635.411 were unclear, were not being implemented uniformly, and resulted in barriers to the use of innovation in material and product selection on highway projects.

On December 1, 2017, the American Road and Transportation Builders Association (ARTBA) submitted comments to the DOT's **Federal Register** Notice soliciting Regulatory Review ideas (82 FR 45750, October 2, 2017) (docket ID: DOT–OST–2017–0069–2774). On March 27, 2018, ARTBA submitted a Petition for Rulemaking to repeal the patented and proprietary materials requirements in 23 CFR 635.411. The ARTBA comments and Petition for Rulemaking are available for review on the docket for this rulemaking.

General Discussion of the Proposed Action

Ensuring competition and requiring low bid contracting in the Federal-aid highway program remain statutory duties of the Secretary. Statutory text codified at 23 U.S.C. 112(a) provides, ''the Secretary shall require such plans and specifications and such methods of bidding as shall be effective in securing competition.'' The statute also mandates that the Secretary ensure Federal-aid projects are performed pursuant to a contract awarded through competitive bidding to the lowest responsible bidder under 23 U.S.C. 112(b)(1). The regulation at 23 CFR 635.411 was promulgated to implement the statutory requirement to secure competition.

The existing regulation could do more to provide States further opportunity to consider the use of innovative, proprietary, or patented materials in Federal-aid projects. The proposals contained in this NPRM would promote the benefits of innovation and new technology and afford the flexibility necessary to take advantage of technological advancements in highway transportation. Such added flexibility may also provide State DOTs an advantage by potentially obtaining highway materials or products at a lower price. Specifying a patented article in the solicitation materials may not, by itself, limit competition. Rather, this practice might encourage various bidders to offer lower prices in the competition to deliver needed materials and ultimately lead to a more cost effective use of Federal funds in the long-term.

The FHWA believes most State DOTs utilize new product evaluation processes and approved product lists that provide fair and transparent procedures for the evaluation, selection, and use of materials, including patented and proprietary products.

State DOTs are responsible for the effective and efficient use of Federal-aid funds, subject to the requirements of Federal law. The FHWA believes, absent the current Federal patented and proprietary products requirements, State DOTs may implement material selection procedures that ensure fair and open competition while allowing for, and encouraging, innovation. Nevertheless,

[8] Public Law 75–584, 12, 52 Stat. 633, 636 (1938).

[9] Daily Congressional Record, May 6, 1938, pp. 6383–6.

[10] Federal-aid Highway Act of 1954, Public Law 83–350, 17(a), 68 Stat. 70, 75 (1954).

the statutory requirements of 23 U.S.C. 112 for competition and competitive bidding continue to apply to Federal-aid assisted State contracts.

Over the past century, States have assumed greater responsibility for Federal-aid project approval and oversight. For example, States may assume responsibility for ''design, plans, specifications, estimates, contract awards, and inspection of projects'' on the National Highway System (NHS), including the Interstate System, pursuant to 23 U.S.C. 106(c)(1). For projects that are not on the NHS, the States have assumed responsibility for those activities unless doing so would be inappropriate under 23 U.S.C. 106(c)(2). Providing State DOTs greater flexibility in the selection of products and materials used in Federal-aid projects may also be consistent with the provisions of 23 U.S.C. 106(c).

Put in context, and pursuant to 23 U.S.C. 145, the Federal-aid highway program is a federally-assisted, State-administered program. To potentially reduce costs and allow greater flexibility for the States in considering innovative products or materials for use in Federal-aid projects, FHWA proposes to amend the requirements at 23 CFR 635.411 related to patented and proprietary product approval. The FHWA seeks comment on two proposals: (1) Amending section 635.411 to allow States to certify compliance with the fair and open competition requirements of 23 U.S.C. 112 in selecting materials in Federal-aid projects; or alternatively, (2) rescinding parts of section 635.411.

Neither proposal would alter any requirements in the Manual on Uniform Traffic Control Devices found in 23 CFR part 655, subpart F.

Section-by-Section Discussion

Option 1: State Certification and Procedural Requirements

Under Option 1, the existing regulatory requirements of 23 CFR 635.411(a)–(e) are being proposed for removal. The FHWA proposes replacing them with general certification requirements in new paragraphs 23 CFR 635.411(a) and 23 CFR 630.112(c)(6) to ensure competition in the selection of materials and products. This change would require a State DOT to: (1) Implement procedures and specifications that provide for fair, open, and transparent competition awarded only by contract to the lowest responsive bid submitted by a responsible bidder pursuant to 23 U.S.C. 112; and (2) certify that it adheres to those procedures and specifications. As mentioned above, FHWA believes that many States already have procedures in place that would comply with this proposed requirement. The requirement of 23 CFR 635.411(f) would be retained because it was implemented to fulfill the mandate of section 1525 of the Moving Ahead for Progress in the 21st Century Act (MAP–21). This section is not concerned with patented and proprietary products, but with material types for culverts and storm sewers.

Option 2: Repeal of 23 CFR 635.411(a)–(e)

Alternatively, FHWA proposes to rescind the current proprietary and patented materials requirements contained in current paragraphs (a) through (e) and change the title of section 635.411 to ''Culvert and Storm Sewer Material Types.'' Under its new title, the former paragraph (f) of section 635.411 would be retained to fulfill the mandate of section 1525 of MAP–21 for States to retain autonomy for the selection of culvert and storm sewer material types.

Request for Comment

The FHWA is seeking comment on these alternative proposals, including the potential effects of the alternative proposals for the patented and proprietary products rule. Therefore, comments are invited with respect to the following questions:

(1) What are the challenges in incorporating patented and proprietary products into projects under the current regulatory process?

(2) How does the current regulation hinder the incorporation of innovative or cost-effective safety and other products into projects?

(3) How does the current regulation hinder the incorporation of proprietary products into projects?

(4) How would the proposals support or deter deployment of innovative or cost-effective products on projects? Could the proposals result in any unintended consequences that might deter such deployment?

(5) How could the proposals to allow specification of patented and proprietary products be implemented consistent with existing competition and low bid requirements?

(6) If FHWA rescinds the rule, what standards should FHWA rely on to determine if a State's specification of a patented or proprietary product violates the competition mandate in 23 U.S.C. 112? For example, should FHWA rely on the standard found in the Office of Management and Budget's (OMB) Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at 2 CFR 200.319(a)(6)? OMB's regulations at Part 200 provide a governmentwide framework for grants management, and 2 CFR 200.319(a)(6) describes seven situations considered to be restrictive of competition.[11]

(7) What positive or negative consequences might result from implementation of the proposals? Could the proposals result in potential costs or cost savings? If so, please describe the costs or cost savings and provide data to support these estimates. What might be the effects of the proposals on transparency in the materials selection process?

(8) What positive or negative consequences might affect small businesses that do not have the same marketing resources as larger firms?

(9) What differences in effects and compliance, if any, could result from the two alternative proposals?

(10) What is the difference between the number of proprietary products used on State and Federal-funded projects?

(11) Do the States follow rules or processes on State-funded projects similar to the Federal process embodied in section 635.411?

Rulemaking Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), Executive Order 13771 (Reducing Regulations and Controlling Regulatory Costs), and DOT Regulatory Policies and Procedures

The FHWA has determined that this action would not be a significant regulatory action within the meaning of Executive Order (E.O.) 12866, and within the meaning of the U.S. Department of Transportation's regulatory policies and procedures. This action complies with EOs 12866, 13563, and 13771 to improve regulation. The FHWA anticipates that the economic impact of this rulemaking would be minimal. The FHWA anticipates that the proposed rule would not adversely affect, in a material way, any sector of the economy. In addition, these changes would not interfere with any action

[11] The regulations at 2 CFR 200.319(a)(6) describes some situations considered to be restrictive of competition, including: (1) Placing unreasonable requirements on firms in order for them to qualify to do business; (2) requiring unnecessary experience and excessive bonding; (3) noncompetitive pricing practices between firms or between affiliated companies; (4) Noncompetitive contracts to consultants that are on retainer contracts; (5) organizational conflicts of interest; (6) specifying only a ''brand name'' product instead of allowing ''an equal'' product to be offered and describing the performance or other relevant requirements of the procurement; and (7) any arbitrary action in the procurement process.

taken or planned by another agency and would not materially alter the budgetary impact of any entitlements, grants, user fees, or loan programs.

Although FHWA has determined that this action would not be a significant regulatory action, this proposed rule is expected to be an E.O. 13771 deregulatory action. This proposal could generate cost savings that are applicable to offsetting the costs associated with other regulatory actions as required by E.O. 13771. The FHWA has determined the cost savings of both proposed options are nearly the same. These cost savings, measured in 2018 dollars, are expected to be $313,848 per year.

The cost savings resulting from this proposed regulatory action result from reduced administrative burden associated with the efforts by the States and FHWA related to the existing methods for approving patented and proprietary materials.

Currently there are three methods available to approve specific patented and proprietary products for use on Federal aid highway construction projects: [12]

1. *Certification:* A certification is the written and signed statement of an appropriate contracting agency official certifying that a particular patented or proprietary product is either:

a. Necessary for synchronization with existing facilities; or

b. A unique product for which there is no equally suitable alternative.

2. *Experimental Products:* If a contracting agency requests to use a proprietary product for research or for a distinctive type of construction on a relatively short section of road for experimental purposes, it must submit an experimental product work plan for review and approval. The work plan should provide for the evaluation of the proprietary product, and where appropriate, a comparison with current technology.

3. *Public Interest Finding (PIF):* A PIF is an approval by the FHWA Division Administrator, based on a request from a contracting agency that it is in the public interest to allow the contracting agency to require the use of a specific material or product even though other equally acceptable materials or products are available.

To estimate the cost savings from removing the need for the above categories of approvals, FHWA estimated the number of new approvals that would be generated in the future in the above categories if the rule does not change as a baseline scenario and compared it to a scenario with the proposed rule. The estimated number of new approvals per year is multiplied by the estimated number of hours required to process the documentation for that specific type of approval (including conducting analysis and documenting methods and results) by the appropriate labor cost (wage rate multiplied by a factor to account for employer provided benefits). Currently, the work related to approvals is conducted by both FHWA and State agencies because, in some cases, FHWA has delegated authority to States via stewardship and oversight agreements for such issues. In addition to the time required to process the approvals, time is also required by FHWA to review the resulting documentation. Finally, both of those activities require a small time allowance for management of the process.

Under the proposed rule, the costs associated with approvals for patented and proprietary materials may not be completely removed. This is because a number of States are known (according to information from FHWA Division offices) to have their own laws or policies that are similar to the FHWA requirements. Absent other information, this analysis assumes those State laws or policies would remain in place even after an FHWA rule change. For those States, this analysis assumes that the total number of hours associated with processing and managing approvals would remain unchanged but that the work would be conducted solely by State agency staff (rather than a mix of State and FHWA staff as is assumed in the baseline calculations) and that time spent on FHWA review would no longer be needed.

In addition to the cost savings that have been quantified here, there may be additional positive impacts from the rulemaking related to supporting the adoption of patented and proprietary products. Although FHWA has undertaken various efforts to grant States the flexibility to use such products, to the extent that the current rules and guidance discourage their use, the proposed rule removes those barriers. In the short term, this could lead to States paying more for proprietary and patented products if certain products are specified in Federal-aid contracts. However, ARTBA, in its petition for repeal, states that such products could ''save lives, minimize congestion, and otherwise improve the quality of our nation's highways.'' [13] Thus, there may be benefits associated with greater adoption of existing products. An increase in the willingness to adopt patented and proprietary products may have secondary impacts and spur additional innovation if product developers perceive there to be a larger market for new products. Those potential benefits from additional innovation have not been quantified in this analysis.

The public is invited to comment and provide information related to any aspect of this estimation of cost savings.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), the FHWA has evaluated the effects of this action on small entities and has determined that the action is not anticipated to have a significant economic impact on a substantial number of small entities. The proposed amendment addresses obligation of Federal funds to States for Federal-aid highway projects. As such, it affects only States and States are not included in the definition of small entity set forth in 5 U.S.C. 601. Therefore, the Regulatory Flexibility Act does not apply, and FHWA certifies that the proposed action will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This proposed rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48, March 22, 1995) as it will not result in the expenditure by State, local, Tribal governments, in the aggregate, or by the private sector, of $155 million or more in any 1 year (2 U.S.C. 1532 *et seq.*). Additionally, the definition of ''Federal mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or Tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government. The Federal-aid highway program permits this type of flexibility.

Executive Order 13132 (Federalism)

This proposed action has been analyzed in accordance with the principles and criteria contained in E.O. 13132 dated August 4, 1999, and FHWA has determined that this proposed action would not have a substantial direct effect or sufficient federalism implications on the States. The FHWA has also determined that this proposed action would not preempt any State law or regulation or affect the States' ability

[12] *https://www.fhwa.dot.gov/programadmin/contracts/011106qa.cfm#_Hlk307505978.*

[13] ARTBA, ''Petition for Rulemaking to Repeal the Proprietary and Patented Products Rule 23 CFR 635.411'', March 27, 2018.

to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing E.O. 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et. seq.*), Federal agencies must obtain approval from OMB for each collection of information they conduct, sponsor, or require through regulations. The FHWA has determined that the proposed rule does not contain collection of information requirements for the purposes of the PRA. Any action that might be contemplated in subsequent phases of this proceeding will be analyzed for the purpose of the Paperwork Reduction Act for its impact.

National Environmental Policy Act

The FHWA has analyzed this action for the purpose of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), and has determined that this action would not have any effect on the quality of the environment and meets the criteria for the categorical exclusion at 23 CFR 771.117(c)(20).

Executive Order 12630 (Taking of Private Property)

The FHWA has analyzed this proposed rule under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights. The FHWA does not anticipate that this proposed action would affect a taking of private property or otherwise have taking implications under E.O. 12630.

Executive Order 12988 (Civil Justice Reform)

This action meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

We have analyzed this rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. The FHWA certifies that this proposed action would not cause an environmental risk to health or safety that might disproportionately affect children.

Executive Order 13175 (Tribal Consultation)

The FHWA has analyzed this action under E.O. 13175, dated November 6, 2000, and believes that the proposed action would not have substantial direct effects on one or more Indian tribes; would not impose substantial direct compliance costs on Indian Tribal governments; and would not preempt Tribal laws. The proposed rulemaking addresses obligations of Federal funds to States for Federal-aid highway projects and would not impose any direct compliance requirements on Indian Tribal governments. Therefore, a Tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

We have analyzed this action under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. The FHWA has determined that this is not a significant energy action under that order since it is not a significant regulatory action under E.O. 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required.

Regulation Identification Number

A regulation identification number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the heading of this document can be used to cross-reference this action with the Unified Agenda.

List of Subjects

23 CFR Part 630

Grant programs, transportation, highways and roads.

23 CFR Part 635

Construction materials, Design-build, Grant programs, transportation, highways and roads.

Issued on: November 6, 2018.

Brandye L. Hendrickson,

Deputy Administrator, Federal Highway Administration.

Option 1

In consideration of the foregoing, FHWA proposes to amend title 23, Code of Federal Regulations, parts 630 and 635 as follows:

PART 630—PRECONSTRUCTION PROCEDURES

Subpart A—Project Authorization and Agreements

■ 1. The authority citation for part 630 continues to read as follows:

Authority: 23 U.S.C. 106, 109, 112, 115, 315, 320, and 402(a); Sec. 1501 and 1503 of Pub. L. 109–59, 119 Stat. 1144; Pub. L. 105–178, 112 Stat. 193; Pub. L. 104–59, 109 Stat. 582; Pub. L. 97–424, 96 Stat. 2106; Pub. L. 90–495, 82 Stat. 828; Pub. L. 85–767, 72 Stat. 896; Pub. L. 84–627, 70 Stat. 380; 23 CFR 1.32 and 49 CFR 1.48(b), and Pub. L. 112–141, 126 Stat. 405, section 1303.

■ 2. Amend § 630.112 by adding paragraph (c)(6) as follows:

* * * * *

(c) * * *

(6) *Competition in Products Certification*—By signing the project agreement, the State Department of Transportation (State DOT) agrees to abide by and certify that its product evaluation and selection process, and the specifications used for Federal-aid projects, will provide for fair, open, and transparent competition awarded only by contract to the lowest responsive bid submitted by a responsible bidder pursuant to 23 U.S.C. 112. By signing the project agreement, the State DOT is providing the certification required in 23 CFR 635.411(a).

* * * * *

PART 635—CONSTRUCTION AND MAINTENANCE

Subpart D—General Material Requirements

■ 1. The authority citation for part 635 continues to read as follows:

Authority: Sections 1525 and 1303 of Pub. L. 112–141, Sec. 1503 of Pub. L. 109–59, 119 Stat. 1144; 23 U.S.C. 101 (note), 109, 112, 113, 114, 116, 119, 128, and 315; 31 U.S.C. 6505; 42 U.S.C. 3334, 4601 *et seq.;* Sec. 1041(a), Pub. L. 102–240, 105 Stat. 1914; 23 CFR 1.32; 49 CFR 1.85(a)(1).

■ 2. Revise § 635.411 to read as follows:

§ 635.411 Material or product selection.

(a) As a condition of receiving Federal-aid funds, the State Department of Transportation (State DOT) certifies that its product evaluation process and the specifications used for Federal-aid projects will provide for fair, open, and transparent competition pursuant to 23 CFR 630.112(c)(6).

(b) State DOTs shall have the autonomy to determine culvert and storm sewer material types to be included in the construction of a project on a Federal-aid highway.

Option 2

In consideration of the foregoing, FHWA proposes to revise title 23, Code of Federal Regulations, part 635 as follows:

PART 635—CONSTRUCTION AND MAINTENANCE

Subpart D—General Material Requirements

■ 1. The authority citation for part 635 continues to read as follows:

Authority: Sections 1525 and 1303 of Pub. L. 112–141, Sec. 1503 of Pub. L. 109–59, 119 Stat. 1144; 23 U.S.C. 101 (note), 109, 112, 113, 114, 116, 119, 128, and 315; 31 U.S.C. 6505; 42 U.S.C. 3334, 4601 *et seq.;* Sec. 1041(a), Pub. L. 102–240, 105 Stat. 1914; 23 CFR 1.32; 49 CFR 1.85(a)(1).

■ 2. Revise § 635.411 to read as follows:

§ 635.411 Culvert and Storm Sewer Material Types.

State Departments of Transportation (State DOTs) shall have the autonomy to determine culvert and storm sewer material types to be included in the construction of a project on a Federal-aid highway.

[FR Doc. 2018–24687 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–107813–18]

RIN–1545–BO82

Hardship Distributions of Elective Contributions, Qualified Matching Contributions, Qualified Nonelective Contributions, and Earnings

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed amendments to the regulations relating to hardship distributions from section 401(k) plans. The amendments reflect statutory changes affecting section 401(k) plans, including recent changes made by the Bipartisan Budget Act of 2018. These regulations would affect participants in, beneficiaries of, employers maintaining, and administrators of plans that contain cash or deferred arrangements or provide for employee or matching contributions.

DATES: Comments and requests for a public hearing must be received by January 14, 2019.

ADDRESSES: Send submissions to CC:PA:LPD:PR (REG–107813–18) 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–107813–18), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224, or sent electronically via the Federal eRulemaking Portal at *www.regulations.gov/* (indicate IRS and REG–107813–18).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Roger Kuehnle at (202) 317–6060 or; concerning submissions of comments, the hearing, or to be placed on the building access list to attend the hearing, Regina L. Johnson at (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking will be submitted, under approval number 1545–1669, to the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by January 14, 2019. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

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

The collection of information in this proposed regulation is in § 1.401(k)–1(d)(3)(iii)(B). The collection of information relates to the certification by participants in section 401(k) plans that they have insufficient cash or other liquid assets to cover expenses resulting from a hardship and, thus, will need a distribution from the plan to meet the expenses. The collections of information are required to obtain a benefit.

The likely recordkeepers are individuals.

Estimated total annual reporting burden: 101,250 hours.

Estimated average annual burden per respondent: 45 minutes.

Estimated number of respondents: 135,000.

Estimated frequency of responses: On occasion.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

Background

Section 401(k)

Section 401(k)(1) of the Internal Revenue Code (Code) provides that a profit-sharing, stock bonus, pre-ERISA money purchase, or rural cooperative plan will not fail to qualify under section 401(a) merely because it contains a cash or deferred arrangement (CODA) that is a qualified CODA. Under section 401(k)(2), a CODA (generally, an arrangement providing for an election by an employee between contributions to a plan or payments directly in cash) constitutes a qualified CODA only if it satisfies certain requirements. Section 401(k)(2)(B) provides that contributions made pursuant to a qualified CODA (referred to as ''elective contributions'') may be distributed only on or after the occurrence of certain events, including death, disability, severance from employment, termination of the plan, attainment of age 59–½, hardship, or, in the case of a qualified reservist distribution, the date a reservist is called to active duty. Section 401(k)(2)(C) requires that elective contributions be nonforfeitable at all times.

Section 401(k)(3)(A)(ii) requires that elective contributions satisfy the actual deferral percentage (ADP) test set forth in section 401(k)(3). Sections 401(k)(11), 401(k)(12), and 401(k)(13) each provide an alternative method of meeting the ADP test. Under section 401(k)(3)(D), qualified nonelective contributions (QNECs) and qualified matching contributions (QMACs), as described in

sections 401(m)(4)(C) and 401(k)(3)(D)(ii)(I), respectively, are permitted to be taken into account under the ADP test. Among other requirements, QNECs and QMACs must satisfy the distribution limitations of section 401(k)(2)(B) and the nonforfeitability requirements of section 401(k)(2)(C). Similarly, employer contributions that are made pursuant to the safe harbor plan designs of section 401(k)(12) or (13) must meet the distribution limitations of section 401(k)(2)(B).

Section 401(m)(2)(A) requires that matching contributions and employee contributions satisfy the actual contribution percentage (ACP) test set forth in section 401(m)(2). Sections 401(m)(10), 401(m)(11), and 401(m)(12) each provide an alternative method of meeting the ACP test with respect to matching contributions. As with contributions made to section 401(k) plans pursuant to safe harbor plan designs, employer contributions made pursuant to the safe harbor plan designs of section 401(m)(11) or (12) must meet the distribution limitations of section 401(k)(2)(B).

The Department of the Treasury (Treasury Department) and the IRS issued comprehensive final regulations under sections 401(k) and 401(m) on December 29, 2004 (TD 9169, 69 FR 78143). Since that time, the regulations have been updated to reflect certain subsequent changes to the applicable statute (see TD 9237, 71 FR 6, and TD 9324, 72 FR 21103, providing guidance on designated Roth contributions under section 402A; and TD 9447, 74 FR 8200, providing guidance on section 401(k)(13)). However, the regulations have not been updated to reflect other statutory changes. The regulations have been amended to address other specific issues (see TD 9319, 72 FR 16878, relating to the definition of compensation; TD 9641, 78 FR 68735, relating to mid-year amendments to safe harbor plan designs; and TD 9835, 83 FR 34469, relating to whether QNECs and QMACs must be nonforfeitable when contributed to the plan).

Section 1.401(k)–1(d)(3) provides rules for determining whether a distribution is made on account of an employee's hardship. Under those rules, a distribution is made on account of hardship only if the distribution is made on account of an immediate and heavy financial need and the amount of the distribution is not in excess of the amount necessary to satisfy that need (plus any amounts necessary to pay any taxes or penalties reasonably anticipated to result from the distribution). These determinations must be made on the basis of all the relevant facts and circumstances and in accordance with nondiscriminatory and objective standards set forth in the plan.

Section 1.401(k)–1(d)(3)(iv)(B) provides that a distribution is not treated as necessary to satisfy an immediate and heavy financial need of an employee to the extent the need may be relieved from other resources that are reasonably available to the employee. Under § 1.401(k)–1(d)(3)(iv)(C), in determining whether the need can be relieved from other resources that are reasonably available to an employee, the employer may rely on the employee's representation (unless the employer has actual knowledge to the contrary) that the need cannot reasonably be relieved from resources specified in § 1.401(k)–1(d)(3)(iv)(C).

To simplify administration, the regulations provide certain safe harbors that may be used to determine whether a distribution is made on account of an employee's hardship. Specifically, § 1.401(k)–1(d)(3)(iii)(B) provides a safe harbor under which distributions for six types of expenses are deemed to be made on account of an immediate and heavy financial need. One of the six types is ''expenses for the repair of damage to the employee's principal residence that would qualify for the casualty deduction under section 165 (determined without regard to whether the loss exceeds 10% of adjusted gross income).''

In addition, § 1.401(k)–1(d)(3)(iv)(E) provides a safe harbor under which a distribution is deemed necessary to satisfy an immediate and heavy financial need. Under that safe harbor, an employee must first obtain all currently available distributions (including distributions of employee stock ownership plan (ESOP) dividends under section 404(k), but not hardship distributions), and nontaxable plan loans from the plan and any other plan maintained by the employer. Under the safe harbor, an employee's ability to make elective contributions and employee contributions to the plan (and any other plan maintained by the employer) must be suspended for at least 6 months after receipt of the hardship distribution. Pursuant to § 1.401(k)–3(c)(6)(v)(B), in the case of a safe harbor plan described in section 401(k)(12) or (13), the suspension period may not exceed 6 months.

Under § 1.401(k)–1(d)(3)(ii), the maximum amount that may be distributed on account of hardship is the total of the employee's elective contributions that have not previously been distributed (plus earnings, QNECs, and QMACs credited before a specified grandfather date that generally is before 1989). Thus, the maximum amount that may be distributed on account of hardship does not include earnings, QNECs, or QMACs that are not grandfathered.

Section 403(b)

Section 403(b)(7)(A)(ii) provides distribution limitations on amounts contributed to a custodial account that is treated as a section 403(b) annuity contract. Section 403(b)(11) provides that contributions made pursuant to a salary reduction agreement (within the meaning of section 402(g)(3)(C)) (generally referred to in the regulations under section 403(b) as ''section 403(b) elective deferrals'') may be distributed only on or after the occurrence of certain events, one of which is the employee's hardship. Section 403(b)(11) also provides that no income attributable to these contributions may be distributed on account of hardship.

Section 1.403(b)–6 provides rules for applying these distribution limitations. Section 1.403(b)–6(b) applies to distributions of amounts that are neither attributable to section 403(b) elective deferrals nor made from custodial accounts, § 1.403(b)–6(c) applies to distributions from custodial accounts that are not attributable to section 403(b) elective deferrals, and § 1.403(b)–6(d) applies to distributions of amounts attributable to section 403(b) elective deferrals. Section 1.403(b)–6(d)(2) provides that a hardship distribution of section 403(b) elective deferrals is subject to the rules and restrictions set forth in § 1.401(k)–1(d)(3) and is limited to the aggregate dollar amount of a participant's section 403(b) elective deferrals, without earnings thereon.

Statutory Changes Relating to Section 401(k)

Section 41113 of the Bipartisan Budget Act of 2018, Public Law 115–123 (BBA 2018), directs the Secretary of the Treasury to modify § 1.401(k)–1(d)(3)(iv)(E) to (1) delete the 6-month prohibition on contributions following a hardship distribution, and (2) make any other modifications necessary to carry out the purposes of section 401(k)(2)(B)(i)(IV). Section 41114 of BBA 2018 modifies the hardship distribution rules under section 401(k)(2)(B) by adding section 401(k)(14)(A) to the Code, which states that the maximum amount available for distribution upon hardship includes (i) contributions to a profit-sharing or stock bonus plan to which section 402(e)(3) applies, (ii) QNECs, (iii) QMACs, and (iv) earnings on these contributions. Section 41114 of BBA 2018 also adds

section 401(k)(14)(B) to the Code, which provides that a distribution is not treated as failing to be made upon the hardship of an employee solely because the employee does not take any available loan under the plan.

Section 11044 of the Tax Cuts and Jobs Act, Public Law 115–97 (TCJA), added section 165(h)(5) to the Code. Section 165(h)(5) provides that, for taxable years 2018 through 2025, the deduction for a personal casualty loss generally is available only to the extent the loss is attributable to a federally declared disaster (as defined in section 165(i)(5)).

Section 826 of the Pension Protection Act of 2006, Public Law 109–280 (PPA '06), directs the Secretary of the Treasury to modify the rules relating to hardship distributions to permit a section 401(k) plan to treat a participant's beneficiary under the plan the same as the participant's spouse or dependent in determining whether the participant has incurred a hardship. Notice 2007–07, 2007–5 I.R.B. 395, provides guidance for applying this provision.

Section 827(a) of PPA '06 added to the Code section 72(t)(2)(G), which exempts certain distributions from the application of the section 72(t) additional income tax on early distributions. These distributions, referred to as ''qualified reservist distributions,'' include distributions attributable to elective contributions that are made during the period that a reservist has been called to active duty. Section 827(b)(1) of PPA '06 added section 401(k)(2)(B)(i)(V) to the Code, which permits qualified reservist distributions to be made from a section 401(k) plan.[1]

Section 105(b)(1)(A) of the Heroes Earnings Assistance and Relief Tax Act of 2008, Public Law 110–245 (HEART Act), added section 414(u)(12) to the Code. Section 414(u)(12)(B)(ii) provides for a 6-month suspension of elective contributions and employee contributions after certain distributions to individuals performing service in the uniformed services.

Explanation of Provisions

Overview

These proposed regulations update the section 401(k) and (m) regulations to reflect: (1) The enactment of (a) sections 41113 and 41114 of BBA 2018, (b) sections 826 and 827 of PPA '06, and (c) section 105(b)(1)(A) of the HEART Act; and (2) the application of the hardship distribution rules in light of the modification to the casualty loss deduction rules made by section 11044 of the TCJA.

Deemed Immediate and Heavy Financial Need

The proposed regulations modify the safe harbor list of expenses in current § 1.401(k)–1(d)(3)(iii)(B) for which distributions are deemed to be made on account of an immediate and heavy financial need by: (1) Adding ''primary beneficiary under the plan'' as an individual for whom qualifying medical, educational, and funeral expenses may be incurred; (2) modifying the expense listed in § 1.401(k)–1(d)(3)(iii)(B)(*6*) (relating to damage to a principal residence that would qualify for a casualty deduction under section 165) to provide that for this purpose the new limitations in section 165(h)(5) (added by section 11044 of the TCJA) do not apply; and (3) adding a new type of expense to the list, relating to expenses incurred as a result of certain disasters. This new safe harbor expense is similar to relief given by the IRS after certain major federally declared disasters, such as the relief relating to Hurricane Maria and California wildfires provided in Announcement 2017–15, 2017–47 I.R.B. 534, and is intended to eliminate any delay or uncertainty concerning access to plan funds following a disaster that occurs in an area designated by the Federal Emergency Management Agency (FEMA) for individual assistance.

Distribution Necessary To Satisfy Financial Need

Pursuant to BBA 2018 sections 41113 and 41114, the proposed regulations modify the rules for determining whether a distribution is necessary to satisfy an immediate and heavy financial need by eliminating (1) any requirement that an employee be prohibited from making elective contributions and employee contributions after receipt of a hardship distribution, and (2) any requirement to take plan loans prior to obtaining a hardship distribution. In particular, the proposed regulations eliminate the safe harbor in current § 1.401(k)–1(d)(3)(iv)(E), under which a distribution is deemed necessary to satisfy the financial need only if elective contributions and employee contributions are suspended for at least 6 months after a hardship distribution is made and, if available, nontaxable plan loans are taken.

In addition, the proposed regulations eliminate the rules in current § 1.401(k)–1(d)(3)(iv)(B) (under which the determination of whether a distribution is necessary to satisfy a financial need is based on all the relevant facts and circumstances) and provide one general standard for determining whether a distribution is necessary. Under this general standard, a hardship distribution may not exceed the amount of an employee's need (including any amounts necessary to pay any federal, state, or local income taxes or penalties reasonably anticipated to result from the distribution), the employee must have obtained other available distributions under the employer's plans, and the employee must represent that he or she has insufficient cash or other liquid assets to satisfy the financial need. A plan administrator may rely on such a representation unless the plan administrator has actual knowledge to the contrary. In light of the timing of the publication of these proposed regulations, the requirement to obtain this representation would only apply for a distribution that is made on or after January 1, 2020.

The proposed regulations clarify that a plan generally may provide for additional conditions, such as those described in 26 CFR 1.401(k)–1(d)(3)(iv)(B) and (C) (revised as of April 1, 2018) or, for distributions made before January 1, 2020, the representation described in the preceding paragraph, to demonstrate that a distribution is necessary to satisfy an immediate and heavy financial need of an employee. To implement Congress' purpose in enacting section 41113 of BBA 2018 (for example, Congress' concern that a suspension impedes an employee's ability to replace distributed funds), the proposed regulations do not permit a plan to provide for a suspension of elective contributions or employee contributions as a condition of obtaining a hardship distribution. However, in light of the timing of the publication of these proposed regulations, this prohibition would only apply for a distribution that is made on or after January 1, 2020.

Expanded Sources for Hardship Distributions

Pursuant to section 41114 of BBA 2018, the proposed regulations modify § 1.401(k)–1(d)(3) to permit hardship distributions from section 401(k) plans of elective contributions, QNECs, QMACs, and earnings on these amounts, regardless of when contributed or earned. However, plans may limit the type of contributions available for

[1] While section 827(b)(2) and (3) of PPA '06 amended sections 403(b)(7)(A)(ii) and 403(b)(11) to permit qualified reservist distributions to be made from a section 403(b) plan, the regulations under section 403(b) have not yet been updated to reflect these statutory amendments.

hardship distributions and whether earnings on those contributions are included. Safe harbor contributions made to a plan described in section 401(k)(13) may also be distributed on account of an employee's hardship (because these contributions are subject to the same distribution limitations applicable to QNECs and QMACs). See § 1.401(k)–3(k)(3)(i).

Section 403(b) Plans

Section 1.403(b)–6(d)(2) provides that a hardship distribution of section 403(b) elective deferrals is subject to the rules and restrictions set forth in § 1.401(k)–1(d)(3); thus, the proposed new rules relating to a hardship distribution of elective contributions from a section 401(k) plan generally apply to section 403(b) plans. However, Code section 403(b)(11) was not amended by section 41114 of BBA 2018; therefore, income attributable to section 403(b) elective deferrals continues to be ineligible for distribution on account of hardship.

Amounts attributable to QNECs and QMACs may be distributed from a section 403(b) plan on account of hardship only to the extent that, under § 1.403(b)–6(b) and (c), hardship is a permitted distributable event for amounts that are not attributable to section 403(b) elective deferrals. Thus, QNECs and QMACs in a section 403(b) plan that are not in a custodial account may be distributed on account of hardship, but QNECs and QMACs in a section 403(b) plan that are in a custodial account continue to be ineligible for distribution on account of hardship.

Relief for Victims of Hurricanes Florence and Michael

The Treasury Department and the IRS realize that employees adversely affected by Hurricane Florence or Hurricane Michael may need expedited access to plan funds. Accordingly, the relief provided under Announcement 2017–15 is extended to similarly situated victims of Hurricanes Florence and Michael, except that the ''Incident Dates'' (as defined in that announcement) are as specified by FEMA for these 2018 hurricanes, relief is provided through March 15, 2019, and any necessary amendments must be made no later than the deadline for plan amendments set forth in this preamble under *Plan Amendments*.

Applicability Dates and Reliance

The changes to the hardship distribution rules made by BBA 2018 are effective for plan years beginning after December 31, 2018, and the proposed regulations provide that they generally would apply to distributions made in plan years beginning after December 31, 2018. However, the prohibition on suspending an employee's elective contributions and employee contributions as a condition of obtaining a hardship distribution may be applied as of the first day of the first plan year beginning after December 31, 2018, even if the distribution was made in the prior plan year. Thus, for example, a calendar-year plan that provides for hardship distributions under the pre-2019 safe harbor standards may be amended to provide that an employee who receives a hardship distribution in the second half of the 2018 plan year will be prohibited from making contributions only until January 1, 2019 (or may continue to provide that contributions will be suspended for the originally scheduled 6 months).

In addition, the revised list of safe harbor expenses may be applied to distributions made on or after a date that is as early as January 1, 2018. Thus, for example, a plan that made hardship distributions relating to casualty losses deductible under section 165 without regard to the changes made to section 165 by the TCJA (which, effective in 2018, require that, to be deductible, losses must result from a federally declared disaster) may be amended to apply the revised safe harbor expense relating to casualty losses to distributions made in 2018 so that plan provisions will conform to the plan's operation. Similarly, a plan may be amended to apply the revised safe harbor expense relating to losses (including loss of income) incurred by an employee on account of a disaster that occurs in 2018 (such as Hurricane Florence or Hurricane Michael), provided that the employee's principal residence or principal place of employment at the time of the disaster was located in an area designated by FEMA for individual assistance with respect to the disaster.

Plan Amendments

The Treasury Department and the IRS expect that, if these regulations are finalized as they have been proposed, plan sponsors will need to amend their plans' hardship distribution provisions. The deadline for amending a disqualifying provision is set forth in Rev. Proc. 2016–37, 2016–29 I.R.B. 136. For example, with respect to an individually designed plan that is not a governmental plan, the deadline for amending the plan to reflect a change in qualification requirements is the end of the second calendar year that begins after the issuance of the Required Amendments List described in section 9 of Rev. Proc. 2016–37 that includes the change. A plan provision that is not a disqualifying provision, but is integrally related to a plan provision that is a disqualifying provision, may be amended by the same deadline applicable to a disqualifying provision.

A plan amendment that is related to the final regulations, but does not correct a disqualifying provision, including a plan amendment reflecting (1) the change to section 165 (relating to casualty losses) or (2) the addition of the new safe harbor expense (relating to expenses incurred as a result of certain federally declared disasters), will be treated as integrally related to a disqualifying provision. Therefore all amendments that relate to the final regulations will have the same amendment deadline. This deadline will also apply to an amendment reflecting the extension of the relief under Announcement 2017–15 to victims of Hurricanes Florence and Michael, as provided in this preamble.

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 the Treasury and the Office of Management and Budget (OMB).

Because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Comments and Requests for 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 *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 author of these regulations is Roger Kuehnle of the Office of Associate Chief Counsel (Tax Exempt and Governmental Entities). However, other personnel from the IRS and Treasury Department participated in their development.

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 continues to read in part as follows:

Authority: 26 U.S.C. 401(m)(9) and 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.401(k)–1 is amended by:
■ 1. Revising paragraphs (d)(1)(ii) and (iii) and adding new paragraph (d)(1)(iv).
■ 2. Removing paragraph (d)(3)(ii) and redesignating paragraphs (d)(3)(iii), (iv) and (v) as paragraphs (d)(3)(ii), (iii) and (iv).
■ 3. Revising newly redesignated paragraph (d)(3)(ii)(B) and adding new paragraph (d)(3)(ii)(C).
■ 4. Revising newly redesignated paragraphs (d)(3)(iii) and (iv) and adding new paragraph (d)(3)(v).
■ 5. In paragraph (d)(6), removing examples 3, 4, and 5 and redesignating example 6 as example 3.

The additions and revisions read as follows:

§ 1.401(k)–1 Certain cash or deferred arrangements.

* * * * *

(d) * * *

(1) * * *

(ii) In the case of a profit-sharing, stock bonus or rural cooperative plan—

(A) The employee's attainment of age 59 ½; or

(B) In accordance with section 401(k)(14), the employee's hardship;

(iii) In accordance with section 401(k)(10), the termination of the plan; or

(iv) In the case of a qualified reservist distribution defined in section 72(t)(2)(G)(iii), the date the reservist was ordered or called to active duty.

* * * * *

(3) * * *

(ii) * * *

(B) *Deemed immediate and heavy financial need.* A distribution is deemed to be made on account of an immediate and heavy financial need of the employee if the distribution is for—

(*1*) Expenses for (or necessary to obtain) medical care that would be deductible under section 213(d), determined without regard to the limitations in section 213(a) (relating to the applicable percentage of adjusted gross income and the recipients of the medical care) provided that, if the recipient of the medical care is not listed in section 213(a), the recipient is a primary beneficiary under the plan;

(*2*) Costs directly related to the purchase of a principal residence for the employee (excluding mortgage payments);

(*3*) Payment of tuition, related educational fees, and room and board expenses, for up to the next 12 months of post-secondary education for the employee, for the employee's spouse, child or dependent (as defined in section 152 without regard to section 152(b)(1), (b)(2) and (d)(1)(B)), or for a primary beneficiary under the plan;

(*4*) Payments necessary to prevent the eviction of the employee from the employee's principal residence or foreclosure on the mortgage on that residence;

(*5*) Payments for burial or funeral expenses for the employee's deceased parent, spouse, child or dependent (as defined in section 152 without regard to section 152(d)(1)(B)) or for a deceased primary beneficiary under the plan;

(*6*) Expenses for the repair of damage to the employee's principal residence that would qualify for the casualty deduction under section 165 (determined without regard to section 165(h)(5) and whether the loss exceeds 10% of adjusted gross income); or

(*7*) Expenses and losses (including loss of income) incurred by the employee on account of a disaster declared by the Federal Emergency Management Agency (FEMA) under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, Public Law 100–707, provided that the employee's principal residence or principal place of employment at the time of the disaster was located in an area designated by FEMA for individual assistance with respect to the disaster.

(C) *Primary beneficiary under the plan.* For purposes of paragraph (d)(3)(ii)(B) of this section, a ''primary beneficiary under the plan'' is an individual who is named as a beneficiary under the plan and has an unconditional right, upon the death of the employee, to all or a portion of the employee's account balance under the plan.

(iii) *Distribution necessary to satisfy financial need*—(A) *Distribution may not exceed amount of need.* A distribution is treated as necessary to satisfy an immediate and heavy financial need of an employee only to the extent the amount of the distribution is not in excess of the amount required to satisfy the financial need (including any amounts necessary to pay any federal, state, or local income taxes or penalties reasonably anticipated to result from the distribution).

(B) *No alternative means reasonably available.* A distribution is not treated as necessary to satisfy an immediate and heavy financial need of an employee unless the employee has obtained all other currently available distributions (including distributions of ESOP dividends under section 404(k), but not hardship distributions) under the plan and all other plans of deferred compensation, whether qualified or nonqualified, maintained by the employer. In addition, for a distribution that is made on or after January 1, 2020, the employee must represent (in writing, by an electronic medium, or in such other form as may be prescribed by the Commissioner) that he or she has insufficient cash or other liquid assets to satisfy the need. The plan administrator may rely on the employee's representation unless the plan administrator has actual knowledge to the contrary.

(C) *Additional conditions.* A plan generally may provide for additional conditions, such as those described in 26 CFR 1.401(k)–1(d)(3)(iv)(B) and (C) (revised as of April 1, 2018) or, for distributions made before January 1, 2020, the representation described in paragraph (d)(3)(iii)(B) of this section, to demonstrate that a distribution is necessary to satisfy an immediate and heavy financial need of an employee. For example, a plan may provide that, before a hardship distribution may be made, an employee must obtain all nontaxable loans (determined at the time a loan is made) available under the plan and all other plans maintained by the employer. However, for a distribution that is made on or after January 1, 2020, a plan may not provide for a suspension of an employee's elective contributions or employee contributions as a condition of obtaining a hardship distribution.

(iv) *Commissioner may expand standards.* The Commissioner may prescribe additional guidance of general applicability, published in the Internal Revenue Bulletin (see § 601.601(d)(2) of

this chapter), expanding the list of distributions deemed to be made on account of immediate and heavy financial needs and setting forth additional methods to demonstrate that a distribution is necessary to satisfy an immediate and heavy financial need.

(v) *Effective/applicability date*—(A) *General rule.* This paragraph (d)(3) applies to distributions made in plan years beginning after December 31, 2018. Except as otherwise provided in this paragraph (d)(3)(v), the rules in 26 CFR 1.401(k)–1(d)(3) (revised as of April 1, 2018) apply to distributions made in plan years beginning before January 1, 2019.

(B) *Options for earlier application.* The last sentence of paragraph (d)(3)(iii)(C) of this section (prohibiting the suspension of contributions as a condition of obtaining a hardship distribution) may be applied as of the first day of the first plan year beginning after December 31, 2018, even if the distribution was made in the prior plan year. Thus, for example, a calendar-year plan that provides for hardship distributions under the rules in 26 CFR 1.401(k)–1(d)(3)(iv)(E) (revised as of April 1, 2018) may be amended to provide that an employee who receives a hardship distribution in the second half of the 2018 plan year will be prohibited from making contributions only until January 1, 2019 (or may continue to provide that contributions will be suspended for the originally scheduled 6 months). In addition, paragraph (d)(3)(ii)(B) of this section may be applied to distributions made on or after a date that is as early as January 1, 2018.

* * * * *

■ **Par. 3.** Section 1.401(k)–3 is amended by:

■ 1. Revising paragraph (c)(6)(v).

■ 2. Removing the language ‘‘, and, in the case of a hardship distribution, suspends an employee's ability to make elective contributions for 6 months in accordance with § 1.401(k)–1(d)(3)(iv)(E)’’ in the fifth sentence in paragraph (c)(7), *Example 1*.

■ 3. Removing the second sentence in paragraph (j)(2)(iv).

The revision reads as follows:

§ 1.401(k)–3 Safe harbor requirements.

* * * * *

(c) * * *

(6) * * *

(v) *Restrictions due to limitations under the Internal Revenue Code.* A plan may limit the amount of elective contributions made by an eligible employee under a plan—

(A) Because of the limitations of section 402(g) or 415;

(B) Due to a suspension under section 414(u)(12)(B)(ii); or

(C) Because, on account of a hardship distribution made before January 1, 2020, an employee's ability to make elective contributions has been suspended for 6 months.

* * * * *

§ 1.401(k)–6 [Amended]

■ **Par. 4.** Section 1.401(k)–6 is amended by:

■ 1. Removing the fourth sentence in paragraph (2) of the definition of *Eligible employee*.

■ 2. Removing the language ‘‘, except as provided otherwise in § 1.401(k)–1(c) and (d),’’ in the definitions of *Qualified matching contributions (QMACs)* and *Qualified nonelective contributions (QNECs)*.

■ **Par. 5.** Section 1.401(m)–3 is amended by revising paragraph (d)(6)(v) to read as follows:

§ 1.401(m)–3 Safe harbor requirements.

* * * * *

(d) * * *

(6) * * *

(v) *Restrictions due to limitations under the Internal Revenue Code.* A plan may limit the amount of contributions made by an eligible employee under a plan—

(A) Because of the limitations of section 402(g) or section 415;

(B) Due to a suspension under section 414(u)(12)(B)(ii); or

(C) Because, on account of a hardship distribution made before January 1, 2020, an employee's ability to make contributions has been suspended for 6 months.

* * * * *

Kirsten Wielobob,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2018–24812 Filed 11–9–18; 4:15 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2018–1011]

RIN 1625–AA00

Safety Zone for Fireworks Displays; Upper Potomac River, Washington Channel, DC

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for certain waters of the Upper Potomac River. This action is necessary to provide for the safety of life on these navigable waters of the Washington Channel adjacent to The Wharf DC, Washington, DC, for recurring fireworks displays from January 12, 2019, through December 31, 2019. This proposed rulemaking would prohibit persons and vessels from being in the safety zone unless authorized by the Captain of the Port Maryland-National Capital Region or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before December 14, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–1011 using the Federal eRulemaking Portal at *http://www.regulations.gov*. See the ‘‘Public Participation and Request for Comments’’ portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Mr. Ron Houck, Sector Maryland-National Capital Region Waterways Management Division, U.S. Coast Guard; telephone 410–576–2674, email *Ronald.L.Houck@uscg.mil*.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background, Purpose, and Legal Basis

On October 30, 2018, Pyrotecnico, Inc., of New Castle, PA, notified the Coast Guard that it will be conducting fireworks displays, sponsored by The Wharf DC, from 7 p.m. to 11:59 p.m. for various events from January 12, 2019, through December 31, 2019. The fireworks are to be launched from a barge in the Washington Channel, adjacent to The Wharf DC in Washington, DC. Hazards from the fireworks displays include accidental discharge of fireworks, dangerous projectiles, and falling hot embers or other debris. The Captain of the Port Maryland-National Capital Region (COTP) has determined that potential hazards associated with the fireworks to

be used in these displays would be a safety concern for anyone within 200 feet of the fireworks barge.

The purpose of this rulemaking is to ensure the safety of vessels on the navigable waters within 200 feet of the fireworks barge on the Washington Channel before, during, and after the scheduled events. The Coast Guard proposes this rulemaking under authority in 33 U.S.C. 1231.

III. Discussion of Proposed Rule

The COTP proposes to establish a temporary recurring safety zone in the Washington Channel from January 12, 2019, through December 31, 2019. The safety zone would cover all navigable waters of the Washington Channel within 200 feet of the fireworks barge. It is anticipated that the safety zone will be activated for eight separate events during 2019. For each event, the barge will be located within an area bounded on the south by latitude 38°52′30″ W, and bounded on the north by the Francis Case (I–395) Memorial Bridge, located at Washington, DC. The safety zone would be enforced from 7 p.m. until 11:59 p.m. for each fireworks display scheduled from January 12, 2019, through December 31, 2019. The duration of the safety zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the scheduled fireworks display. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the size, duration, and time-of-day of the safety zone. It is anticipated that the safety zone will be activated for eight separate events during 2019. Although vessel traffic will not be able to safely transit around this safety zone when being enforced, the impact would be for less than 5 hours during the evening when vessel traffic in Washington Channel is normally low. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone.

B. Impact on Small Entities

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

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

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

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this proposed rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule involves a safety zone that will be in effect for the entire year, however, when activated, lasting less than 5 hours that

would prohibit entry within a portion of the Washington Channel. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. A preliminary Record of Environmental Consideration supporting this determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

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

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, visit *http://www.regulations.gov/privacyNotice*.

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191, 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; and; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T05–1011 to read as follows:

§ 165.T05–1011 Safety Zone for Fireworks Displays, Upper Potomac River, Washington Channel, Washington, DC.

(a) *Location.* The following area is a safety zone: All navigable waters of the Washington Channel within 200 feet of the fireworks barge which will be located within an area bounded on the south by latitude 38°52′30″ W, and bounded on the north by the southern extent of the Francis Case (I–395) Memorial Bridge, located at Washington, DC. All coordinates refer to datum NAD 1983.

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

(1) *Captain of the Port (COTP)* means the Commander, U.S. Coast Guard Sector Maryland-National Capital Region.

(2) *Designated representative* means any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Maryland-National Capital Region to assist in enforcing the safety zone described in paragraph (a) of this section.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative. All vessels underway within this safety zone at the time it is activated are to depart the zone.

(2) To seek permission to enter, contact the COTP or the COTP's designated representative by telephone at 410–576–2693 or on Marine Band Radio VHF–FM channel 16 (156.8 MHz). The Coast Guard vessels enforcing this section can be contacted on Marine Band Radio VHF–FM channel 16 (156.8 MHz).

(3) Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement officials.* The U.S. Coast Guard may be assisted in the patrol and enforcement of the safety zone by Federal, State, and local agencies.

(e) *Enforcement.* This safety zone will be enforced January 12, 2019, through December 31, 2019, from 7 p.m. to 11:59 p.m. each day that a barge with a ''FIREWORKS—DANGER—STAY AWAY'' sign on the port and starboard sides is on-scene or a ''FIREWORKS—DANGER—STAY AWAY'' sign is posted on land adjacent to the shoreline, near the location described in paragraph (a) of this section. The enforcement times of this section are subject to change, but the duration of each enforcement of the zone is expected to be 5 hours or less. Prior to enforcement, the COTP will provide notice by publishing a Notice of Enforcement in the **Federal Register**, as well as issuing a Broadcast Notice to Mariners.

Dated: November 7, 2018.

Joseph B. Loring,

Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.

[FR Doc. 2018–24773 Filed 11–13–18; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2018–0675; FRL–9985–91–Region 6]

Air Plan Approval; Texas; Reasonably Available Control Technology

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to convert its September 22, 2017 conditional approval of revisions to the Texas State Implementation Plan (SIP), addressing Oxides of Nitrogen (NO_X) Reasonably Available Control Technology (RACT) for the TXI Operations, LP (Texas Industries, Inc., TXI) cement manufacturing plant in Ellis County, to full approval. The August 21, 2018 SIP submittal satisfies Texas' commitment which was the basis for our conditional approval of NO_X RACT for this plant. Final approval of this SIP submittal will convert our earlier conditional approval to full approval. We are taking this action in accordance with the Clean Air Act (CAA, the Act) requirements.

DATES: Comments must be received on or before December 14, 2018.

ADDRESSES: Submit your comments, identified by Docket No. EPA–R06–OAR–2018–0675 at *http://www.regulations.gov* or via email to *shar.alan@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 Mr. Alan Shar, (214) 665–6691, *shar.alan@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 the EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available at either location (*e.g.,* CBI).

FOR FURTHER INFORMATION CONTACT: Mr. Alan Shar (6MM–AA), (214) 665–6691, *shar.alan@epa.gov*. To inspect the hard copy materials, please schedule an appointment with Alan Shar.

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

Outline

I. Background

As a part of its July 10, 2015 Dallas Fort Worth (DFW) SIP submittal, TCEQ conducted RACT analyses to demonstrate that the RACT requirements for affected NO_X sources in the DFW 2008 8-Hour Ozone nonattainment area have been satisfied, relying on the NO_X RACT rules EPA had previously approved for the DFW area for its classification as Serious for the 1997 8-Hour Ozone standard. See March 27, 2015 (80 FR 16292), and 40 CFR 51.1112. The RACT analysis is contained in Appendix F of the TCEQ July 10, 2015 SIP submittal as a component of the DFW 2008 8-Hour Ozone attainment demonstration plan. On September 22, 2017, we conditionally approved NO_X RACT for the TXI cement manufacturing plant in Ellis County, and fully approved NO_X RACT for all other affected sources in the ten county DFW 2008 8-Hour Ozone nonattainment area.

On August 21, 2018 TCEQ submitted a revision to Texas SIP addressing NO_X RACT for the TXI cement manufacturing plant in Ellis County as a part of its DFW 2008 8-Hour Ozone National Ambient Air Quality Standards (NAAQS) SIP update. The August 21, 2018 SIP submittal contains both an Agreed Order (AO) concerning TXI and a SIP narrative for DFW NO_X RACT.

A. RACT and the RACT Requirements Relevant for This Action

Section 172(c)(1) of the Clean Air Act (CAA, Act) requires that SIPs for nonattainment areas ''provide for the implementation of all reasonably available control measures as expeditiously as practicable (including such reductions in emissions from existing sources in the area as may be obtained through the adoption, at a minimum, of reasonably available control technology) and shall provide for attainment of the primary National Ambient Air Quality Standards (NAAQS).'' The EPA has defined RACT as the lowest emissions limitation that a particular source is capable of meeting by the application of control technology that is reasonably available, considering technological and economic feasibility.[1]

Section 182(b)(2) of the Act requires states to submit a SIP revision and implement RACT for major stationary sources in moderate and above ozone nonattainment areas. For a Moderate, Serious, or Severe area, a major stationary source is one that emits, or has the potential to emit, 100, 50, or 25 tons per year (tpy) or more of VOCs or NO_X, respectively.[2] The DFW area was classified as Serious on December 20, 2010 (75 FR 79302). Ellis County is one of the ten Counties constituting the DFW 2008 8-Hour Ozone nonattainment area. Thus, per section 182(c) of the CAA, a major stationary source in the DFW area, is one which emits, or has the potential to emit, 50 tpy or more of VOCs or NO_X. The TXI cement manufacturing plant in Ellis County is a major source of NO_X, and subject to RACT.

The terms ''TXI Operations, LP'', ''TXI'', ''Martin Marietta'', and ''MM'' are used interchangeably in this action.[3]

The EPA provides states with guidance concerning what types of controls could constitute RACT for a given source category through the issuance of Control Technique Guidelines (CTG) and Alternative Control Techniques (ACT) documents.[4]

B. Conditional Approval

Under section 110(k)(4) of the Act, the Administrator may approve a plan revision based on a commitment of the State to adopt specific enforceable measures by a date certain, but not later than 1 year after the date of approval of the plan revision. Any such conditional approval shall be treated as a disapproval, if the State fails to comply with such commitment.

The EPA conditionally approved NO_X RACT for the TXI cement manufacturing plant in Ellis County on September 22, 2017 (82 FR 44320), with an effective date of October 23, 2017.[5] The RACT determination action was based on the State's written commitment to EPA that through an AO or rulemaking action, between TCEQ and TXI, certain conditions of their air permit, concerning the NO_X emission limitation of 1.95 lb/ton of clinker produced from kiln #5, would be incorporated into a forthcoming revision to the Texas SIP.[6] This SIP revision was necessary so that the emission limit relied upon to implement NO_X RACT would be part of the Texas SIP. The forthcoming revision to the Texas SIP was to be submitted to EPA no later than one year from the effective date of final conditional approval of the NO_X RACT for kiln #5, or no later than October 23, 2018. See section 110(k)(4) of the CAA.

The August 21, 2018 SIP submittal was provided to fulfil TCEQ's written commitment to EPA. RACT for the TXI

[1] September 17, 1979 (44 FR 53761).

[2] CAA sections 182(b), 182(c), and 182(d).

[3] Index of written testimony, Reference number W–1, August 21, 2018 SIP submission.

[4] See *http://www.epa.gov/airquality/ozonepollution/SIPToolkit/ctgs.html*.

[5] EPA Docket No. EPA–R06–OAR–2015–0496 available at *www.regulations.gov*.

[6] July 29, 2016 letter at *www.regulations.gov* document ID No. EPA–R06–OAR–2015–0496–0035.

cement kiln #5 is fulfilled by an AO[7] which is included in the SIP submittal and will become part of the SIP, if EPA finalizes this proposed approval. The scope of this rulemaking action is strictly limited to evaluating the SIP revision, including the AO, and whether it meets the requirements of the conditional approval. The AO includes incorporation of certain TXI's New Source Review (NSR) SIP permit conditions (Specific Conditions 3.A(1)–(3) of NSR Permit 1360A(PSDTX632M1)) such that the AO stands on its own and insures the necessary requirements will become a part of the Texas SIP. No further RACT review or determination is being conducted here. Comments concerning the area's ozone attainment demonstration plan, or review of NO_X RACT are beyond the scope of this rulemaking action.

II. Evaluation

As a part of our July 19, 2017 proposal (82 FR 33026) and September 22, 2017 final (82 FR 44320) rulemaking actions we, among other things, determined the NO_X emission limitations and control requirements in Appendix F meet RACT for each cement manufacturing plant in Ellis County, including the TXI cement manufacturing plant in Ellis County.[8]

As a part of our RACT determination at 82 FR 44320, we found that emission limitations and control requirements for the TXI plant contained in certain terms of TXI's air permit, including the NO_X emission limitation of 1.95 lb/ton of clinker are consistent with our guidance and ACT documents, and meet the lowest emission limitation through application of control techniques that are reasonably available considering technological and economic feasibility. The air permit, however, is not part of the SIP. Therefore, our approval was *conditioned* on certain terms of the permit being approved by EPA as a source-specific SIP revision. TCEQ committed to address the referenced terms of TXI's air permit through rule revision or an AO in a SIP revision, and submit that SIP to the EPA as a revision to its NO_X RACT SIP no later than October 23, 2018. See section 110(k)(4) of the Act (conditional approval). As stated above, the August 21, 2018 SIP submittal satisfies that commitment.

The August 21, 2018 SIP submittal consists of an AO which states that the kiln #5 NO_X CEMS is subject to the provisions in 30 TAC section 117.3140(b), 40 CFR 60.13, 40 CFR 60 Appendix B, Performance Specification 2, and is subject to audits in accordance with section 5.1 of Appendix F Quality Assurance Procedures.[9]

The kiln #5 stack exhaust flow rate is subject under the AO to 30 TAC section 117.3142(a)(2), which requires monitoring with a flow meter subject to 40 CFR part 60 Appendix B, Performance Specification 6 or 40 CFR part 75 Appendix A.[10]

Pursuant to the AO, the TXI must monitor and record clinker production rates, in tons per hour, tons per day, daily summed on a 30-day rolling basis, and monthly summed on a 12-month rolling basis. Hourly and daily clinker production rates may be based on the previous month's feed-to-clinker ratio multiplied by the measured hourly/daily kiln feed rate, as specified in 40 CFR 60 subpart F section 60.63(b). Records in units of lb NO_X/ton of clinker produced are maintained on a 30-day rolling average basis.[11]

The AO also requires that the NO_X emission limit is 1.95 lb NO_X/ton of clinker for kiln #5, on a 30-day rolling average basis. Furthermore, this limit of 1.95 lb NO_X per ton of clinker cannot be revised to be less stringent without an approved revised RACT determination in accordance with the State and Federal requirements for SIP revisions.[12]

The AO states that the Company shall make records available upon request by the TCEQ or any other air pollution control agency with jurisdiction over the Company.[13]

In addition, Special Conditions outlined in Part II, Item #2, subparagraphs 1, 2, and 3 of the AO shall be incorporated in Company's NSR permit 1360A (PSDTX632M1) as they concern the NO_X RACT limit, averaging periods, and NO_X CEMS provisions for kiln #5, respectively. These provisions will provide for consistency between the TCEQ air permit and the federally enforceable NO_X RACT SIP requirements for kiln #5.

The AO has gone through public notice and comment at the State level, and it adopts *specific enforceable measures* in conformance with section 110(k)(4) of the Act.

We find that the submitted AO meets the conditions for full approval and includes all the required provisions to meet the NO_X RACT requirements that EPA approved in the September 22, 2017 final action.

III. Proposed Action

We are proposing to find TCEQ's August 21, 2018 SIP submittal satisfies its obligation under the September 22, 2017 (82 FR 44320) conditional approval, and to convert the September 22, 2017 (82 FR 44320) rulemaking to full approval. We are proposing to approve the August 21, 2018 SIP submittal, including approval of the AO as a source-specific NO_X RACT revision to the SIP.

IV. Incorporation by Reference

In this action, we are proposing to include in a final rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, we are proposing to incorporate by reference revisions to Texas' regulations, as described in the Proposed Action section above. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and in hard copy at the EPA Region 6 office.

V. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 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

[7] TCEQ Docket No. 2017–1648–SIP, Agreed Order.

[8] Technical Support Document (TSD) ID No. EPA–R06–OAR–2015–0496–0036 at *www.regulations.gov*.

[9] Part I, stipulation 16 of the Agreed Order.

[10] Id.

[11] Id.

[12] Part I, Item #19 of Agreed Order.

[13] Part II, Item #3 of Agreed Order.

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 Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

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

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

Dated: November 5, 2018.

Anne Idsal,

Regional Administrator, Region 6.

[FR Doc. 2018–24658 Filed 11–13–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2018–0419; FRL–9986–48–Region 4]

Air Plan Approval; NC; Miscellaneous Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve portions of State Implementation Plan (SIP) revisions provided by the State of North Carolina through the North Carolina Division of Air Quality (NCDAQ) in letters dated June 5, 2017, and August 22, 2017. The submissions revise several regulations concerning nitrogen oxides, emission control standards, monitoring, and reporting requirements. EPA is proposing to approve these provisions of the SIP revisions because these changes are consistent with the Clean Air Act (CAA or Act) and federal regulations.

DATES: Comments must be received on or before December 5, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2018–0419 at *http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Richard Wong, Air Regulatory Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–8726. Mr. Wong can also be reached via electronic mail at *wong.richard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

NCDAQ submitted SIP revisions through letters dated June 5, 2017 and August 22, 2017 to EPA for review and approval into the North Carolina SIP.[1] North Carolina's SIP revisions include multiple changes to its air quality rules, under subchapter 15A NCAC 2D, specifically at Section .1404, ''Recordkeeping: Reporting: Monitoring,'' Section .0542, ''Control of Particulate Emissions from Cotton Ginning Operations,'' Section .0606, ''Sources Covered by Appendix P of 40 CFR part 51,'' and Section .0608, ''Other Large Coal or Residue Oil Burners.'' EPA is not taking action on Section .0535, ''Excess Emissions Reporting and Malfunctions'' which is included in the changes in the August 22, 2017 SIP revision. EPA will address revisions to Section .0535 in a separate action.

II. Analysis of the State's Submittals

A. June 5, 2017 SIP Submittal

The June 5, 2017 submission revises North Carolina's nitrogen oxides (NO_X) Rule Section .1404, ''Recordkeeping: Reporting: Monitoring'' through several iterations.[2] The State previously submitted the changes as four separate submissions.[3] North Carolina took these rule changes to hearings on May 21, 2001, June 5, 2001, June 22, 2005, and November 11, 2007. NCDAQ subsequently withdrew and resubmitted these changes in a comprehensive submission. The revision that became state-effective on July 15, 2002, made minor and clarifying changes to subsections (a) ''General requirements,'' (b) ''Submittal of information to show compliance status,'' (c) ''Excess emissions reporting,'' (d) ''Continuous emissions monitors,'' (f) ''Missing data,'' (g) ''Interim report for large sources,'' (h) ''Recordkeeping and reporting requirements for large sources,'' and (i) ''Averaging time for continuous emissions monitors.'' Clarifying edits consisted of clarifying that records

[1] The SIP revisions were received by EPA on June 5, 2017 and September 6, 2017, respectively.

[2] NO_X Rule section .1404 was originally submitted to EPA as part of the State's NO_X Budget and Allowance Trading Program in response to EPA's regulation entitled ''Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone,'' otherwise known as the NO_X SIP Call.

[3] The June 5, 2017, cover letter requested withdrawal for submissions or portions of submissions dated August 14, 2002, October 14, 2004, March 24, 2006, and November 19, 2008, with state effective dates July 15, 2002, May 1, 2004, November 1, 2005, and January 1, 2009, respectively. Through a separate rulemaking on May 9, 2013, EPA took final action on portions of the October 14, 2004 submission approving some revisions, including those for section .1404, and conditionally approving other revisions. *See* 78 FR 27065. Additionally, the State previously submitted a revision to Section .1404 on December 14, 2004, and EPA finalized the rulemaking approving that revision on August 22, 2008 (73 FR 49613). Finally, the State previously submitted a revision to Section .1404 on December 27, 2002, and EPA finalized the rulemaking approving that revision on December 27, 2002. *See* 67 FR 78987.

needed to be maintained for five years and changing ''a'' to ''the'' and ''Rule'' to ''Rules.'' Changes were also made to remove an exception for seasonal excess emission reporting because the referenced rules were previously repealed by the State and approved by EPA. The submission makes a change that prescribes a requirement for continuous emission monitoring for sources covered under Section .1418, ''New Electric Generating Units, Large Boilers, and Large I/C Engines.'' Lastly, the SIP revision makes minor typographical changes throughout. EPA is proposing to approve these revisions because the minor typographical and clarifying changes do not relax or alter the meaning of the rule and the other revision pertaining to a requirement for continuous emissions monitoring for sources covered under Section .1418 is SIP-strengthening and is consistent with the requirements of the CAA and federal regulations.[4]

The revision that became state-effective on November 1, 2005, removed the interim reporting requirements for large sources and retained the annual requirement where sources must report NO_X emissions no later than October 30. The revision that became state-effective on January 1, 2009, also made minor changes that consisted of changing ''a'' to ''the,'' renumbering the subparagraphs and removing references to repealed rules, including sections .1416, ''Emission Allocations for Utility Companies,'' .1417, ''Emission Allocations for Large Combustion Sources,'' and .1419, ''Nitrogen Oxide Budget Trading Program.'' [5] EPA is proposing to approve these changes because the minor changes do not relax or alter the meaning of the rule and the other revision pertaining to the date for the end of season reporting requirement is consistent with the requirements of the CAA and federal regulations.

B. August 22, 2017, SIP Submittal

The August 22, 2017 submission revises Sections .0542, ''Control of Particulate Emissions from Cotton Ginning Operations,'' .0606, ''Sources Covered by Appendix P of 40 CFR part 51,'' and .0608, ''Other Large Coal or Residual Oil Burners.'' The SIP revision makes minor and clarifying edits throughout the three rules. The changes in Section .0542 remove obsolete past due dates for Emission Control Requirements and provide clarification edits under paragraph (c)—*Applicability,* paragraph (d)—*Emission Control* Requirements and paragraph (e)—*Raincaps.* Clarifying edits consisted of renumbering and removing references to obsolete control dates and were also made under paragraph (g)—*Fugitive Emissions* and paragraph (l)—*Reporting.* The changes in Sections .0606 and .0608 are minor and revise references to another rule in the same subchapter for fuel analysis for sulfur dioxide emitting sources without continuous emissions monitoring. EPA is proposing to approve these changes because the minor and clarifying changes do not relax or alter the meaning of the rule.

III. Incorporation by Reference

In this rulemaking, 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 under subchapter 2D, Section .1404, ''Recordkeeping: Reporting: Monitoring,'' effective January 1, 2009,[6] which clarifies the rule by updating quality assurance, recordkeeping and reporting requirements and provisions for heat input calculations and removes references to repealed rules. EPA is proposing to incorporate by reference under subchapter 2D Section .0542, ''Control of Particulate Emissions from Cotton Ginning Operations,'' Section .0606, ''Sources Covered by Appendix P of 40 CFR part 51,'' and Section .0608, ''Other Large Coal or Residue Oil Burners,'' effective June 1, 2008, which makes minor and clarifying changes, updates rule references, and removes obsolete controls and dates. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Proposed Action

EPA is proposing to approve the aforementioned changes to the North Carolina SIP, submitted on June 5, 2017, and August 22, 2017 because they are consistent with the CAA and federal regulations.

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. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. These actions merely propose to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, these proposed actions:

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

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

[4] 40 CFR 51.121–5.122 (NO_X SIP Call regulations) and 40 CFR part 75 (Continuous Emissions Monitoring).

[5] EPA approved the repeal of these provisions on May 9, 2013. *See* 78 FR 27065.

[6] January 1, 2009 is the most recent state effective date of subchapter 2D, Section .1404, ''Recordkeeping: Reporting: Monitoring,'' and it reflects the exact version of the text of .1404 that EPA is proposing to approve into the SIP.

direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: November 6, 2018.

Onis ''Trey'' Glenn, III,

Regional Administrator, Region 4.

[FR Doc. 2018–24819 Filed 11–13–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2018–0369 FRL–9986–29–Region 5]

Air Plan Approval; Ohio; Ohio Less Than 10 TPY BAT Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve, under the Clean Air Act (CAA), revisions to Ohio's State Implementation Plan (SIP) as requested by the Ohio Environmental Protection Agency (OEPA) on May 22, 2018. OEPA has submitted, for approval, revisions that exempt sources that emit less than 10 tons per year (tpy) from the need to employ Best Available Technology (BAT). EPA is proposing to approve these revisions because they are consistent with Federal regulations governing state permit programs.

DATES: Comments must be received on or before December 14, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2018–0369 at *http://www.regulations.gov,* or via email to *damico.genevieve@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the 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.*

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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 revisions did OEPA submit?

On May 22, 2018, OEPA submitted a SIP revision to Ohio Administrative Code (OAC) rule 3745–31–05(A)(3)(a)(ii), which is its BAT rule. This revision exempts the smaller emitting sources, those that emit less than 10 tpy of each criteria pollutant, from the need to employ BAT. OEPA's less than 10 tpy BAT exemption is currently in OEPA's OAC 3745–31–05(A)(3)(a)(ii) and reads: ''*BAT is not required if the air contaminant source was installed or modified on or after August 3, 2006 and has the potential to emit (PTE), taking into account air pollution controls installed on the source, less than ten tons per year of emissions of an air contaminant or precursor of an air contaminant for which a national ambient air quality standard has been adopted under the Clean Air Act.*''

Ohio's Federally approved construction program, OAC 3745–31 (''Permits to Install New Sources of Pollution'') provides the authority for OEPA to issue Permits to Install (PTI) to new sources of air pollution or modifications to existing sources of air pollution. For attainment areas, the program was conditionally approved into Ohio's SIP on October 10, 2001 (66 FR 51570), and fully approved on January 22, 2003 (68 FR 2909). For nonattainment areas, the program was fully approved on January 10, 2002 (68 FR 1366). On February 20, 2013, OEPA's SIP was revised (78 FR 28547) to combine the PTI and Permit to Operate (PTO) programs into a single Permit to Install and Operate (PTIO) program so that a minor source not subject to title V of the Clean Air Act in Ohio would be issued a single PTIO instead of a PTI and a PTO permit.

On August 3, 2006, the Ohio General Assembly passed Senate Bill 265 (SB 265) which required OEPA to modify several of its BAT rules. OEPA's BAT is an air permitting mechanism to help control emissions in minor air permits. BAT can be any combination of work practices, air pollution control devices, raw material specifications, throughput limitations, source design characteristics, and OEPA does an evaluation of the annualized cost per ton of air pollutant removed when determining BAT. One of the changes implemented was the less than 10 tpy BAT exemption. To implement the SB 265 changes, OEPA adopted revisions under OAC Chapter 3745–31–05(A)(3)(b) on November 20, 2006, which became effective on December 1, 2006. On January 18, 2008, OEPA requested that EPA approve this rule language as a revision to Ohio's SIP. EPA responded with a June 5, 2008 letter to OEPA indicating that the request was incomplete due to a lack of a CAA section 110(l) demonstration, thus returning the request back to OEPA. On June 2, 2008, OEPA moved the language in OAC rule 3745–31–05 from paragraph (A)(3)(b) to (A)(3)(a)(ii) which became effective at the state level on June 30, 2008. The rule language contained in OAC rule 3745–31–05(A)(3)(a)(ii) was carried over in OAC rule 3745–31–05, which was adopted on April 20, 2016, and became effective at the state level as of May 1, 2016, and is what OEPA is now requesting for EPA approval as a revision to its SIP. EPA considered this May 22, 2018 submittal to be complete.

II. Do the revisions comply with section 110(l) of the Clean Air Act?

OEPA's May 22, 2018 SIP revision submittal included a 110(l) demonstration. This demonstration included an extensive analysis to show the impact that the less than 10 tpy BAT exemption would have on emissions. This analysis evaluated over 400 permits, representing more than 80

source classification codes and 36 different types of categories of sources. Each criteria pollutant was evaluated and then a comparison was made between the emission limit that would occur if BAT applied and if BAT did not apply to the less than 10 tpy sources. The analysis concludes that there would be a negligible increase in emissions due to the less than 10 tpy BAT exemption.

The 110(l) demonstration included a quantitative and qualitative analysis. The analysis estimated an emission increase of 36.89 tpy of volatile organic compounds (VOC) emissions in attainment areas and nonattainment areas, combined, when applying the less than 10 tpy BAT exemption compared to BAT-based emissions. That increase in VOC emissions represented a very small amount (0.12%) of the total actual point source VOC emissions reported for that year, 2010 in Ohio.

The 110(l) analysis estimated the VOC emission increases in the Ohio nonattainment areas combined, as well as to each of the three Ohio ozone nonattainment areas (Cleveland, Cincinnati, Columbus). This analysis links the estimated VOC increases to each of the Ohio ozone nonattainment areas and demonstrates that each nonattainment area will not be negatively impacted by the estimated increase in emissions. The analysis showed an estimated increase of 25.53 tpy of VOC in Ohio nonattainment areas which represented 0.2% of the 2010 total VOC emissions in Ohio. OEPA's analysis also quantified the estimated VOC increases in the three Ohio nonattainment areas: 18.65 tpy in the Cincinnati area, 4.88 tpy in the Cleveland/Akron/Lorain area, and 0 tpy in the Columbus area. OEPA's analysis further broke out the 18.65 tpy Cincinnati nonattainment area VOC emission increase to the following two areas: 13 tpy increase in Hamilton County, and 5.6 tpy in Butler County.

To address the VOC emission increases in the Cincinnati and Cleveland nonattainment areas, OEPA opted to use VOC emission offsets to mitigate any possibility of adverse air quality impact that may result from the small increase in VOC emissions. These relied-upon emission offsets are from permanently shut down emission units at one facility in Ashtabula (4.88 tpy offset VOCs) and one facility in Hamilton (18.65 tpy offset VOCs) counties located in the Cincinnati and Cleveland nonattainment areas, respectively. The 4.88 tpy offset VOCs in Ashtabula County are from the permanently shut down emission unit R010 at the RMC USA Inc. facility (Facility ID 0204000423), the emission unit was permanently shut down on 7/16/2014. The 18.65 tpy offset VOCs in Hamilton County are from the permanently shut down emission unit P001 at the Rock-Tenn Converting Co. facility (Facility ID 1431070952), the emission unit was permanently shut down on 11/21/2014. This 18.65 tpy offset VOCs is to offset the possible VOC increases in Hamilton and Butler Counties, combined. The VOC emission reductions have been verified and validated through OEPA's Stars II system and are considered creditable since they are surplus, quantifiable, permanent and federally enforceable. OEPA maintains a database of all emission reductions used for purpose of CAA 110(l) demonstrations and these VOC reductions will be tracked within this database to ensure they cannot be used again. OEPA has committed to permanently retire the 25.33 tpy of VOC emissions upon EPA's approval of this SIP revision and EPA's proposed approval of this SIP revision is based on that commitment. The VOC emission reductions from the permanent emission unit shut downs will offset the predicted VOC emissions increase in these VOC nonattainment areas resulting from the less than 10 tpy BAT exemption and ensure that plans to bring the VOC nonattainment with the NAAQS are not compromised and thus it is expected there will be no adverse impact on air quality.

OEPA's 110(l) analysis demonstrated that the air quality will not be negatively impacted due to the small increase in emissions as result of the less than 10 tpy BAT exemption. OEPA's 110(l) analysis demonstrated that the VOC emission offsets from the shutdown emission units at the two facilities will counterbalance the estimated emission increase in VOC emissions due to the less than 10 tpy BAT exemption and will not have a negative impact on air quality nor cause backsliding from Ohio's reasonable further progress plans. OEPA will formally retire the VOC emission offsets in order to receive final approval of this SIP revision. OEPA's 110(l) analysis also demonstrated that the small increase in VOC emissions in Ohio's ozone attainment areas will not have a negative impact on air quality because the increase in VOC emissions is very small compared to the VOC emissions emitted state-wide.

III. What action is EPA taking?

EPA is proposing approval, into the SIP, of the rule revision to OAC 3745–31–05(A)(3)(a)(ii) that OEPA submitted on May 22, 2018. The SIP revision submitted, described in section I, above, is consistent with Federal regulations governing state permitting programs. See section II above. EPA is also soliciting comment on this proposed approval.

IV. Incorporation by Reference

In this 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 revisions to Ohio Administrative Code 3745–31–05(A)(3)(a)(ii), effective on May 1, 2016. EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the EPA Region 5 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

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 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).

List of Subjects in 40 CFR Part 52

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

Dated: October 30, 2018.

Cathy Stepp,

Regional Administrator, Region 5.

[FR Doc. 2018–24815 Filed 11–13–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2017–0191; FRL–9986–30–Region 5]

Air Plan Approval; Michigan; Infrastructure SIP Requirements for the 2012 $PM_{2.5}$ NAAQS; Multistate Transport

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve elements of the State Implementation Plan (SIP) submission from Michigan regarding the infrastructure requirements of section 110 of the Clean Air Act (CAA) for the 2012 annual fine particulate matter ($PM_{2.5}$) National Ambient Air Quality Standard (NAAQS or standard). The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA. This action pertains specifically to infrastructure requirements concerning interstate transport provisions.

DATES: Comments must be received on or before December 14, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2017–0191 at *http://www.regulations.gov,* or via email to *blakley.pamela@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*.

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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 is the background of this SIP submission?

This rulemaking addresses a submission from the Michigan Department of Environmental Quality dated March 23, 2017, which describes its infrastructure SIP for the 2012 annual $PM_{2.5}$ NAAQS (78 FR 3086). Specifically, this rulemaking addresses the portion of the submission dealing with interstate pollution transport under CAA Section 110(a)(2)(D)(i), otherwise known as the ''good neighbor'' provision. The requirement for states to make a SIP submission of this type arises from Section 110(a)(1) of the CAA. Pursuant to Section 110(a)(1), states must submit ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof),'' a plan that provides for the ''implementation, maintenance, and enforcement'' of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA's taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that ''[e]ach such plan'' submission must address. EPA commonly refers to such state plans as ''infrastructure SIPs.''

II. What guidance and memoranda is EPA using to evaluate this SIP submission?

EPA highlighted the statutory requirement to submit infrastructure SIPs within three years of promulgation of a new NAAQS in an October 2, 2007, guidance document entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 1997 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards'' (2007 guidance). EPA has issued additional guidance documents and memoranda, including a September 13, 2013, guidance document titled ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)'' (2013 guidance).

The most recent relevant document is a memorandum published on March 17, 2016, titled ''Information on the Interstate Transport ''Good Neighbor'' Provision for the 2012 Fine Particulate Matter National Ambient Air Quality Standards under Clean Air Act Section 110(a)(2)(D)(i)(I)'' (2016 memorandum).

The 2016 memorandum describes EPA's consistent approach over the years to address interstate transport, and provides EPA's general review of relevant modeling data and air quality projections as they relate to the 2012 annual $PM_{2.5}$ NAAQS. The 2016 memorandum provides information relevant to EPA Regional office review of the CAA section 110 (a)(2)(D)(i)(I) ''good neighbor'' provision in infrastructure SIPs with respect to the 2012 annual $PM_{2.5}$ NAAQS. Michigan's submittal and this rulemaking consider information provided in that memorandum.

The 2016 memorandum provides states and EPA Regional offices with future year annual $PM_{2.5}$ design values for monitors in the United States based on quality assured and certified ambient monitoring data and air quality modeling. The 2016 memorandum further describes how these projected potential design values can be used to help determine which monitors should be further evaluated to potentially address whether emissions from other states significantly contribute to nonattainment or interfere with maintenance of the 2012 annual $PM_{2.5}$ NAAQS at those sites. The 2016 memorandum explains that, for purposes of addressing interstate transport for the 2012 $PM_{2.5}$ NAAQS, it may be appropriate to evaluate projected air quality in 2021, which is the attainment deadline for 2012 $PM_{2.5}$ NAAQS nonattainment areas classified as Moderate. Accordingly, because the available data includes 2017 and 2025 projected average and maximum $PM_{2.5}$ design values calculated through the CAMx photochemical model, the 2016 memorandum suggests approaches states might use to interpolate $PM_{2.5}$ values at sites in 2021. The 2016 memorandum indicates that it may be reasonable to assume receptors projected to have average and/or maximum design values above the NAAQS in both 2017 and 2025 are also likely to be either nonattainment or maintenance receptors in 2021. Similarly, the 2016 memorandum indicates that it may be reasonable to assume that receptors that are projected to attain the NAAQS in both 2017 and 2025 are also likely to be attainment receptors in 2021. However, where a potential receptor is projected to be nonattainment or maintenance in 2017, but projected to be attainment in 2025, the 2016 memorandum suggests that further analysis of the emissions and modeling may be needed to make a further judgement regarding the receptor status in 2021.

The 2016 memorandum indicates that for all but one monitor site in the eastern United States with at least one complete and valid $PM_{2.5}$ design value for the annual average 2012 NAAQS in the 2009–2013 period, the modeling data shows that monitors were expected to both attain and maintain the 2012 annual $PM_{2.5}$ NAAQS in both 2017 and 2025. The modeling results provided in the 2016 memorandum show that out of seven $PM_{2.5}$ monitors located in Allegheny County, Pennsylvania, one monitor is expected to be above the 2012 annual $PM_{2.5}$ NAAQS in 2017. Further, that monitor the Liberty monitor (ID number 420030064), is projected to be above the NAAQS only under the model's maximum projected conditions (used in EPA's interstate transport framework to identify maintenance receptors), and is projected to both attain and maintain the NAAQS (along with all Allegheny County monitors) in 2025. The 2016 memorandum therefore indicates that under such a condition (where EPA's photochemical modeling indicates an area will maintain the 2012 annual $PM_{2.5}$ NAAQS in 2025 but not attain in 2017) further analysis of the site should be performed to determine if the site may be a nonattainment or maintenance receptor in 2021 (the attainment deadline for moderate $PM_{2.5}$ areas).

The 2016 memorandum also indicates that based on modeling projections, there are 17 potential nonattainment or maintenance receptors in California, located in the San Joaquin Valley and South Coast nonattainment areas, and one potential receptor in Shoshone County, Idaho.

The 2016 memorandum also indicates that for certain states with incomplete ambient monitoring data, additional information including the latest available data, should be analyzed to determine whether there are potential downwind air quality problems that may be impacted by transported emissions. These states include all or portions of Florida, Illinois, Idaho (outside of Shoshone County), Tennessee, and Kentucky. With the exception of four counties in Florida, the data quality problems have subsequently been resolved for these areas, and these areas now have current design values below the 2012 annual $PM_{2.5}$ NAAQS and are expected to maintain the NAAQS due to downward emission trends for NO_X and SO_2.

Michigan's submittal indicates that the state used data from the 2016 memorandum in its analysis. EPA considered the analysis from Michigan, as well as additional analysis conducted by EPA, in its review of the Michigan submittal.

III. EPA's Review

This rulemaking proposes action on the portion of Michigan's March 23, 2017 SIP submission addressing the good neighbor provision requirements of CAA Section 110(a)(2)(D)(i). State plans must address four requirements of the good neighbor provisions (commonly referred to as ''prongs''), including:

—Prohibiting any source or other type of emissions activity in one state from contributing significantly to nonattainment of the NAAQS in another state (prong one);
—Prohibiting any source or other type of emissions activity in one state from interfering with maintenance of the NAAQS in another state (prong two);
—Prohibiting any source or other type of emissions activity in one state from interfering with measures required to prevent significant deterioration (PSD) of air quality in another state (prong three); and
—Protecting visibility in another state (prong four).

This rulemaking is evaluating Michigan's March 23, 2017 submission, to determine whether Michigan's interstate transport provisions in its $PM_{2.5}$ infrastructure SIP meet prongs one and two of the good neighbor requirements of the CAA. Prongs three and four will be evaluated in a separate rulemaking.

EPA has developed a consistent framework for addressing the prong one and two interstate transport requirements with respect to the $PM_{2.5}$ NAAQS in several previous Federal rulemakings. The four basic steps of that framework include: (1) Identifying downwind receptors that are expected to have problems attaining or maintaining the NAAQS; (2) identifying which upwind states contribute to these identified problems in amounts sufficient to warrant further review and analysis; (3) for states identified as contributing to downwind air quality problems, identifying upwind emissions reductions necessary to prevent an upwind state from significantly contributing to nonattainment or interfering with maintenance of the NAAQS downwind; and (4) for states that are found to have emissions that significantly contribute to nonattainment or interfere with maintenance of the NAAQS downwind, reducing the identified upwind emissions through adoption of permanent and enforceable measures. This framework was most recently

applied with respect to $PM_{2.5}$ in the August 8, 2011 Cross-State Air Pollution Rule (CSAPR) (76 FR 48208), designed to address both the 1997 and 2006 $PM_{2.5}$ standards, as well as the 1997 and 2008 ozone standards.

Michigan's March 23, 2017 submission indicates that the implementation of the Michigan SIP for SO_2 will result in SO_2 reductions of over 11,000 tons per year through permit changes and Rule 336.1430 in the Michigan Administrative Code (Michigan R 336.1430). The submission indicates that rules R 336.1301 through R 336.1374 in the Michigan SIP limit emissions of particulate matter throughout the state. The submission indicates that rules R 336.1401 through R 336.1420 and R 336.1407 reduce SO_2 emissions throughout the state, and that rule R 336.1430 reduces SO_2 emissions in the Detroit area. The submission indicates that rules R 336.1801 through 336.1834 limit emissions of NO_2 throughout the state. In addition, Michigan's submission indicates that power plant retirements across the state have resulted in reductions of approximately 9,800 tons of NO_X and 30,990 tons of SO_2 per year.

Michigan's submittal also contains a technical analysis of its interstate transport of pollution relative to the 2012 annual $PM_{2.5}$ NAAQS. The technical analysis studies Michigan sources' contribution to monitored $PM_{2.5}$ air quality values in other states and whether Michigan would need to take further steps to decrease its emissions to (and therefore impacts on) those areas. Michigan's technical analysis considers CSAPR rule implementation, EPA guidance and memoranda, and other factors such as meteorology and state-wide emissions inventories. Michigan did not focus on potential contribution to areas EPA identified as not attaining the 2012 annual $PM_{2.5}$ NAAQS based on monitor data in Alaska, California, Idaho, Nevada, or Hawaii.

The distance between Michigan these areas, coupled with the prevailing wind directions, leads EPA to propose to find that Michigan will not contribute significantly to any of the potential receptors in those states.

With respect to Illinois, EPA's source apportionment modeling in our original CSAPR analysis predicts that Michigan's emissions impact Illinois monitors. Michigan found, and our review confirmed, that despite the fact that Michigan emissions potentially contribute to increases in $PM_{2.5}$ levels monitored in Illinois, all areas in Illinois are attaining the 2012 annual $PM_{2.5}$ NAAQS based on 2015–2017 data.

EPA considered available data from monitors in Illinois for its analysis of Michigan's submittal. As shown in Table 1, Illinois is now meeting the standard throughout the state.

TABLE 1—ILLINOIS ANNUAL $PM_{2.5}$ DESIGN VALUES FOR 2015–2017 DESIGN PERIOD

Local site name	Monitoring site	2015–2017 Design value ($\mu g/m^3$)
Alsip	17–031–0001	9.5
Washington High School	17–031–0022	9.3
Mayfair Pump Station	17–031–0052	9.1
Springfield Pump Station	17–031–0057	10.2
Com Ed	17–031–0076	9.5
Schiller Park	17–031–3103	10.5
Summit	17–031–3301	9.7
Des Plaines	17–031–4007	9.4
Northbrook	17–031–4201	8.4
Cicero	17–031–6005	10.0
Naperville	17–043–4002	8.3
Elgin	17–089–0003	8.3
Aurora	17–089–0007	8.3
Cary	17–111–0001	+8.2
Joliet	17–197–1002	7.9
Braidwood	17–197–1011	7.9
Jerseyville	17–083–0117	+8.8
Granite City	17–119–1007	9.7
Alton	17–119–2009	8.8
Wood River	17–119–3007	8.7
Houston	17–157–0001	8.5
East St. Louis	17–163–0010	9.8
Champaign	17–019–0006	7.9
Bondville	17–019–1001	7.8
Knight Prairie	17–065–0002	8.2
Normal	17–113–2003	8.0
Decatur	17–115–0013	8.4
Peoria	17–143–0037	8.2
Rock Island	17–161–3002	8.1
Springfield	17–167–0012	8.2
Rockford	17–201–0013	8.3

+ Data incomplete.

Illinois' air quality trends reflect what is shown across the nation: A general downward trend in ambient air concentrations, including sites that Michigan analyzed in its submittal. During the last valid design period, only three Illinois counties reported 2008–2010 annual $PM_{2.5}$ design values above the NAAQS: Cook, Madison, and Saint Clair counties. In Cook County, the 2008–2010 annual design value was 13.0 micrograms per cubic meter ($\mu g/m^3$), and the annual mean values have trended downward. As shown in the table above, these areas are now meeting the NAAQS for the 2015 to 2017 design period. Therefore, EPA expects that all counties in Illinois will attain and maintain the $PM_{2.5}$ NAAQS without the need for additional $PM_{2.5}$ reductions in Michigan, and for this reason, we propose to find that Michigan will not contribute significantly to nonattainment or maintenance problems in Illinois.

Michigan found, and our review confirmed, that despite the fact that Michigan emissions potentially increase $PM_{2.5}$ levels monitored in areas in other states, all of those areas are attaining the 2012 annual $PM_{2.5}$ NAAQS based on 2014–2016 data. Michigan found, and our review confirmed, that despite the fact that Michigan emissions potentially increase $PM_{2.5}$ levels monitored in Pennsylvania, all areas in Pennsylvania except for Allegheny County are attaining the 2012 annual $PM_{2.5}$ NAAQS based on 2015–2017 data.

The modeling information contained in EPA's 2016 memorandum shows that one monitor in Allegheny County, PA (the Liberty monitor, 420030064) may have a maintenance issue in 2017, but is projected to both attain and maintain the NAAQS by 2025. A linear interpolation of the modeled design values to 2021 shows that the monitor is likely to both attain and maintain the standard by 2021. Emissions and air quality data trends help to corroborate this interpolation.

Over the last decade, local and regional emissions reductions of primary $PM_{2.5}$, sulfur dioxide (SO_2), and nitrogen oxide (NO_X), have led to large reductions in annual $PM_{2.5}$ design values in Allegheny County, Pennsylvania. In 2007, all of Allegheny County's $PM_{2.5}$ monitors exceeded the level of the 2012 annual $PM_{2.5}$ NAAQS (the 2005–2007 annual average design values ranged from 12.9–19.8 $\mu g/m^3$, as shown in Table 3). The 2015–2017 annual average $PM_{2.5}$ design values now show that only one monitor (Liberty, at 13.0 $\mu g/m^3$) exceeds the health-based annual $PM_{2.5}$ NAAQS of 12.0 $\mu g/m^3$.

TABLE 3—$PM_{2.5}$ ANNUAL DESIGN VALUES IN $\mu g/m^3$

Monitor	2005–2007	2006–2008	2007–2009	2008–2010	2009–2011	2010–2012	2011–2013	2012–2014	2013–2015	2014–2016	2015–2017
Avalon	.....	.....	.....	*16.3	*14.7	13.4	11.4	10.6	10.6	*10.4	*10.2
Lawrenceville	15.0	14.0	13.1	12.2	11.6	11.1	10.3	10.0	9.7	9.5	9.2
Liberty	19.8	18.3	17.0	16.0	15.0	14.8	13.4	13.0	12.6	12.8	13.0

TABLE 3—$PM_{2.5}$ ANNUAL DESIGN VALUES IN µg/m^3—Continued

Monitor	2005–2007	2006–2008	2007–2009	2008–2010	2009–2011	2010–2012	2011–2013	2012–2014	2013–2015	2014–2016	2015–2017
South Fayette ..	12.9	*11.8	11.7	11.1	11.0	10.5	9.6	9.0	8.8	*8.5	*8.4
North Park	*13.0	*12.3	*11.3	*10.1	9.7	9.4	8.8	8.5	8.5	*8.2	*8.2
Harrison	15.0	14.2	13.7	13.0	12.4	*11.7	10.6	10.0	9.8	9.8	9.8
North Braddock	16.2	15.2	14.3	13.3	12.7	12.5	*11.7	11.4	11.2	11.0	10.8
Parkway East Near-Road ...	.....	.....	.....	.....	.....	.....	.....	.....	.....	*10.6	*10.6
Clairton	15.3	14.3	13.2	12.4	*11.5	*10.9	*9.8	9.5	9.8	*9.8	*9.8

*Value does not contain a complete year's worth of data.

The Liberty monitor is already close to attaining the NAAQS, and expected emissions reductions in the next three years will lead to additional reductions in measured $PM_{2.5}$ concentrations. There are both local and regional components to the measured $PM_{2.5}$ levels in Allegheny County and the greater Pittsburgh area. Previous CSAPR modeling showed that regional emissions from upwind states, particularly SO_2 and NO_X emissions, contribute to $PM_{2.5}$ nonattainment at the Liberty monitor. In recent years, large SO_2 and NO_X reductions from power plants have occurred in Pennsylvania and states upwind from the Greater Pittsburgh region. Based on existing CSAPR budgets, Pennsylvania's energy sector emissions of SO_2 will have decreased 166,000 tons between 2015–2017 as a result of CSAPR implementation. This is due to both the installation of emissions controls and retirements of electric generating units (EGUs).

Between 2011 and 2016, 27.4 gigawatts of coal-fired EGUs have retired in Pennsylvania and the closest upwind states (West Virginia, Ohio, Kentucky, Indiana, Illinois, and Michigan) according to the Energy Information Administration's Preliminary Monthly Electric Generator Inventory, April 2017 (form EIA–860M, at *https://www.eia.gov/electricity/data/eia860m/xls/april_generator2017.xlsx*). In addition, between 2017 and 2021, an additional 8.8 gigawatts of coal-fired EGUs are expected to retire in the same upwind states. This includes large EGUs such as JM Stuart in Ohio (2,308 megawatts [MW]), Killen Station in Ohio (600 MW), WH Sammis in Ohio (720 MW), Michigan City in Indiana (469 MW), Will County in Illinois (510 MW), Baldwin Energy Complex in Illinois (576 MW), Paradise in Kentucky (1,230 MW), and Baily in Indiana (480 MW). These regional coal unit retirements will lead to further emissions reductions which will help ensure that Alleghany County monitors will not have nonattainment or maintenance issues by 2021.

In addition to regional emissions reductions and plant closures noted above, additional local reductions in both direct $PM_{2.5}$ and SO_2 emissions are also expected to occur and should also contribute to further declines in Allegheny County's $PM_{2.5}$ monitor concentrations. For example, significant SO_2 reductions will occur at U.S. Steel's integrated steel mill facilities in southern Allegheny County due to reductions required via federally-enforceable permits issued by Allegheny County to support its attainment plan submitted to meet requirements in CAA section 172(c) for the 1-hr SO_2 NAAQS. Reductions are expected by October 2018 largely due to declining sulfur content in the Clairton Coke Work's coke oven gas (COG) due to upgraded controls. Because this COG is burned at U.S. Steel's Clairton Coke Works, Irvin Mill, and Edgar Thompson Steel Mill, these reductions in sulfur content should contribute to much lower $PM_{2.5}$ emissions from precursors in the immediate future after October 4, 2018 as SO_2 is a precursor to $PM_{2.5}$. Additionally, improvement in SO_2 removal efficiency due to an upgrade in the Bruce Mansfield Power Plant's flue gas desulfurization (FGD) units expected by October 2018 should also help reduce precursor emissions from neighboring Beaver County, Pennsylvania. The Allegheny County and Beaver County SO_2 SIP submissions, which EPA is reviewing pursuant to CAA requirements, also discuss expected lower SO_2 emissions in the Allegheny County area resulting from reduced sulfur content requirements in vehicle fuels, reductions in general emissions due to declining population in the Greater Pittsburgh region, and several shutdowns of significant emitters of SO_2 in Allegheny County.

Projected power plant closures and additional emissions controls in Pennsylvania and upwind states will help further reduce both direct $PM_{2.5}$ and $PM_{2.5}$ precursors. Regional emission reductions will continue to occur from current on-the-books Federal and state regulations such as the Federal on-road and non-road vehicle programs, and various rules for major stationary emissions sources.

In addition to regional emissions reductions and plant closures, additional local reductions to both direct $PM_{2.5}$ and SO_2 emissions are expected to occur and should also contribute to further declines in Allegheny County's $PM_{2.5}$ monitor concentrations. For example, significant SO_2 reductions have recently occurred at US Steel's integrated steel mill facilities in southern Allegheny County as part of a 1-hr SO_2 NAAQS SIP.[1] Reductions are largely due to declining sulfur content in the Clairton Coke Work's COG. Because this COG is burned at US Steel's Clairton Coke Works, Irvin Mill, and Edgar Thompson Steel Mill, these reductions in sulfur content should contribute to much lower $PM_{2.5}$ precursor emissions in the immediate future. The Allegheny SO_2 SIP also projects lower SO_2 emissions resulting from vehicle fuel standards, reductions in general emissions due to declining population in the Greater Pittsburgh region and several shutdowns of significant sources of emissions in Allegheny County.

EPA modeling projections, the recent downward trend in local and upwind emissions reductions, the expected continued downward trend in emissions between 2018 and 2021, and the downward trend in monitored $PM_{2.5}$ concentrations all indicate that the Liberty monitor will attain and be able to maintain the 2012 annual $PM_{2.5}$ NAAQS by 2021.

With respect to Florida, in the CSAPR modeling analysis for the 1997 $PM_{2.5}$ NAAQS, Florida did not have any potential nonattainment or maintenance receptors identified for the 1997 or 2006 $PM_{2.5}$ NAAQS. At this time, it is anticipated that this trend will continue, however, as there are ambient monitoring data gaps in the 2009–2013 data that could have been used to identify potential $PM_{2.5}$ nonattainment and maintenance receptors for Miami/Dade, Gilchrist, Broward and Alachua

[1] *http://www.achd.net/air/publichearing2017/SO2_2010_NAAQS_SIP_5-1-2017.pdf.*

counties in Florida, the modeling analysis of potential receptors was not complete for these counties. However, the most recent ambient data (2015–2017) for these counties indicates design values well below the level of the 2012 annual $PM_{2.5}$ NAAQS. In addition, the highest value for these observed monitors is 8.0 μg/m³ at the Hillsborough County monitor (12–057–3002), which is well below the NAAQS. This is also consistent with historical data: Complete and valid design values in the 2006–2008, 2007–2009 and/or 2008–2010 periods for these counties were all well below the 2012 annual $PM_{2.5}$ NAAQS. This is also consistent with historical data: Complete and valid design values in the 2006–2008 and/or 2007–2009 periods for these counties were well below the 2012 annual $PM_{2.5}$ NAAQS. For these reasons, we find that none of the counties in Florida with monitoring gaps between 2009–2013 should be considered either nonattainment or maintenance receptors for the 2012 annual $PM_{2.5}$ NAAQS. For these reasons, we propose to find that emissions from Michigan will not significantly contribute to nonattainment or interfere with maintenance of the 2012 annual $PM_{2.5}$ NAAQS in Florida. We find further support in the fact that EPA's source apportionment modeling predicting state impacts on downwind monitors in 2012 under the base case scenario in our original CSAPR analysis, showing little impact from Michigan to any of Florida's counties.

The conclusions of Michigan's analysis are consistent with EPA's expanded review of its March 23, 2017 submittal. All areas that Michigan sources potentially contribute to are expected to attain and maintain the 2012 annual $PM_{2.5}$ NAAQS, and as demonstrated in its submittal, Michigan will not contribute to projected nonattainment or maintenance issues at any sites in 2021. Michigan's analysis shows that through permanent and enforceable measures currently contained in its SIP, and other emissions reductions occurring in Michigan and in other states, monitored $PM_{2.5}$ air quality in all identified areas that Michigan sources may impact will continue to improve, and that no further measures are necessary to satisfy Michigan's responsibilities under CAA section 110(a)(2)(D)(i)(I). Therefore, EPA is proposing that prongs one and two of the interstate pollution transport element of Michigan's infrastructure SIP are approvable.

IV. What action is EPA taking?

EPA is proposing to approve a portion of Michigan's March 23, 2017, submittal certifying that the current Michigan SIP is sufficient to meet the required infrastructure requirements under CAA section 110(a)(2)(D)(i)(I), specifically prongs one and two, as set forth above. EPA is requesting comments on the proposed approval.

V. Statutory and Executive Order Reviews

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

List of Subjects in 40 CFR Part 52

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

Dated: October 29, 2018.

Cathy Stepp,

Regional Administrator, Region 5.

[FR Doc. 2018–24817 Filed 11–13–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–HQ–OAR–2018–0226; FRL–9986–44–OAR]

RIN 2060–AT97

Determinations of Attainment by the Attainment Date, Extensions of the Attainment Date, and Reclassification of Several Areas Classified as Moderate for the 2008 Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing three actions related to the attainment date for 11 areas classified as ''Moderate'' for the 2008 ozone National Ambient Air Quality Standards (NAAQS). First, the agency is proposing to determine that two areas—the Baltimore, Maryland, and Mariposa County, California, nonattainment areas—attained the standard by the July 20, 2018, attainment date. Second, the agency is proposing to grant requests for a 1-year attainment date extension to two other areas: Denver-Boulder-Greeley-Ft. Collins-Loveland, Colorado, and Sheboygan County, Wisconsin. Third,

the agency is proposing to determine that seven areas failed to attain the standards by the attainment date: Chicago-Naperville, Illinois-Indiana-Wisconsin; Dallas-Fort Worth, Texas; Greater Connecticut, Connecticut; Houston-Galveston-Brazoria, Texas; Nevada County (Western part), California; New York-North New Jersey-Long Island, Connecticut-New York-New Jersey; and San Diego County, California. The effect of failing to attain by the attainment date is that such areas will be reclassified by operation of law to ''Serious'' upon the effective date of the final reclassification notice. Consequently, the responsible state air agencies must submit State Implementation Plan (SIP) revisions required to satisfy the statutory and regulatory requirements for Serious areas for the 2008 ozone NAAQS. The EPA is proposing deadlines for submittal of those SIP revisions and implementation of the related control requirements. This proposed action is necessary to fulfill the EPA's statutory obligation to determine whether ozone nonattainment areas attained the NAAQS by the attainment date, and, within 6 months of the attainment date, publish a notice in the **Federal Register** identifying each area that is determined as having failed to attain and identifying the reclassification.

DATES:

Comments. Written comments must be received on or before December 14, 2018.

Public Hearings. If anyone contacts us requesting a public hearing on or before November 29, 2018, we will hold a public hearing. Additional information about the hearing, if requested, will be published in a subsequent **Federal Register** document. Please refer to **SUPPLEMENTARY INFORMATION** for additional information on the comment period and the public hearing.

ADDRESSES: *Comments:* Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2018–0226, at *https://www.regulations.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, 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/comments.html*.

Public Hearing. If anyone contacts us requesting a public hearing on or before November 29, 2018, we will hold a public hearing. Please refer to **SUPPLEMENTARY INFORMATION** for additional information on the comment period and the public hearing.

FOR FURTHER INFORMATION CONTACT: For further general information on this proposed rule, contact Ms. Virginia Raps, Office of Air Quality Planning and Standards (OAQPS), Air Quality Policy Division, U.S. Environmental Protection Agency, Mail Code: C539–01, Research Triangle Park, NC 27711, telephone (919) 541–4383; fax number: (919) 541–5315; email address: *raps.virginia@epa.gov*. To request a public hearing or information pertaining to a public hearing on this notice, contact Ms. Pamela Long at (919) 541–0641 or *long.pam@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Entities potentially directly affected by this proposed action include state, local, and tribal air pollution control or management agencies. Individuals and entities potentially indirectly affected by this action include owners and operators of sources that emit volatile organic compounds (VOC) and nitrogen oxides (NO_X) emissions, which contribute to ground-level ozone formation within the ozone nonattainment areas that are the subject of this proposed notice.

B. What should I consider as I prepare my comments for the EPA?

1. Submitting CBI. Do not submit this information to the EPA through *https://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, mark the outside of the digital storage media as CBI and then identify electronically within the digital storage media 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 to be 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 Code of Federal Regulations (CFR) part 2 ''Public Information.''

2. Tips for Preparing Your Comments. When submitting comments, remember to:

a. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

b. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a CFR part or section number.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow reproduction of your method and the results.

f. Provide specific examples to illustrate your concerns and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified under **DATES** in this notice.

C. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this notice will be posted at *https://www.epa.gov/ozone-pollution*.

D. What information should I know about a possible public hearing?

To request a public hearing or information pertaining to a public hearing on this notice, contact Ms. Pamela Long at (919) 541–0641 or *long.pam@epa.gov* before 5 p.m. on or before November 29, 2018. If requested, further details concerning a public hearing for this proposed rule will be published in a separate **Federal Register** document. For updates and additional information on a public hearing, please check the EPA's website for this rulemaking at *https://www.epa.gov/ozone-pollution*.

E. How is this preamble organized?

The information and proposals presented in this notice are organized as follows:

II. Overview and Basis of Proposal

A. Overview of Proposal

The EPA Administrator is required to determine whether areas designated nonattainment for an ozone NAAQS attained the standard by the applicable attainment date, and to take certain steps for areas that failed to attain.[1] For a concentration-based standard, such as the 2008 ozone NAAQS,[2] a determination of attainment [3] is based on a nonattainment area's design value.[4]

The 2008 ozone NAAQS are met at an ambient monitoring site when the design value does not exceed 0.075 parts per million (ppm). For areas classified as Moderate nonattainment for the 2008 ozone NAAQS, the attainment date is July 20, 2018. Because the design value is based on the three most recent, complete calendar years of data, attainment must occur no later than December 31 of the year prior to the attainment date (*i.e.,* December 31, 2017, in the case of Moderate nonattainment areas for the 2008 ozone NAAQS). As such, the EPA's proposed determinations for each area are based upon the complete, quality-assured and certified ozone monitoring data from calendar years 2015, 2016, and 2017.

All monitors in an area must be considered when determining if the area attains the NAAQS. To make the determination that an area attains the NAAQS, each monitor must have a valid [5] design value meeting the standard. If one or more monitors in an area have a design value that exceeds the standard, the area does not attain the NAAQS.

This proposed action addresses 11 of the 14 nonattainment areas that were classified as Moderate for the 2008 ozone NAAQS as of the Moderate area attainment date of July 20, 2018, that have not already been reclassified to Serious.[6] The remaining three areas will be addressed in separate actions:

(1) On September 27, 2016, May 17, 2018, and July 17, 2018, the Arizona Department of Environmental Quality submitted to the EPA for review exceptional events demonstrations for the Phoenix-Mesa, Arizona, Moderate nonattainment area.[7] Actions taken by the EPA on the demonstrations may affect a determination of attainment by the attainment date for the area. The proposed action to determine attainment for the Phoenix-Mesa, Arizona, area by the attainment date for the Moderate 2008 ozone NAAQS will, therefore, be addressed in a separate **Federal Register** notice.

(2) The Imperial County, California, Moderate nonattainment area is not included in this proposed action. On July 9, 2018, the California Air Resources Board submitted the ''Imperial County Clean Air Act Section 179B(b) Retrospective Analysis for the 75 ppb 8-Hour Ozone Standard,'' which may affect a determination of attainment by the attainment date for this area.[8] The proposed action to determine attainment for the Imperial County, California, area by the attainment date for the Moderate 2008 ozone NAAQS will be addressed in a separate **Federal Register** notice.

(3) The Moderate nonattainment area for the Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation based in California is not included in this proposed action because the EPA has not yet finalized a 2015–2017 design value for the nonattainment area.

Table 1 provides a summary of the design values and the EPA's proposed air quality-based determinations for the 11 Moderate areas addressed in this action.

[1] *See* CAA section 181(b)(2).

[2] Because the 2008 primary and secondary NAAQS for ozone are identical, for convenience, the EPA refers to them together as ''the 2008 ozone NAAQS.''

[3] The criteria for determining if an area is attaining the 2008 ozone NAAQS are set out in 40 CFR 50.15 and 40 CFR part 50, Appendix P.

[4] A design value is a statistic used to compare data collected at an ambient air quality monitoring site to the applicable NAAQS to determine compliance with the standard. The design value for the 2008 ozone NAAQS is the 3-year average of the annual fourth highest daily maximum 8-hour average ozone concentration. The design value is calculated for each air quality monitor in an area and the area's design value is the highest design value among the individual monitoring sites in the area.

[5] Design values attaining the 2008 ozone NAAQS must also meet minimum data completeness requirements specified in 40 CFR part 50, Appendix P to be considered valid.

[6] The Kern County (Eastern Kern), California, nonattainment area was reclassified from Moderate to Serious effective August 6, 2018, in response to a voluntary reclassification request submitted by the state of California (*see* 83 FR 31334, July 5, 2018). SIP revisions addressing Serious area requirements for Eastern Kern County will be due on August 6, 2019, and the area must attain the 2008 ozone standards by July 20, 2021.

[7] CAA section 319(b) defines an exceptional event as an event that (i) affects air quality; (ii) is not reasonably controllable or preventable; (iii) is an event caused by human activity that is unlikely to recur at a particular location or a natural event; and (iv) is determined by the Administrator through process established in regulation to be an exceptional event. ADEQ submitted its demonstration pursuant to 40 CFR 50.14, which establishes the process by which states may request that the Administrator determine that air quality monitoring data showing exceedances or violations of the NAAQS that are directly due to an exceptional event may be excluded from regulatory determinations, including whether a nonattainment area has met the NAAQS by its deadline.

[8] CAA section 179B(b) provides that where a state demonstrates to the Administrator's satisfaction that an ozone nonattainment area would have attained the NAAQS by the applicable attainment date but for emissions emanating from outside the United States, that area shall not be subject to the mandatory reclassification provision, CAA section 181(b)(2). Note that the statute cites 42 U.S.C. 7511(a)(2), but that provision establishes ozone attainment deadlines for severe areas under the 1-hour standard. The EPA has long interpreted the citation in CAA section 179B(b) to be a scrivener's error that was supposed to refer to 42 U.S.C. 7511(b)(2), which refers to consequences for failure to attain by the attainment date.

TABLE 1—2008 OZONE NAAQS MODERATE NONATTAINMENT AREA EVALUATION SUMMARY

2008 NAAQS nonattainment area	2015–2017 Design value (ppm)	2008 NAAQS attained by the Moderate attainment date	2017 4th Highest daily maximum 8-hr average (ppm)	Area failed to attain 2008 NAAQS but eligible for 1-year attainment date extension based on 2017 4th highest daily maximum 8-hr average ≤0.075 ppm
Baltimore, MD	0.075	Attained	Not applicable	Not applicable.
Chicago-Naperville, IL-IN-WI	0.078	Failed to Attain	0.079	No.
Dallas-Fort Worth, TX	0.079	Failed to Attain	0.077	No.
Denver-Boulder-Greeley-Ft. Collins-Loveland, CO.	0.079	Failed to Attain	0.075	Yes.
Greater Connecticut, CT	0.076	Failed to Attain	0.078	No.
Houston-Galveston-Brazoria, TX.	0.081	Failed to Attain	0.079	No.
Mariposa County, CA	0.075	Attained	Not applicable	Not applicable.
Nevada County (Western part), CA.	0.087	Failed to Attain	0.090	No.
New York-N. New Jersey-Long Island, CT-NJ-NY.	0.083	Failed to Attain	0.086	No.
San Diego County, CA	0.084	Failed to Attain	0.090	No.
Sheboygan County, WI	0.080	Failed to Attain	0.075	Yes.

The data used to calculate both the 2015–2017 design values and the 2017 fourth highest daily maximum 8-hour averages are provided in the technical support document (TSD) found in the docket for this proposed action.[9]

The EPA proposes to find that the Baltimore, Maryland, and Mariposa County, California, Moderate nonattainment areas attained by the attainment date as evidenced by the 2015–2017 design values presented in Table 1, which do not exceed 0.075 ppm. The EPA proposes to grant a 1-year attainment date extension for the Denver-Boulder-Greeley-Ft. Collins-Loveland, Colorado, and Sheboygan County, Wisconsin, nonattainment areas. Colorado and Wisconsin have complied with all requirements and commitments pertaining to the area in the applicable implementation plan,[10] and demonstrated that the 2017 fourth highest daily maximum 8-hour average ozone concentrations do not exceed 0.075 ppm. Accordingly, the EPA proposes to establish a new attainment date of July 20, 2019, for these areas.

The EPA proposes to determine that seven Moderate areas with a 2015–2017 design value greater than 0.075 ppm did not attain by the attainment date and do not qualify for a 1-year attainment date extension under CAA section 181(a)(5), as interpreted by the EPA in 40 CFR 51.1107. If the EPA determines that a nonattainment area classified as Moderate failed to attain by the attainment date, the EPA shall publish the identity of each such area in the **Federal Register** no later than 6 months following the attainment date and identify the reclassification as required under CAA section 181(b)(2)(B).

Furthermore, as required under CAA section 181(b)(2)(A), if the EPA finalizes the determinations that these seven areas failed to attain by the attainment date, they will be reclassified to Serious by operation of law.[11] The reclassified areas will then be subject to the Serious area requirement to attain the 2008 ozone NAAQS as expeditiously as practicable, but not later than July 20, 2021.

Once reclassified as Serious, the relevant states must submit to the EPA the SIP revisions for these areas that satisfy the statutory and regulatory requirements applicable to Serious areas established in CAA section 182(c) and in the 2008 Ozone NAAQS SIP Requirements Rule (*see* 80 FR 12264, March 6, 2015).[12] However, the deadlines specified in section 182(c) have passed for plan submissions applicable to areas originally classified as Serious on July 20, 2012. For instance, 40 CFR 51.1108 established the deadline for Serious-area attainment demonstrations to be 48 months after the effective date of nonattainment designation, or July 20, 2016, a date that has passed and cannot be met by areas reclassified in this notice. Under CAA section 182(i), reclassified areas are required to meet the requirements associated with their newly reclassified status according to the schedules prescribed in connection with such requirements, except that the Administrator may adjust applicable deadlines (other than attainment dates) to the extent such adjustment is ''necessary or appropriate to assure consistency among the required submissions.'' Because these dates have already passed, the EPA is using its discretion granted under CAA section 182(i) to propose adjusting the deadlines for submitting SIP revisions that would otherwise apply under CAA section 182(c).

As discussed in Section III.D of this notice, the EPA proposes that the SIP revisions, not including the Reasonably Available Control Technology (RACT) SIP revision required under CAA sections 182(b)(2) and 182(f), will be due 12 months after the effective date of the final reclassification notice. The EPA also discusses its proposed deadlines, and solicits comments on alternative due dates and deadlines, for RACT SIP revisions and RACT

[9] ''Technical Support Document Regarding Ozone Monitoring Data—Determinations of Attainment, 1-Year Attainment Date Extensions, and Reclassifications for Moderate Areas under the 2008 8-Hour Ozone National Ambient Air Quality Standards (NAAQS),'' Docket ID No. EPA–OAR–2018–0226.

[10] *See* CAA section 181(a)(5).

[11] None of the 2015–2017 design values shown in Table 1 for any of the seven areas proposed to be reclassified as Serious equals or exceeds 0.113 ppm, which is the threshold for reclassifying an area to Severe under CAA section 181(b)(2)(A) and 40 CFR 51.1103. Therefore, none of these areas are required to be reclassified by operation of law to Severe or Extreme.

[12] In *South Coast Air Quality Mgmt. Dist.* v. *EPA,* 882 F.3d 1138 (DC Cir. 2018), the D.C. Circuit granted in part and denied in part petitions for review challenging the 2008 ozone NAAQS SIP Requirements Rule. Among other things, the D.C. Circuit vacated the portion of the rule that allowed states to select an alternative baseline year (*i.e.,* a year other than 2011) for purposes of calculating reasonable further progress. *See id.* at 882 F.3d at 1152–53. South Coast Air Quality Management District petitioned the Court for rehearing on this issue and the Court denied that petition. *South Coast,* No. 15–1123, Order No. 1750751 (DC Cir. September 14, 2018).

implementation for the newly reclassified Serious areas.

B. What is the background for the proposed actions?

On March 12, 2008, the EPA issued its final action to revise the NAAQS for ozone to establish new 8-hour standards (73 FR 16436, March 27, 2008). In that action, the EPA promulgated identical revised primary and secondary ozone standards designed to protect public health and welfare that specified an 8-hour ozone level of 0.075 ppm. Specifically, the standards require that the 3-year average of the annual fourth highest daily maximum 8-hour average ozone concentration may not exceed 0.075 ppm. The 2008 ozone NAAQS retain the same general form and averaging time as the 0.08 ppm ozone NAAQS set in 1997, so that the only difference is the more protective level of 0.075 ppm.

Effective on July 20, 2012, the EPA designated 46 areas throughout the country as nonattainment for the 2008 ozone NAAQS (77 FR 30088, May 21, 2012, and 77 FR 34221, June 11, 2012). In a separate action, the EPA assigned classification thresholds and attainment dates based on the severity of each nonattainment area's ozone problem, determined by the area's design values (77 FR 30160, May 21, 2012).[13] In that rule, the EPA established the attainment date for Moderate and Serious nonattainment areas as 6 years and 9 years, respectively, from the effective date of the final designation, July 20, 2012. Thus, the attainment date for Moderate nonattainment areas for the 2008 ozone NAAQS was July 20, 2018, and the attainment date for Serious areas is July 20, 2021. In a separate action effective on June 3, 2016, the EPA reclassified 11 of the 36 Marginal areas to Moderate for failing to attain the NAAQS by the July 20, 2015, Marginal attainment date (81 FR 26697, May 4, 2016). In that action, two Marginal areas received 1-year attainment date extensions. However, these two areas were later reclassified to Moderate for failing to attain the NAAQS by the July 20, 2016, extended Marginal area attainment date (Houston-Galveston-Brazoria, Texas—81 FR 90207, December 14, 2016; Sheboygan County, Wisconsin—81 FR 91841 December 19, 2016).

C. What is the statutory authority for the proposed actions?

The statutory authority for the actions proposed in this notice is provided by the CAA, as amended (42 U.S.C. 7401 *et seq.*). Relevant portions of the CAA include, but are not necessarily limited to, sections 181(a)(5) and 181(b)(2).

By way of background, CAA section 107(d) provides that when the EPA establishes or revises a NAAQS, the agency must designate areas of the country as nonattainment, attainment, or unclassifiable based on whether they are not meeting (or contributing to air quality in a nearby area that is not meeting) the NAAQS, meeting the NAAQS or cannot be classified as meeting or not meeting the NAAQS, respectively. Subpart 2 of part D of title I of the CAA governs the classification, state planning and emissions control requirements for any areas designated as nonattainment for a revised primary ozone NAAQS. In particular, CAA section 181(a)(1) requires each area designated as nonattainment for a revised ozone NAAQS to be ''classified'' at the same time as the area is designated based on the extent of the ozone problem in the area (as determined based on the area's ''design value,'' which represents air quality in the area for the most recent 3 years). Classifications for ozone nonattainment areas range from ''Marginal'' to ''Extreme'' based on the severity of the area's air quality problem. CAA section 182 provides the specific attainment planning and additional requirements that apply to each ozone nonattainment area based on its classification. CAA section 182, as interpreted by the EPA's implementing regulations at 40 CFR 51.1108—1117, also establishes the timeframes by which air agencies must submit and implement SIP revisions to satisfy the applicable attainment planning elements, and the timeframes by which nonattainment areas must attain the 2008 ozone NAAQS. However, the EPA is proposing in Section III.D of this notice to adjust the deadlines for SIP revisions for any newly classified Serious nonattainment areas, as provided for in CAA section 182(i), including deadlines for RACT SIP revisions and RACT implementation.

Section 181(b)(2)(A) of the CAA requires that within 6 months following the applicable attainment date, the EPA shall determine whether an ozone nonattainment area attained the ozone standard based on the area's design value as of that date. Section 181(a)(5) of the CAA gives the EPA the discretion to grant a 1-year extension of the attainment date upon application by any state if: (1) The state has complied with all requirements and commitments pertaining to the area in the applicable implementation plan; and (2) no more than one measured exceedance of the NAAQS for ozone has occurred in the area preceding the extension year. The EPA may grant a second 1-year extension if these same criteria are met by the end of the first extension year.

In 40 CFR 51.1107, the EPA interpreted CAA section 181(a)(5)(B)'s exceedance-based air quality requirement of the extension criteria for purposes of a concentration-based standard like the 2008 8-hour ozone NAAQS. For purposes of determining an area's eligibility for an attainment date extension for the 2008 ozone NAAQS, the EPA has interpreted the criteria of CAA section 181(a)(5)(B) to mean that an area is eligible for a 1-year extension of the attainment date if it fourth highest daily maximum 8-hour value for the attainment year does not exceed the level of the standard.[14]

In the event an area fails to attain the ozone NAAQS by the applicable attainment date, CAA section 181(b)(2)(A) requires the EPA to make the determination that an ozone nonattainment area failed to attain the ozone standard by the applicable attainment date, and requires the area to be reclassified by operation of law to the higher of: (1) the next higher classification for the area, or (2) the classification applicable to the area's design value as of the determination of failure to attain.[15] Section 181(b)(2)(B) of the CAA requires the EPA to publish the determination of failure to attain and accompanying reclassification in the **Federal Register** no later than 6 months after the attainment date, which in the case of the Moderate nonattainment areas considered in this proposal would be no later than January 20, 2019.

Once an area is reclassified as a result of this action, each state is required to submit certain SIP revisions. The SIP

[13] Three areas were initially classified Moderate for the 2008 ozone NAAQS: Baltimore, Maryland, Dallas-Ft. Worth, Texas, and the Pechanga Reservation, located in southern California. Classifications for the remaining areas (of the 46 areas designated nonattainment for the 2008 ozone NAAQS) were 36 Marginal, two Serious, three Severe, and two Extreme areas.

[14] *See* 40 CFR 51.1107 pertaining to determining eligibility under CAA section 181(a)(5)(B) for the first and the second 1-year attainment date extensions for the 2008 ozone NAAQS. For the second 1-year extension, the area's fourth highest daily maximum 8-hour average concentration of ozone cannot not exceed 0.075 ppm when averaged over both the original attainment year and the first extension year.

[15] All nonattainment areas named in this notice that failed to attain by the attainment date would be classified to the next highest classification of Serious. None of the affected areas has a design value that would otherwise place an area in a higher classification (*i.e., see* CAA section 181(b)(2)(A) reference to Severe and Extreme areas).

revisions are intended to, among other things, demonstrate how the area will attain the NAAQS as expeditiously as practicable, but no later than July 20, 2021, the attainment date for Serious nonattainment areas for the 2008 ozone NAAQS. According to CAA section 182(i), each state containing an ozone nonattainment area reclassified as Serious under CAA section 181(b)(2) shall submit SIP revisions consistent with the schedules contained in CAA section 182(b) for Moderate areas and 182(c) for Serious areas. However, CAA section 181(b)(2) provides that the EPA ''may adjust applicable deadlines (other than attainment dates) to the extent such adjustment is necessary or appropriate to assure consistency among the required submissions.'' In Section III.D of this notice, the EPA explains its proposal to adjust such deadlines.

D. How does the EPA determine whether an area has attained the 2008 ozone standards?

Under EPA regulations at 40 CFR part 50, Appendix P, the 2008 ozone NAAQS is attained at a site when the 3-year average of the annual fourth highest daily maximum 8-hour average ambient air quality ozone concentration does not exceed 0.075 ppm. This 3-year average is referred to as the ''design value.'' When the design value does not exceed 0.075 ppm at each ambient air quality monitoring site within the area, the area is deemed to be attaining the ozone NAAQS. The rounding convention in Appendix P dictates that concentrations shall be reported in ''ppm'' to the third decimal place, with additional digits to the right being truncated. Thus, a computed 3-year average ozone concentration of 0.076 ppm is greater than 0.075 ppm and would exceed the standard, but a design value of 0.0759 is truncated to 0.075 and attains the 2008 ozone NAAQS.

The EPA's determination of attainment is based upon data that have been collected and quality-assured in accordance with 40 CFR part 58 and recorded in the EPA's Air Quality System (AQS) database.[16] Ambient air quality monitoring data for the 3-year period preceding the attainment date (which for the 2008 ozone NAAQS Moderate areas is the period from 2015–2017) must meet the data completeness requirements in Appendix P.[17] The completeness requirements are met for the 3-year period at a monitoring site if daily maximum 8-hour average concentrations of ozone are available for at least 90 percent of the days within the ozone monitoring season, on average, for the 3-year period, and no single year has less than 75 percent data completeness.

III. What is the EPA proposing and what is the rationale?

The EPA is proposing this action to fulfill its statutory obligation under CAA section 181(b)(2) to determine whether 11 Moderate ozone nonattainment areas attained the 2008 ozone NAAQS as of the attainment date of July 20, 2018. The EPA evaluated air quality monitoring data submitted by the appropriate state and local air agencies to determine the attainment status of the 11 areas as of the applicable attainment date of July 20, 2018. This section describes the separate determinations and actions being taken in this proposed rule.

A. Determinations of Attainment by the Attainment Date

Two of the 11 nonattainment areas' monitoring sites had a design value that did not exceed 0.075 ppm based on the 2015–2017 data. Thus, the EPA proposes to determine, in accordance with CAA section 181(b)(2)(A) and the provisions of the SIP Requirements Rule (40 CFR 51.1103), that the two areas, Baltimore, Maryland, and Mariposa County, California, listed in Table 1, attained the standard by the applicable attainment date for Moderate nonattainment areas for the 2008 ozone NAAQS.

The EPA's Clean Data Policy,[18] as codified for the 2008 ozone NAAQS at 40 CFR 51.1118, suspends the requirements for states to submit certain attainment planning SIPs such as the attainment demonstration, including reasonably available control measures (RACM), reasonable further progress (RFP), and contingency measures for so long as an area continues to attain the standard. The EPA determined that Mariposa County, California, had attained the 2008 ozone standard and therefore suspended the requirements for the state to submit an attainment demonstration and associated RACM, RFP plans, contingency measures, and other attainment planning elements, in accordance with 40 CFR 51.1118.[19] The EPA proposes that, following a final determination of attainment by the attainment date for Mariposa County, California, these requirements would remain suspended. Similarly, the EPA also proposes that a final determination of attainment by the attainment date for Baltimore, Maryland, would continue to suspend the state's attainment planning requirements for that area in accordance with 40 CFR 51.1118, as the EPA previously determined the area attained the 2008 ozone NAAQS and issued a Clean Data Determination.[20]

These proposed determinations of attainment by the attainment date do not constitute formal redesignations to attainment as provided for under CAA section 107(d)(3). Redesignations to attainment require the states responsible for ensuring attainment and maintenance of the NAAQS to meet the requirements under CAA section 110 and part D, including submitting for EPA approval a maintenance plan to ensure continued attainment of the standard for 10 years following redesignation, as provided under CAA section 175A.

The EPA is soliciting comments on these proposed determinations of attainment by the applicable attainment date for the Baltimore, Maryland, and Mariposa County, California, areas. Further technical analysis supporting this proposed determination is located in the TSD for this rule, which is available in the docket for this action.

B. Extensions of Moderate Area Attainment Date

The EPA is proposing to grant a 1-year extension of the attainment date for two areas: Denver-Boulder-Greeley-Ft. Collins-Loveland, Colorado, and Sheboygan County, Wisconsin. Approval of the 1-year attainment date extensions is based on the states' compliance under CAA section 181(a)(5) as interpreted by the EPA in 40 CFR 51.1107. These areas meet the specific air quality criteria for the 1-year extension under 51.1107(a)(1), meaning the fourth highest daily maximum 8-hour average ozone concentration recorded during the attainment year

[16] The EPA maintains the AQS, a database that contains ambient air pollution data collected by the EPA, state, local, and tribal air pollution control agencies. The AQS also contains meteorological data, descriptive information about each monitoring station (including its geographic location and its operator) and data quality assurance/quality control information. The AQS data is used to (1) assess air quality, (2) assist in attainment/non-attainment designations, (3) evaluate SIPs for non-attainment areas, (4) perform modeling for permit review analysis, and (5) prepare reports for Congress as mandated by the CAA. Access is through the website at *https://www.epa.gov/aqs*.

[17] *See* 40 CFR part 50, Appendix P, section 2.3(b).

[18] More information about the Clean Data Policy and redesignation guidance is available at *https://www.epa.gov/ozone-pollution/redesignation-and-clean-data-policy-cdp*.

[19] For Mariposa, California, the final 2008 ozone NAAQS Clean Data Determination was initially effective on February 21, 2017 (81 FR 93624, December 21, 2016) and was delayed until March 21, 2017, due to a Presidential directive (82 FR 8499, January 26, 2017).

[20] For Baltimore, Maryland, the final 2008 ozone NAAQS Clean Data Determination was effective on July 1, 2015 (80 FR 30941, June 1, 2015).

(2017) did not exceed the 2008 ozone NAAQS of 0.075 ppm. In addition, state officials have certified that they have complied with all requirements and commitments pertaining to these areas in their respective implementation plan.

By way of letter dated June 4, 2018,[21] the Colorado Department of Public Health and Environment (CDPHE) requested an extension for the Denver-Boulder-Greeley-Ft. Collins-Loveland, Colorado, Moderate area attainment date. The state's request for an extension also includes a certification that the state of Colorado has complied with all requirements and commitments pertaining to the Denver-Boulder-Greeley-Ft. Collins-Loveland, Colorado, Moderate ozone area SIP, in accordance with CAA section 181(a)(5)(A). The EPA evaluated the information submitted by the state and is proposing to determine that the state has met the requirement of CAA section 181(a)(5)(A) for this area.

The state also submitted an exceptional events demonstration claiming that the area's fourth highest daily maximum 8-hour average ozone concentration at one monitor, which exceeded the 0.075 ppm standard, was caused by wildfires in Montana and Pacific Northwest states in late summer 2017. On July 11, 2018, the EPA concurred with the state's demonstration that prevailing winds transported smoke from those wildfires to the Denver area on September 2 and 4, 2017, causing exceedances of the 2008 ozone NAAQS. Pursuant to 40 CFR 50.14, the EPA is proposing to exclude the air quality data submitted in the state's exceptional events demonstration for purposes of this determination of attainment by the attainment deadline. With the exceptional events data excluded, the fourth highest daily maximum 8-hour average for the area in 2017 does not exceed 0.075 ppm. Thus, the EPA is proposing to grant a 1-year attainment date extension for the Denver-Boulder-Greeley-Ft. Collins-Loveland, Colorado, Moderate nonattainment area in this proposed action.

In a letter from the Wisconsin Department of Natural Resources (DNR), dated May 24, 2018,[22] the state requested a 1-year attainment date extension for the Sheboygan County, Wisconsin, Moderate nonattainment area stating the requirements and commitments given under CAA section 181(a)(5)(A) had been met. In their request, the state officials also provided their certification of the 2017 ambient air monitoring data for the area. The EPA has evaluated this information from the state and is proposing to determine that the state has met the requirement of CAA section 181(a)(5)(A) for this area.[23]

In the letter, the state also explains that the fourth highest daily 8-hour ozone concentration from monitors in the area did not exceed 0.075 ppm during the 2017 calendar year and presented the state's ''2017 Wisconsin Ambient Air Monitoring Data Certification'' to support the analysis. Upon evaluation of the information submitted by the Wisconsin DNR, the EPA is proposing to grant a 1-year attainment date extension for the Sheboygan County, Wisconsin, Moderate nonattainment area in this proposed action.

If we finalize our action as proposed, upon the effective date of the final action, the attainment date for these areas would be extended to July 20, 2019. The areas would remain classified as Moderate for the 2008 ozone NAAQS unless and until the EPA makes a determination that either or both areas failed to attain the NAAQS by the new attainment date.

The EPA is soliciting comments on the proposed 1-year attainment date extensions for the Denver-Boulder-Greeley-Ft. Collins-Loveland, Colorado, and Sheboygan County, Wisconsin, Moderate nonattainment areas.

C. Determinations of Failure To Attain and Reclassification

The EPA is proposing to determine that seven Moderate nonattainment areas failed to attain the 2008 ozone NAAQS by the attainment date of July 20, 2018. These areas are not eligible for a 1-year attainment date extension because they do not meet the extension criteria under CAA section 181(a)(5) as interpreted by the EPA in 40 CFR 51.1107. The areas' ozone design values for 2015–2017 are shown in Table 1.

If we finalize our action as proposed, each of these areas will be reclassified to Serious, the next higher classification, as provided under CAA section 181(b)(2)(A)(i) and codified at 40 CFR 51.1103. These areas are required to attain the standard ''as expeditiously as practicable'' but no later than 9 years after the initial designation as nonattainment, which in this case would be no later than July 20, 2021. After reclassification to Serious, if any of these areas attains the 2008 ozone NAAQS prior to the Serious-area attainment date, the relevant state may seek a Clean Data Determination, under which certain attainment planning SIPs would be suspended under 40 CFR 51.1118 or a redesignation to attainment.[24]

The EPA is soliciting comments on this proposal for determining that these areas did not attain the 2008 ozone NAAQS by the Moderate area attainment date.

D. Serious Area SIP Revision Submission Deadlines and RACT Implementation Deadlines

Moderate nonattainment areas that failed to attain the 2008 ozone NAAQS by the attainment date will be reclassified as Serious by operation of law upon the effective date of the final reclassification notice. Each responsible state air agency must submit SIP revisions that satisfy the air quality planning requirements for a Serious area under CAA section 182(c).

On July 20, 2012, when final nonattainment designations became effective for the 2008 ozone NAAQS, states responsible for areas initially classified as Serious were required to prepare and submit SIP revisions by deadlines relative to that effective date. For those areas, the deadlines ranged from 2 to 4 years after July 20, 2012, depending on the SIP ''element'' required (*e.g.,* 2 years for the RACT SIP and 4 years for the attainment demonstration). Since those deadlines were passed, the EPA is proposing to use its discretion under CAA section 182(i) to adjust the SIP deadlines that would otherwise apply. Thus, the EPA is proposing that each state within which all or part of an area reclassified to Serious is located shall submit SIP revisions according to the following adjusted schedules:

[21] Kaufman, Garrison, Director, Air Pollution Control Division, CDPHE. ''Submittal of Exceptional Events Demonstration and Request to Extend 2008 Ozone National Ambient Air Quality Standard Attainment Deadline for the Denver Metropolitan/North Front Range Nonattainment Area.'' June 4, 2018. Attachments included the ''CDPHE Exceptional Event Demonstration for Ozone on September 2 and 4, 2017,'' and the ''Colorado 2017 Data Certification Request Letter.''

[22] Good, Gail, Director, Air Management Program, Wisconsin Department of Natural Resources, ''Request for a one-year extension of the 2008 ozone standard attainment date for the Sheboygan County, Wisconsin moderate nonattainment area,'' letter dated May 24, 2018, which includes as an attachment the ''2017 Wisconsin Ambient Air Monitoring Data Certification—Criteria Network Data,'' dated April 30, 2018.

[23] Letter dated July 11, 2018, to Garry Kaufman, Director, Air Pollution Control Division, Colorado Department of Public Health and Environment, from Martin Hestmark, Assistant Regional Administrator, Office of Partnerships and Regulatory Assistance, U.S. EPA Region 8, which inclused as an enclosure a TSD. This document is available in the rulemaking docket for this action.

[24] For a fuller description of the effects of a Clean Data Determination, *see* Section III.A of this preamble.

1. Due date for non-RACT Serious area SIP revisions, SIP revisions, and implementation deadline for RACT tied to attainment. The EPA proposes that states submit all SIP revisions—with the exception of any RACT revisions not needed for attainment purposes—no later than 12 months after the effective date of the final reclassification notice.[25] The state submittal requirements for attainment plans, in general, are provided under CAA section 172(c); the SIP requirements that apply to Serious areas for the 2008 ozone NAAQS are listed under CAA section 182(c) and include: (1) Enhanced monitoring; (2) attainment demonstration and reasonable further progress (RFP) plan; (3) an enhanced vehicle inspection and maintenance program, if applicable; (4) clean-fuel vehicle programs and transportation control; (5) nonattainment New Source Review program revisions; and (6) contingency measures. States must also provide an analysis of—and adopt all—RACM, including RACT needed for purposes of meeting RFP or timely attaining the NAAQS. Such an analysis should include: (1) An evaluation of controls for sources emitting 100 tons per year (tpy) or more that may have become reasonably available since the January 1, 2017, Moderate area deadline for adopting and implementing RACT, and (2) an evaluation of controls for sources emitting 50 tpy or more that are currently reasonably available, consistent with the Serious area classification.

The ''schedule prescribed in connection with'' the attainment planning requirements for Serious areas is 4 years from designation. *See* CAA section 182(i). However, given the Serious area attainment date of July 20, 2021, and the fact that these areas are reclassified rather than newly designated Serious areas, the EPA proposes that a 12-month deadline for the attainment planning requirements for all areas newly reclassified as Serious ''is necessary and appropriate'' to assure consistency among these submissions. Although not directly applicable, the EPA notes that the analogous provision in the general nonattainment area requirements in Subpart 1 also provides 12 months for submission of a new attainment demonstration and associated controls after the EPA determines that an area has failed to attain by its attainment date. *See* CAA section 179(d). We also believe the proposed timeframe is consistent with how the EPA handled setting SIP submission deadlines for other nonattainment areas that were reclassified from Moderate to Serious for past ozone NAAQS. Examples include Dallas-Ft. Worth, Texas,[26] an area reclassified in 2010 as Serious for the 1997 8-hour ozone NAAQS, and the Beaumont-Port Arthur, Texas,[27] and St. Louis, Missouri,[28] areas, reclassified in 2003 and 2004, respectively, from Moderate to Serious for the 1979 1-hour ozone NAAQS. Twelve months generally provides the time necessary for states and local air districts to finish reviews of available control measures, adopt revisions to necessary attainment strategies, address other SIP requirements and complete the public notice process necessary to adopt and submit timely SIP revisions.[29]

The EPA also proposes that any RACT that states determine is needed for meeting RFP or timely attainment of the 2008 ozone NAAQS must be implemented by the date that the attainment plan is due, *i.e.,* no later than 12 months after the effective date of the final reclassification notice. As a general matter, the Act requires implementation of those requirements needed for timely attainment ''as expeditiously as practicable.'' *See* CAA section 172(c)(1). The EPA believes that an implementation deadline of 12 months from the effective date of the reclassification is consistent with the requirement to act expeditiously and moreover is consistent with the start of the attainment year ozone season for all 2008 ozone NAAQS Serious areas, which is the start of the 2020 ozone season. All emissions control strategies designed to help areas attain the 2008 ozone NAAQS by the applicable Serious area attainment date of July 20, 2021, or to qualify for a 1-year extension of that attainment date, necessarily must be in place and in effect no later than the start of the final full ozone season preceding the attainment date, as that is the last ozone season of air quality monitoring data that could affect the area's design value as of the attainment date or would decide whether the area met the 1-year extension air quality eligibility criterion (*see* 40 CFR 51.1108(d)). The EPA discusses its proposed deadlines for RACT SIP revisions and implementation of RACT beyond what may be needed in a Serious area for attainment purposes in Sections III.D.2 and III.D.3 of this notice.

The EPA seeks comment on its proposed date of 12 months from the effective date of the final reclassification notice both for Serious area SIP revisions to be due and the implementation deadline for any RACT measures states determine necessary for meeting RFP or demonstrating timely attainment in the area.

2. Due date for additional Serious area RACT SIP revisions. For Serious areas reclassified from Moderate, the requirement for RACT expands to include all sources that emit, or have the potential to emit, 50 tons per year (tpy) of VOC or NO_X.[30] State air agencies responsible for Moderate areas are already required to implement RACT for major sources,[31] defined as sources that emit or have the potential to emit 100 tpy.[32] Thus, states must revise their RACT SIPs to include those other sources emitting or having the potential to emit 50 to 100 tpy. The EPA proposes that states submit their SIP revisions for any RACT not otherwise needed for attainment purposes by August 3, 2020. This deadline is anticipated to be approximately 18 months after the effective date of the final reclassification notice.

This proposed deadline would align the Serious area RACT SIP deadline for the 2008 ozone NAAQS with some of

[25] The EPA has long taken the position that the statutory requirement for states to assess and adopt RACT for sources in ozone nonattainment areas classified Moderate and higher generally exists independently from the attainment planning requirements for such areas. *See* Memo from John Seitz, ''Reasonable Further Progress, Attainment Demonstration, and Related Requirements for Ozone Nonattainment Areas Meeting the Ozone National Ambient Air Quality Standard'' (1995), at 5 (explaining that Subpart 2 requirements linked to the attainment demonstration are suspended by a finding that a nonattainment area is attaining but that requirements such as RACT must be met whether or not an area has attained the standard); *see also* 40 CFR 51.1118 (suspending attainment demonstrations, RACM, RFP, contingency measures, and other attainment planning SIPs with a finding of attainment). In addition to the independent RACT requirement, states have a statutory obligation to apply RACM (including such reductions in emissions from existing sources in the area as may be obtained through implementation of RACT) to meet RFP requirements and to demonstrate attainment as expeditiously as practicable. Therefore, to the extent that a state adopts new or additional RACT controls to meet RFP requirements or to demonstrate attainment as expeditiously as practicable, those states must include such RACT revisions with the other SIP elements due as part of the attainment plan required under CAA sections 172(c) and 182(c) and must implement them by the same date as explained further in Section III.D.3 of this notice.

[26] *See* 75 FR 79302, December 20, 2010, Dallas-Ft. Worth, Texas, reclassification to Serious for the 1997 8-hour ozone NAAQS.

[27] *See* 69 FR 16483, March 30, 2004, Beaumont-Port Arthur, Texas, reclassification to Serious for the 1979 1-hour ozone NAAQS.

[28] *See* 68 FR 4836, January 30, 2003, St. Louis, Missouri, reclassification to Serious for the 1979 1-hour ozone NAAQS.

[29] *Cf.* CAA section 179(d)(1).

[30] *See* CAA sections 182(c) and 182(f).

[31] *See* CAA section 182(b)(2) and 182(f).

[32] *See* CAA section 302(j).

the nonattainment area SIP revision deadlines associated with the 2015 ozone NAAQS.[33] CAA section 182(i) provides that the Administrator may adjust deadlines for reclassified areas ''to the extent such adjustment is necessary or appropriate to assure consistency among the required submissions.'' The EPA interprets ''consistency among the required submissions'' to allow for consideration of ''required submissions'' for various ozone NAAQS that are being implemented simultaneously. Since all the areas that would be reclassified to Serious upon the effective date of the final reclassification notice are also designated nonattainment for the 2015 ozone NAAQS or are in the Ozone Transport Region (OTR), the responsible state air agencies are required under CAA section 182 to submit SIP revisions for certain SIP elements for the 2015 ozone NAAQS within 2 years of the effective date of the nonattainment area designations. The effective date of nonattainment area designations for the 2015 ozone NAAQS was August 3, 2018, and, therefore, the deadline for submitting nonattainment SIP revisions associated with that standard would be August 3, 2020. Consistent with CAA section 182(i), the EPA believes coordinating the SIP deadlines related to the 2008 and 2015 ozone NAAQS for these nonattainment areas is appropriate and could result in more effective implementation of the NAAQS.

Under CAA section 182(i), reclassified areas generally are required to submit SIP revisions associated with their new classification ''according to the schedules prescribed in connection with such requirements.'' CAA section 182(b)(2), which establishes the RACT requirement for ozone nonattainment areas classified as Moderate or above, and CAA section 184(b), which establishes RACT requirements for areas in the ozone transport region, provide a 24-month schedule for compliance with those requirements.[34] Although the proposed deadline of August 3, 2020, provides less than 24 months, the EPA believes the anticipated timeframe is appropriate given coordination with the 2015 ozone NAAQS SIP deadlines and the nature of the submission, *i.e.,* because states with newly reclassified Serious areas should already have addressed RACT requirements commensurate with the Moderate area classification.

The EPA is proposing (and soliciting comments) on an August 3, 2020, deadline for RACT SIP revisions. The EPA is also taking comment on whether allowing states a full 24 months from the effective date of the final reclassification notice to submit SIP revisions for RACT not otherwise needed for attainment purposes would yield a more desirable end result in terms of emissions reductions and air quality benefits, state processing and resource burden, and/or burden on emissions sources.

3. Implementation deadline for additional Serious area RACT. CAA section 182(b)(2) establishes the RACT area requirements for ozone areas designated and classified Moderate and higher.[35] That provision, which was written for the 1-hour ozone NAAQS, established a deadline of five years from November 15, 1990, *i.e.,* the date of designation, for the implementation of RACT. In the 2008 ozone NAAQS SIP Requirements Rule, the EPA interpreted this statutory deadline for the 2008 standard by establishing a RACT implementation deadline of January 1 of the fifth year after the effective date of nonattainment designation, and explained that this was consistent with the maximum timeframe provided under the CAA for implementing RACT in nonattainment areas classified Moderate or higher.[36] For nonattainment areas initially classified as Moderate or higher for the 2008 ozone NAAQS and for OTR states, RACT measures were required to be implemented by January 1, 2017. Because that date has passed and cannot be applied to the areas subject to reclassification by this action, the EPA is proposing to set a new deadline of August 3, 2020, for implementation of any new RACT requirements not otherwise needed for RFP or timely attainment purposes.

This proposed deadline, approximately 18 months after the anticipated effective date of the final reclassification notice, is the same deadline proposed for the submission of the related RACT SIP revisions discussed in Section III.D.2 of this notice. Ideally, SIP submission deadlines would precede the implementation of control strategies contained in those SIP submissions. However, given the compressed timeframe available for states to meet the July 20, 2021, attainment date for Serious areas, the EPA believes that, at the very least, it is appropriate to align the deadline for RACT SIP submissions with the deadline for implementation of any new controls contained in that RACT SIP.

The EPA acknowledges the fact that the majority of ozone nonattainment areas in the country were designated and classified as Marginal for the 2015 ozone NAAQS, and so will likely not be required to have any additional RACT in place for the 2015 standard until 2023, and only if such areas are eventually reclassified as Moderate.[37] Providing a slightly longer timeframe (*i.e.,* 18 months rather than 12 months) for implementation of any additional RACT for newly reclassified Serious areas for the 2008 standards could lead states to determine that additional controls are reasonable, thus helping areas attain both the 2008 and 2015 standards more expeditiously.

The Moderate areas subject to reclassification by this proposed action should have already implemented RACT for sources emitting 100 tpy or more of VOC or NO_X. Therefore, at this stage, states should be primarily focused on adopting and implementing new RACT measures required to control sources emitting 50 to 100 tpy of VOC or NO_X. The EPA believes 18 months will provide adequate time to implement any new controls determined to be RACT for this group of sources. However, as noted above, areas originally classified as Moderate and higher for the 2008 ozone NAAQS had just under five years to implement ozone RACT requirements (by January 1 of the fifth year after effective date of designation, *i.e.,* January 1, 2017). By contrast, areas reclassified from Marginal to Moderate for the 2008 ozone NAAQS in 2016 became subject to the RACT requirement less than seven months (and in one case significantly less than seven months) before the RACT implementation deadline.[38] [39] In some areas, states may have been able to adopt additional RACT controls had

[33] All the areas subject to reclassification in this notice are among those designated nonattainment for the 2015 ozone NAAQS, effective August 3, 2018 (*see* 83 FR 25776, June 4, 2018).

[34] *See* 40 CFR 51.1112(a)(2).

[35] CAA Section 182(b)(2) sets the RACT requirement for Moderate areas, and the Act requires other higher-classified areas to fulfill the CAA section 182(b) requirements. *See* CAA sections 182(c), (d), and (e) (requiring states with Serious, Severe, and Extreme nonattainment areas, respectively, to fullfil the obligations required of lower-classified areas).

[36] *See* 40 CFR 51.1112(a)(3); 80 FR 12264, 12280 (March 6, 2015).

[37] *See* CAA section 182(b) and (c), as applied only to Moderate areas and above. All areas in the OTR, regardless of classification for the 2015 ozone NAAQS, would be required to have any additional RACT in place for the 2015 ozone standard by RACT implementation deadlines interpreted from CAA section 182(b) in EPA's final ''2015 Ozone NAAQS SIP Requirements Rule,'' which is forthcoming.

[38] *See* 81 FR 26697; May 4, 2016.

[39] *See* 81 FR 90207, December 14, 2016, Houston-Galveston-Brazoria, Texas, reclassification to Moderate for the 2008 8-hour ozone NAAQS.

there been additional time to implement them. The EPA, therefore, seeks comment on whether an extended RACT implementation deadline—beyond August 3, 2020, but no later than January 1 of the fifth year after effective date of reclassification to Serious (*i.e.,* January 1, 2024)—would yield additional and substantial emission reductions in newly-reclassified Serious areas (beyond what could be achieved by the due date of August 3, 2020, proposed in this notice) to justify an extended compliance due date for RACT not otherwise needed in an area for timely attainment by the July 20, 2021, attainment date for Serious areas.

In summary, the EPA is propsing (and soliciting comments) on an August 3, 2020, deadline for implementing RACT in newly reclassified Serious nonattainment areas for the 2008 ozone NAAQS. The EPA is also taking comment on an extended deadline up to January 1, 2024, for implementing RACT in newly reclassified Serious nontainment areas for the 2008 ozone NAAQS.

IV. Environmental Justice Considerations

The EPA believes that this proposed action will not have disproportionately high or adverse human health or environmental effects on minority, low-income, or indigenous populations.

The purpose of this rule is to make the determination whether certain areas attained the 2008 ozone NAAQS by the attainment date, which is required by the CAA for purposes of implementing the 2008 ozone NAAQS. As such, this action does not directly affect the level of protection provided for human health or the environment. Moreover, it is intended that the actions and deadlines resulting from this notice will lead to greater protection for United States citizens, including minority, low-income, or indigenous populations, by ensuring that states meet their statutory obligation to develop and submit SIPs to ensure that areas make progress toward attaining the 2008 ozone NAAQS.

V. Statutory and Executive Order Reviews

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 Regulations and Controlling Regulatory Costs

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

C. Paperwork Reduction Act (PRA)

This rule does not impose any new information collection burden under the PRA not already approved by the Office of Management and Budget. This action proposes to: (1) Find that certain Moderate ozone nonattainment areas listed in Table 1 failed to attain the 2008 NAAQS by the applicable attainment date; (2) identify those areas subject to reclassification as Serious ozone nonattainment areas by operation of law upon the effective date of the reclassification notice; and (3) adjust any applicable implementation deadlines. Thus, the proposed action does not establish any new information collection burden that has not already been identified and approved in the EPA's information collection request.[40]

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. The proposed determinations of attainment and failure to attain the 2008 ozone NAAQS (and resulting reclassifications), and the proposed determination to grant 1-year attainment date extensions do not in and of themselves create any new requirements beyond what is mandated by the CAA. Instead, this rulemaking only makes factual determinations, and does not directly regulate any entities.

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. This 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, tribes, or the relationship between the national government and the states and tribes, 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 has tribal implications. However, it will neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. The EPA has identified a few tribal areas implicated in the 11 areas covered by the EPA's action proposing determinations of attainment for the 2008 ozone NAAQS. The EPA intends to communicate with potentially affected tribes located within the boundaries of the nonattainment areas for the 2008 ozone NAAQS as the agency moves forward in developing a final rule.

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

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

J. National Technology Transfer Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes 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. The results of this evaluation are contained in the section of the preamble titled ''Environmental Justice Considerations.''

[40] On April 30, 2018, the OMB approved EPA's request for renewal of the previously approved information collection request (ICR). The renewed request expires on April 30, 2021, 3 years after the approval date (*see* OMB Control Number 2060–0695 and ICR Reference Number 201801–2060–003 for EPA ICR No. 2347.03).

List of Subjects

40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Designations and classifications, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements and Volatile organic compounds.

40 CFR Part 81

Environmental protection, Administrative practice and procedure, Air pollution control, Designations and classifications, Intergovernmental relations, Nitrogen oxides, Ozone, Reporting and recordkeeping requirements, and Volatile organic compounds.

Dated: November 7, 2018.

William L. Wehrum,

Assistant Administrator.

[FR Doc. 2018–24816 Filed 11–13–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 355

[EPA–HQ–OLEM–2018–0318; FRL–9986–40–OLEM]

RIN 2050–AH00

Emergency Release Notification Regulations on Reporting Exemption for Air Emissions From Animal Waste at Farms; Emergency Planning and Community Right-to-Know Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is proposing to amend the release notification regulations under the Emergency Planning and Community Right-to-Know Act (EPCRA) to add the reporting exemption for air emissions from animal waste at farms provided in section 103(e) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA). In addition, EPA is proposing to add definitions of ''animal waste'' and ''farm'' to the EPCRA regulations to delineate the scope of this reporting exemption. This proposed rulemaking maintains consistency between the emergency release notification requirements of EPCRA and CERCLA in accordance with the statutory text, framework and legislative history of EPCRA, and is consistent with the Agency's prior regulatory actions.

DATES: Comments must be received on or before December 14, 2018.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2018–0318, at *https://www.regulations.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, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

FOR FURTHER INFORMATION CONTACT: Sicy Jacob, United States Environmental Protection Agency, Office of Land and Emergency Management, 1200 Pennsylvania Ave. NW (Mail Code 5104A), Washington, DC 20460; telephone number: (202) 564–8019; email address: *jacob.sicy@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

A list of entities that could be affected by this final rule include, but are not necessarily limited to:

Type of entity	Examples of affected entities
Industry	NAICS code 111—Crop production. NAICS code 112—Animal production.
States and/or Local Governments	NAICS code 999200—State Government, excluding schools and hospitals. NAICS code 999300—Local Government, excluding schools and hospitals. State Emergency Response Commissions, Tribal Emergency Response Commissions, Tribal Emergency Planning Committees and Local Emergency Planning Committees.

This table is not intended to be exhaustive, but rather provide a guide for readers regarding the types of entities that EPA is aware could be involved in the activities affected by this action. However, other types of entities not listed in this table could be affected by this proposed rulemaking. To determine whether your entity is affected by this action, you should carefully examine the applicability criteria found in § 355.30 of title 40 of the Code of Federal Regulations (CFR). 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.

B. What action is the Agency taking?

The EPA is proposing to amend the EPCRA emergency release notification regulations to include the reporting exemption for air emissions from animal waste at farms provided in CERCLA section 103(e). In addition, EPA is proposing to add definitions of ''animal waste'' and ''farm'' to the EPCRA regulations to delineate the scope of this reporting exemption.

C. What is the Agency's authority for taking this action?

This proposed rulemaking is being issued under EPCRA, which was enacted as Title III of the Superfund Amendments and Reauthorization Act (SARA) of 1986 (Pub. L. 99–499). EPA proposes this rulemaking under the

authority of EPCRA section 304 (42 U.S.C. 11004) and the Agency's general rulemaking authority under EPCRA section 328 (42 U.S.C. 11048).

II. Background of the Proposed Rule

A. Overview

Section 103 of CERCLA requires the person in charge of a vessel or facility to immediately notify the National Response Center (NRC) when there is a release of a hazardous substance, as defined under CERCLA section 101(14), in an amount equal to or greater than the reportable quantity for that substance within a 24-hour period. In addition to these CERCLA reporting requirements, EPCRA section 304 requires owners or operators of certain facilities to immediately notify state and local authorities when there is a release of an extremely hazardous substance (EHS), as defined under EPCRA section 302, or of a CERCLA hazardous substance in an amount equal to or greater than the reportable quantity for that substance within a 24-hour period.

EPCRA and CERCLA are two separate but interrelated environmental laws that work together to provide emergency release notifications to Federal, state and local officials. Notice given to the NRC under CERCLA serves to inform the Federal government of a release so that Federal personnel can evaluate the need for a response in accordance with the National Oil and Hazardous Substances Contingency Plan (NCP),[1] the Federal government's framework for responding to both oil discharges and hazardous substance releases. Relatedly, notice under EPCRA is given to the State Emergency Response Commission (SERC) for any state likely to be affected by the release and to the community emergency coordinator for the Local Emergency Planning Committee (LEPC) for any area likely to be affected by the release so that state and local authorities have information to help protect the community.

Release reporting under EPCRA depends, in part, on whether reporting is required under CERCLA.[2] Specifically, EPCRA section 304(a) provides for reporting under the following three release scenarios:

- EPCRA section 304(a)(1) requires notification if a release of an EPCRA EHS occurs from a facility at which a hazardous chemical is produced, used or stored, and such release requires a notification under CERCLA section 103(a).
- EPCRA section 304(a)(2) requires notification if a release of an EPCRA EHS occurs from a facility at which a hazardous chemical is produced, used or stored, and such release is not subject to the notification requirements under CERCLA section 103(a), but only if the release:
  - Is not a federally permitted release as defined in CERCLA section 101(10),
  - Is in an amount in excess of the reportable quantity as determined by EPA, and
  - Occurs in a manner that would require notification under CERCLA section 103(a).
- EPCRA section 304(a)(3) requires notification if a release of a substance not designated as an EPCRA EHS occurs from a facility at which a hazardous chemical is produced, used or stored, and such release requires a notification under CERCLA section 103(a).

B. Fair Agricultural Reporting Method Act and Legislative Amendments to CERCLA

On March 23, 2018, the President signed into law the Consolidated Appropriations Act, 2018 (''Omnibus Bill''). Title XI of the Omnibus Bill is entitled the ''Fair Agricultural Reporting Method Act'' or the ''FARM Act.'' *See* Fair Agricultural Reporting Method Act, Public Law 115–141, sections 1101–1103 (2018). The FARM Act expressly exempts reporting of air emissions from animal waste (including decomposing animal waste) at a farm from CERCLA section 103. The FARM Act also provides definitions for the terms ''animal waste'' and ''farm.'' On August 1, 2018, the Agency published a final rule to amend the CERCLA regulations at 40 CFR part 302 by adding the reporting exemption for air emissions from animal waste at farms and adding definitions of ''animal waste'' and ''farm'' from the FARM Act.

C. Proposed Revisions to EPCRA Section 304 Release Notification Regulations

Based on the criteria for EPCRA section 304 release reporting, EPA is proposing to amend the EPCRA release notification regulations in 40 CFR 355.31 to include the reporting exemption for air emissions from animal waste at farms. EPA is also proposing to add definitions of ''animal waste'' and ''farm'' to the definition section of the EPCRA regulations in 40 CFR 355.61 to delineate the scope of this reporting exemption. EPA believes these proposed changes appropriately reflect the relationship between CERCLA and EPCRA release reporting requirements and are consistent with the statutory text, framework and legislative history of EPCRA, as well as the Agency's prior regulatory actions.

III. Legal Rationale for the Proposed Rule

This proposed rulemaking maintains consistency between the emergency release notification requirements of EPCRA and CERCLA in accordance with the statutory text, framework and legislative history of EPCRA, and is consistent with the Agency's prior regulatory actions. Specifically, this proposed rulemaking is based on the relationship of the EPCRA section 304 reporting requirements to the CERCLA section 103 reporting requirements, as recently amended. As previously noted, EPCRA section 304 reporting depends, in part, on whether reporting is required under CERCLA section 103. EPCRA's legislative history further indicates that the EPCRA section 304 reporting requirements are designed to be consistent with the reporting requirements of CERCLA section 103. EPA has thus revised the EPCRA emergency release notification regulations from time to time, as appropriate, to maintain consistency with the CERCLA reporting requirements.

Consistent with the Agency's interpretation of EPCRA section 304 and the Agency's prior regulatory actions, EPA now proposes to amend the EPCRA release notification regulations to explicitly exempt air emissions from animal waste at farms from reporting under EPCRA section 304.

A. Statutory Text and Framework

EPCRA section 304 provides for release reporting under three scenarios, each of which depends in some way on whether the release requires notice under CERCLA. If a release requires notice under CERCLA section 103(a), the release may be subject to reporting under EPCRA if the release meets the requirements of EPCRA section 304(a)(1) or 304(a)(3). If a release is *not* subject to notification under CERCLA section 103(a), the release may nonetheless be subject to reporting under EPCRA if the release meets the requirements of EPCRA section 304(a)(2). Because the FARM Act exempted air emissions from animal waste at farms from CERCLA reporting, these types of releases no longer require notice under CERCLA section 103(a) and thus do not fall within the EPCRA section 304(a)(1) or (a)(3) reporting scenarios. Instead, these releases fall within the EPCRA section 304(a)(2) reporting scenario. Pursuant to EPCRA section 304(a)(2), a release of an EPCRA EHS that is not subject to notification

[1] 40 CFR part 300.

[2] In this document, emergency release notification and release reporting are used interchangeably.

under section 103(a) of CERCLA need only be reported under EPCRA if the release:

- Is not a federally permitted release as defined in section 101(10) of CERCLA,
- Is in an amount in excess of the reportable quantity as determined by EPA, and
- Occurs in a manner that would require notification under section 103(a) of CERCLA.

A release that is not subject to CERCLA section 103(a) reporting must meet all three criteria in EPCRA section 304(a)(2) to be subject to EPCRA reporting. Here, air emissions from animal waste at farms could meet the first two criteria because such releases are generally not federally permitted and may exceed the applicable reportable quantity. Yet these types of releases do not ''occur[] in a manner'' that would require notification under CERCLA section 103(a) and thus do not meet the third criterion of EPCRA section 304(a)(2). Because air emissions from animal waste at farms do not meet all three criteria under EPCRA section 304(a)(2), and do not fall within the EPCRA section 304(a)(1) or (a)(3) reporting scenarios, these types of releases are not subject to EPCRA reporting. As such, EPA is proposing to amend EPCRA's emergency release notification regulations to clarify reporting exemptions for certain types of releases under EPCRA section 304.

Air emissions from animal waste at farms no longer ''occur[] in a manner'' that would require notification under CERCLA section 103(a) because the recent amendment exempted these types of releases from CERCLA reporting. Importantly, the CERCLA reporting exemption is specifically tied to the nature or manner of these releases rather than to a specific substance. For example, the recent amendment does not exempt specific substances typically associated with animal waste (such as ammonia and hydrogen sulfide) from reporting; rather, it exempts from reporting releases of any substance from animal waste at a farm *into the air*. Because air emissions from animal waste do not ''occur[] in a manner'' that would require notification under CERCLA section 103(a), these types of releases do not meet the third criterion of EPCRA section 304(a)(2) and are thus not subject to EPCRA reporting.

EPCRA section 304(a)(2) promotes consistency between the reporting requirements of EPCRA and CERCLA by ensuring that only releases that ''occur[ ] in a manner'' that would require CERCLA notification be reported under EPCRA. Yet, the provision also contemplates scenarios where releases not subject to reporting under CERCLA may still need to be reported under EPCRA, such as releases of substances designated as EHSs under EPCRA but not as hazardous substances under CERCLA. For example, trimethylchlorosilane (Chemical Abstract Service No. 75–77–4) is designated as an EPCRA EHS but not as a CERCLA hazardous substance. Since trimethylchlorosilane is not a CERCLA hazardous substance, its releases are not subject to notification under CERCLA section 103(a) and need only be reported under EPCRA if such releases meet the criteria of EPCRA section 304(a)(2). A trimethylchlorosilane release that (1) is not a federally permitted release as defined in CERCLA section 101(10); (2) exceeds the applicable reportable quantity; and (3) ''occurs in a manner'' that would require notification under CERCLA section 103(a) would still be subject to EPCRA reporting. In this example, a release of trimethylchlorosilane ''occurs in a manner'' that would require notification under CERCLA section 103(a) where, for example, the release is ''into the environment'' as defined in CERCLA section 101(22), and is not one of the excluded or exempted types of releases described in CERCLA sections 101(22), 103(e), or 103(f). (See section C of this preamble, for further explanation of these exemptions.) Therefore, the release of trimethylchlorosilane would be similar to other releases that require notification under CERCLA section 103(a).[3]

As another example, petroleum (including crude oil or any fraction thereof) is expressly excluded from the definition of ''hazardous substance'' in CERCLA section 101(14). Because of this ''petroleum exclusion,'' releases of petroleum are not subject to notification under CERCLA section 103(a) and so need to be reported under EPCRA only if such releases meet the criteria of EPCRA section 304(a)(2). Where a petroleum release meets the first two criteria of EPCRA section 304(a)(2), the question becomes whether the release ''occurs in a manner'' that would require notification under CERCLA section 103(a). Notably, unlike air emissions from animal waste at farms, Congress did not exempt petroleum releases from CERCLA reporting based on the manner or nature of these releases. Instead, Congress exempted these types of releases from CERCLA reporting by excluding petroleum (including crude oil or any fraction thereof) from the definition of ''hazardous substance.'' *See* 42 U.S.C. 9601(14). As such, these types of releases still ''occur[ ] in a manner'' that would require notification under CERCLA section 103(a) and could thus be subject to reporting under EPCRA section 304(a)(2) where the petroleum release contains an EHS. *See* 52 FR 13378, 13385 (April 22, 1987). In sum, where a CERCLA reporting exemption or the reason a release is not subject to CERCLA reporting is *unrelated to the manner* in which such releases occur, EPCRA section 304(a)(2) may compel reporting of such releases.

In addition to the statutory text of EPCRA section 304(a)(2), the statutory framework of EPCRA's reporting requirements indicates a desire to maintain consistency between the EPCRA and CERCLA reporting requirements. Indeed, ''[i]n drafting the EPCRA reporting requirements, Congress expressly tied them to CERCLA's'' such that ''all of EPCRA's reporting mandates are piggybacked on the CERCLA mandates in one form or another.'' *Waterkeeper Alliance* v. *EPA,* 853 F.3d 527, 532 (D.C. Cir. 2017). Under EPCRA sections 304(a)(1) and (a)(3), EPCRA reporting depends on whether a release requires notification under CERCLA section 103(a), and under EPCRA section 304(a)(2), EPCRA reporting depends on whether a release ''occurs in a manner'' that would require notification under CERCLA section 103(a). Therefore, EPCRA requires reporting only for releases that require notification under CERCLA or occur in a manner that would require notification under CERCLA. Under CERCLA section 103 as amended, air emissions from animal waste at farms do not require notification under CERCLA section 103(a) and do not occur in a manner that would require such notification. As a result, these types of releases are not subject to reporting under EPCRA section 304(a)(1), (a)(2) or (a)(3). Thus, to clarify that these types of releases are not subject to reporting under EPCRA section 304, EPA is proposing to amend the EPCRA release notification regulations to exempt air emissions from animal waste at farms from reporting under section 304. In doing so, EPA seeks to avoid inconsistent regulation of these types of releases under EPCRA and CERCLA, in

[3] *See, e.g.,* 48 FR 23552, 23555 (May 25, 1983) (describing the nature of releases subject to CERCLA notification requirements); 52 FR 13378, 13383 (April 22, 1987) (explaining that the method used to determine whether a release meets or exceeds the applicable RQ under CERCLA ''should be equally applicable to releases under [EPCRA] section 304 due to similarity to section 103 of CERCLA'').

furtherance of the underlying purpose of this statutory framework.

B. Legislative History

EPA's understanding of EPCRA section 304(a)(2) is informed by the legislative history of EPCRA itself. In 1986, Congress passed EPCRA pursuant to Title III of the Superfund Amendments and Reauthorization Act (SARA). In the committee conference report addressing EPCRA, Congress discussed the three scenarios requiring release reporting under EPCRA section 304. With respect to EPCRA section 304(a)(2), the report states: ''This requires notification where there is a release of an extremely hazardous substance that would require notice under section 103(a) of CERCLA but for the fact that the substance is not specifically listed under CERCLA as requiring such notice.'' *See* 99 Cong. Conf. Report H. Rep. 962, October 3, 1986; SARA Leg. Hist. 38 (Section 304 Emergency Notification).

Congress thus expressed its intent that state and local authorities be notified of a qualifying release under EPCRA, even if the substance released is not identified as a hazardous substance under CERCLA, when the release occurs in a manner as the types of releases that require notification under CERCLA section 103(a). Conversely, if the release occurs in a manner that Congress determines does not require notification under CERCLA section 103(a)—such as air emissions from animal waste at farms—then no reporting is required under EPCRA section 304(a)(2) (*i.e.,* the third criterion of EPCRA section 304(a)(2) has not been met).

The legislative history also reveals that Congress intended EPCRA section 304(a)(2) to operate to exclude continuous releases from EPCRA's immediate notification requirements because such releases do not occur in a manner that requires reporting under CERCLA section 103(a).[4] The committee conference report explains: ''[R]eleases which are continuous or frequently recurring and do not require reporting under CERCLA are not required to be reported under [EPCRA section 304].'' Rather, continuous releases are subject to reduced reporting requirements pursuant to CERCLA section 103(f). As explained in section C.3. of this preamble, EPA incorporated an alternative for continuous releases into EPCRA and promulgated regulations that allow continuous releases to be reported in a manner consistent with CERCLA's continuous release reporting requirements.

Congress's intent in adopting the three scenarios in EPCRA section 304(a)(1)–(3) was to ensure that when Federal authorities receive notice of a release under CERCLA section 103(a), state and local authorities receive similar notice under EPCRA. Note that CERCLA notification applies to the list of hazardous substances (located in 40 CFR 302.4), while EPCRA notification applies to the lists of both CERCLA hazardous substances *and* EPCRA EHSs (located in 40 CFR part 355 Apps. A and B). When a substance is not a listed CERCLA hazardous substance, but is on the EPCRA EHSs list, EPCRA section 304(a)(2) provides for notification only if the release of such substance occurs in a manner as the types of releases that require notification under CERCLA section 103(a). On the other hand, if Congress determines that a release occurs in a manner that does not require notification under CERCLA section 103(a), EPCRA section 304(a)(2) works to logically exclude that release from EPCRA reporting.

C. Prior Regulatory Actions

As noted, CERCLA release notification was established to alert Federal authorities to a release so that the need for a response can be evaluated and any necessary response undertaken in a timely fashion. EPCRA release notification supplements CERCLA release notification by similarly preparing the community at the state and local level. Based on the criteria for EPCRA section 304 release reporting, and to promote consistency between CERCLA and EPCRA release notification requirements, the Agency has incorporated many of CERCLA's release notification exemptions into the EPCRA release notification regulations through prior rulemakings. Each of these prior regulatory actions are summarized below.

1. Exemptions From the Definition of ''Release'' Under CERCLA and EPCRA

Both CERCLA and EPCRA define the term ''release.'' Under CERCLA section 101(22), the term ''release'' generally means ''any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment (including the abandonment or discarding of barrels, containers, and other closed receptacles containing any hazardous substance or pollutant or contaminant),'' but also includes specific exclusions for workplace releases, vehicle emissions, nuclear material releases and fertilizer application. Similar to the CERCLA workplace exposure exclusion, EPCRA section 304(a)(4) exempts from reporting any release which results in exposure to persons solely within the site or sites on which a facility is located. Though the definition of ''release'' under EPCRA section 329 mirrors the CERCLA definition, it does not contain three exclusions provided in the CERCLA section 101(22) definition of ''release'': (1) Emissions from the engine exhaust of a motor vehicle, rolling stock, aircraft, vessel or pipeline pumping station engine; (2) releases of source, byproduct or special nuclear material from a nuclear incident; and (3) the normal application of fertilizer. However, because the types of releases excluded from CERCLA's definition of ''release'' do not occur in a manner that would be reportable under CERCLA section 103(a), these types of releases do not meet the reporting requirements under EPCRA section 304. *See* 52 FR 13381, 13384–85 (April 22, 1987) and related Response to Comments document, April 1987, Docket Number 300PQ. Thus, EPA adopted these statutory CERCLA exclusions into the EPCRA regulations codified at 40 CFR 355.31.[5]

2. Exemptions From Immediate Notification Requirements

There are four types of statutory exemptions from the immediate notification requirements for releases of hazardous substances provided in CERCLA sections 101(10) and 103(e) and (f). Specifically, these statutory exemptions include: (1) Federally permitted releases, as defined in section 101(10); (2) releases from the application of a pesticide product registered under the Federal Insecticide, Fungicide and Rodenticide Act or from the handling and storage of such a pesticide product by an agricultural producer (section 103(e)); (3) certain releases of hazardous wastes that are required to be reported under the provisions of the Resource Conservation and Recovery Act and that are reported to the NRC (section 103(f)(1)); and (4)

[4] CERCLA section 103(a) requires the person in charge of a vessel or facility to ''immediately notify'' the NRC when there is a release of a hazardous substance in an amount equal to or greater than the reportable quantity for that substance within a 24-hour period. In contrast, releases that are continuous and stable in quantity and rate may qualify for reduced, ''continuous release'' reporting under CERCLA section 103(f)(2). Similarly, EPCRA section 304 requires owners or operators of certain facilities to ''immediately'' notify state and local authorities of qualifying releases, and EPA has promulgated regulations that allow continuous releases to be reported under EPCRA in a manner consistent with CERCLA's continuous release reporting requirements.

[5] The 1987 rule codified these exemptions at 40 CFR 355.40(a)(2), which was later reorganized into 40 CFR 355.31. *See* 73 FR 65451 (November 3, 2008).

certain releases that are determined to be continuous under the provisions of section 103(f)(2).

In the final rulemaking on April 22, 1987 (52 FR 13378) for emergency planning and release notification requirements under EPCRA, the Agency adopted exemptions from CERCLA section 103(a) reporting ''based on the language in EPCRA section 304(a) which requires that releases reportable under that Section occur in a manner which would require notification under section 103(a) of CERCLA.'' 52 FR 13378, 13381 (April 22, 1987).

Although EPA stated in the April 1987 rulemaking that it was incorporating CERCLA reporting exemptions into the EPCRA regulations based on the criteria for EPCRA section 304 release reporting, the Agency inadvertently omitted the exclusion for the ''application of a pesticide product registered under the Federal Insecticide, Fungicide, and Rodenticide Act or to the handling and storage of such a pesticide product by an agricultural producer'' from the EPCRA section 304 regulations at that time. Thus, in a technical amendment published on May 24, 1989 (54 FR 22543), EPA added a provision to the EPCRA regulations in 40 CFR 355.40(a)(2)(iv) (currently codified at 40 CFR 355.31(c)) providing that releases exempted from CERCLA section 103(a) reporting by CERCLA section 103(e) are also exempt from reporting under EPCRA section 304. In addition, the May 1989 technical amendment clarified the language in paragraph (a)(2)(v) of 40 CFR 355.40 (currently codified at 40 CFR 355.31(d)), explaining that this section exempts from EPCRA section 304 reporting ''any occurrence not meeting the definition of release under section 101(22) of CERCLA,'' as ''[s]uch occurrences are also exempt from reporting under CERCLA section 103(a).'' *See* 54 FR 22543, 22543 (May 24, 1989).

3. Continuous Release Reporting

CERCLA section 103(f) provides relief from the immediate notification requirements of CERCLA section 103(a) for a release of a hazardous substance that is continuous and stable in quantity and rate. Instead, continuous releases are subject to a significantly reduced reporting requirement under regulations promulgated pursuant to CERCLA section 103(f). In adopting the implementing regulations for EPCRA in 40 CFR part 355, EPA relied on EPCRA section 304(a)(2) to likewise exclude continuous releases from the immediate notification requirement of EPCRA section 304, reasoning: ''Because such releases do not 'occur in a manner' which requires immediate release reporting under section 103(a) of CERCLA, they are also not reportable under section 304 of [EPCRA].'' *See* 52 FR 13381, 13384 (April 22, 1987). EPA later promulgated continuous release reporting regulations for EPCRA that cross-reference and follow the CERCLA continuous release reporting regulations, finding that EPCRA release reporting is ''closely tied'' and ''parallel'' to CERCLA release reporting. *See* 55 FR 30169, 30179 (July 24, 1990). At that time, the Agency also reiterated that ''[t]o the extent that releases are continuous and stable in quantity and rate as defined by CERCLA section 103(f)(2) . . . , they do not *occur in a manner* that requires notification under CERCLA section 103(a)'' and are thus not subject to the EPCRA section 304 immediate notification requirements. *Id.* (emphasis added).

IV. Scope of Proposed Rule

The scope of this proposed rulemaking is limited to air emissions from animal waste (including decomposing animal waste) at a farm. The Agency proposes to add this reporting exemption to the EPCRA section 304 emergency release notification regulations as implemented in 40 CFR part 355, subpart C, entitled ''Emergency Release Notification.'' The scope of the proposed rulemaking stems from existing requirements under EPCRA section 304(a)(2) and under CERCLA section 103(e), as amended, and is tied to the nature or manner of these releases rather than to a specific substance. In other words, the Agency is not proposing to exempt substances typically associated with animal waste (such as ammonia or hydrogen sulfide) from reporting. Rather, this proposal codifies EPA's interpretation that air emissions from animal waste at farms are not subject to EPCRA section 304 release reporting by explicitly exempting releases from animal waste *into the air* at farms from reporting. Thus, the Agency is proposing to exclude all releases to the air from animal waste at a farm from reporting under EPCRA section 304.

The proposed rulemaking does not apply to releases of substances from animal waste into non-air environmental media, nor to releases into the air from sources other than animal waste or decomposing animal waste at a farm. For example, a release from animal waste into water (*e.g.,* a lagoon breach) or a release from an anhydrous ammonia storage tank into the air might trigger reporting requirements if the release exceeds the applicable reportable quantities.

This proposed exemption would be added to those currently listed in the EPCRA regulations codified at 40 CFR 355.31, entitled ''What types of releases are exempt from the emergency release notification requirements of this subpart?'' To delineate the scope of this proposed exemption, EPA is also proposing to amend the definition section of the EPCRA regulations at 40 CFR 355.61 to add definitions of ''animal waste'' and ''farm'' that are consistent with CERCLA section 103(e). By proposing to add a reporting exemption for air releases from animal waste at farms to the EPCRA emergency release notification regulations, EPA is not reopening or proposing revisions to the existing reporting exemptions codified in 40 CFR 355.31, nor will EPA consider or respond to comments related to the existing reporting exemptions. Comments received on the existing reporting exemptions will be outside the scope of this proposed action.

V. Relationship of Waterkeeper Alliance v. EPA to This Proposed Rule

In 2008, EPA issued an administrative reporting exemption for air releases from animal waste at farms (73 FR 76948, December 18, 2008). Specifically, the rule exempted all farms from CERCLA's reporting requirements for air releases of any hazardous substance from animal waste. Under EPCRA, the 2008 rule exempted reporting of such releases if the farm had fewer animals than a large concentrated animal feeding operation, as defined by the Clean Water Act. The 2008 administrative reporting exemption was ultimately vacated by the U.S. Court of Appeals for the District of Columbia Circuit in *Waterkeeper Alliance* v. *EPA,* 853 F.3d 527 (D.C. Cir. 2017). In vacating the rule, the court found that the Agency could not rely on general rulemaking authority or a *de minimis* exception to issue an administrative reporting exemption for this category of releases, particularly where the Agency had failed to identify any statutory ambiguity as the basis for its interpretation of the reporting requirements.

This proposal to amend the EPCRA section 304 release notification regulations to exempt air emissions from animal waste at farms is not constrained by the D.C. Circuit's decision in *Waterkeeper*. In contrast to the 2008 rule, this proposed rulemaking is not an administrative reporting exemption stemming from EPA's general rulemaking authority. This proposal is instead rooted in EPCRA section 304 and its relationship with CERCLA section 103 and as informed by

EPCRA section 304's statutory text, framework and legislative history.

VI. Proposed Revisions to 40 CFR Part 355

A. Exemption for Air Emissions From Animal Waste at Farms

For the reasons stated throughout this preamble, EPA is proposing to amend the EPCRA section 304 release notification regulations to exempt air emissions from animal waste (including decomposing animal waste) at a farm from reporting. Currently, the regulations at 40 CFR 355.31 list the releases that are exempt from reporting under EPCRA section 304, including the exemptions adopted from CERCLA through prior rulemakings. The Agency is proposing to amend 40 CFR 355.31 by adding a reporting exemption for air emissions from animal waste at farms. EPA seeks comment on this proposed revision.

B. Definitions

EPA is proposing to add the definitions of ''animal waste'' and ''farm'' applicable to CERCLA section 103(e) to the definition section of the EPCRA regulations codified at 40 CFR 355.61. EPA requests comment on adding these definitions to 40 CFR 355.61.

VII. Statutory and Executive Orders 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 a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket.

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

This action is not an Executive Order 13771 regulatory action because the proposed rule would not result in additional costs.

C. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA. The Agency is proposing to codify a provision exempting farms from reporting air releases from animal waste under EPCRA section 304 release notification regulations.

D. Regulatory Flexibility Act (RFA)

I certify that this action would 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. Consistent with the Agency's interpretation that air emissions from animal waste at farms are not subject to EPCRA section 304 release reporting, the proposed rule explicitly exempts these types of releases from EPCRA reporting and would not result in additional costs.

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. The Agency is proposing to amend the EPCRA section 304 release notification regulations to add the reporting exemption for air emissions from animal waste at farms provided in CERCLA section 103(e), as amended.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It would 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. The EPA is proposing to amend the EPCRA section 304 release notification regulations to add the reporting exemption for air emissions from animal waste at farms provided in CERCLA section 103(e), as amended. Thus, Executive Order 13175 does not apply to this action.

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

The EPA interprets Executive Order 13045 as applying to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of *covered regulatory action* in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not pose an environmental health risk or safety risk. This proposed rule is intended to maintain consistency between EPCRA section 304 and CERCLA section 103(a) emergency release notification requirements by exempting reporting of air emissions from animal waste at farms.

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. The EPA is proposing to amend the EPCRA section 304 release notification regulations to add the reporting exemption for air emissions from animal waste at farms provided in CERCLA section 103(e), as amended.

J. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This proposed rule is intended to maintain consistency between EPCRA section 304 and CERCLA section 103(a) emergency release notification requirements by exempting reporting of air emissions from animal waste at farms under EPCRA.

List of Subjects in 40 CFR Part 355

Environmental protection, Chemicals, Disaster assistance, Hazardous substances, Hazardous waste, Natural resources, Penalties, Reporting and recordkeeping requirements, Superfund.

Dated: October 30, 2018.

Andrew R. Wheeler,

Acting Administrator

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR part 355 as follows:

PART 355—EMERGENCY PLANNING AND NOTIFICATION

■ 1. The authority citation for part 355 continues to read as follows:

Authority: Sections 302, 303, 304, 325, 327, 328, and 329 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) (42 U.S.C. 11002, 11003, 11004, 11045, 11047, 11048, and 11049).

■ 2. Amend § 355.31 by adding paragraph (g) to read as follows:

§ 355.31 What types of releases are exempt from the emergency release notification requirements of this subpart?

* * * * *

(g) Air emissions from animal waste (including decomposing animal waste) at a farm.

■ 3. Amend § 355.61 by adding in alphabetical order the definitions ''*Animal waste*'' and ''*Farm*'' to read as follows:

§ 355.61 How are key words in this part defined?

Animal waste means feces, urine, or other excrement, digestive emission, urea, or similar substances emitted by animals (including any form of livestock, poultry, or fish). This term includes animal waste that is mixed or commingled with bedding, compost, feed, soil, or any other material typically found with such waste.

* * * * *

Farm means a site or area (including associated structures) that—

(1) Is used for—

(i) The production of a crop; or

(ii) The raising or selling of animals (including any form of livestock, poultry, or fish); and

(2) Under normal conditions, produces during a farm year any agricultural products with a total value equal to not less than $1,000.

* * * * *

[FR Doc. 2018–24821 Filed 11–13–18; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register
Vol. 83, No. 220
Wednesday, November 14, 2018

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

National Agricultural Statistics Service

Notice of Intent To Request To Conduct a New Information Collection

AGENCY: National Agricultural Statistics Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 this notice announces the intention of the National Agricultural Statistics Service (NASS) to seek approval to conduct a new information collection to gather data related to rates paid for custom agricultural work done on farms. This clearance will allow NASS to conduct surveys in a timely manner for the cooperating institutions who provide funding for these surveys.

DATES: Comments on this notice must be received by January 14, 2019 to be assured of consideration.

ADDRESSES: You may submit comments, identified by docket number 0535–NEW, by any of the following methods:

- *Email: ombofficer@nass.usda.gov.* Include docket number above in the subject line of the message.
- *E-fax:* 855–838–6382.
- *Mail:* Mail any paper, disk, or CD–ROM submissions to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.
- *Hand Delivery/Courier:* Hand deliver to: David Hancock, NASS Clearance Officer, U.S. Department of Agriculture, Room 5336 South Building, 1400 Independence Avenue SW, Washington, DC 20250–2024.

FOR FURTHER INFORMATION CONTACT: Kevin L. Barnes, Associate Administrator, National Agricultural Statistics Service, U.S. Department of Agriculture, 202–720–4333. Copies of this information collection and related instructions can be obtained without charge from David Hancock, NASS—OMB Clearance Officer, at 202–690–2388 or at *ombofficer@nass.usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Custom Rates Surveys.

OMB Control Number: 0535–NEW.

Type of Request: Intent to seek approval to conduct a group of new information collections for a period of three years.

Abstract: The primary objective of the National Agricultural Statistics Service (NASS) is to collect, prepare, and issue state and national estimates of crop and livestock production, prices, and disposition; as well as economic statistics, environmental statistics related to agriculture; and also to conduct the Census of Agriculture. The Custom Rates program will collect information from farmers who have knowledge of rates for custom agricultural services (custom rates) during a specified reference period. These services include land tillage, application of fertilizers and chemicals, planting, harvesting, hauling, various livestock tasks, and many more tasks. The program will provide farm operators with rates for different custom services in their state and/or local area. All questionnaires included in this information collection will be voluntary. These surveys will be conducted through cooperative agreements with State Departments of Agriculture and/or universities; with the cooperators providing the funding. The time between funding being secured and the desired start of data collection is often too short to allow for a separate OMB approval for each survey. With this approval NASS will be able to provide services in a timelier manner.

Authority: These data will be collected under authority of 7 U.S.C. 2204(a). Individually identifiable data collected under this authority are governed by Section 1770 of the Food Security Act of 1985 as amended, 7 U.S.C. 2276, which requires USDA to afford strict confidentiality to non-aggregated data provided by respondents.

This Notice is submitted in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–113, 44 U.S.C. 3501, *et seq.*) and Office of Management and Budget regulations at 5 CFR part 1320.

NASS also complies with OMB Implementation Guidance, ''Implementation Guidance for Title V of the E-Government Act, Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA),'' **Federal Register**, Vol. 72, No. 115, June 15, 2007, p. 33362.

Estimate of Burden: Public reporting burden for this information collection is based on similar surveys with expected response time of 20 minutes. The estimated sample size will be approximately 40,000. The frequency of data collection for each survey is annual. The estimated number of responses per respondent is 1. Publicity materials and instruction sheets will account for approximately 5 minutes of additional burden per respondent. Respondents who refuse to complete a survey will be allotted 2 minutes of burden per attempt to collect the data. NASS will conduct the survey initially by mail with phone follow-up for non-response.

Respondents: Farmers who have a knowledge of rates for custom services.

Estimated Number of Respondents: Approximately 40,000 annually.

Frequency of Responses: On occasion.

Estimated Total Burden on Respondents: Approximately 14,500 hours annually. This will include burden for both the initial mailing and phone follow-up to non-respondents, as well as publicity and instruction materials mailed out with questionnaires.

Comments: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, through the use of appropriate automated, electronic, mechanical, technological, or other forms of information technology collection methods.

All responses to this notice will become a matter of public record and be summarized in the request for OMB approval.

Signed at Washington, DC, October 23, 2018.

Kevin L. Barnes,

Associate Administrator.

[FR Doc. 2018–24775 Filed 11–13–18; 8:45 am]

BILLING CODE 3410–20–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Virginia Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA) that a meeting of the Virginia Advisory Committee to the Commission will convene by conference call at 12:00 p.m. (EST) on Wednesday, November 28, 2018. The purpose of the meeting is for Committee members to continue discussing plans for the in-person briefing titled: Hate Crimes in VA—Incidences and Responses.

DATES: Wednesday, November 28, 2018, at 12:00 p.m. EST

ADDRESSES: *Public call-in information:* Conference call-in number: 1–800–474–8920 and conference call ID number: 8310490.

FOR FURTHER INFORMATION CONTACT: Ivy Davis at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 1–800–474–8920 and conference call ID number: 8310490. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free conference call-in number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–877–8339 and providing the operator with the toll-free conference call-in number: 1–800–474–8920 and conference call ID number: 8310490.

Members of the public are invited to make statements during the open comment period of the meeting or submit written comments. The comments must be received in the regional office approximately 30 days after each scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376–7548, or emailed to Corrine Sanders at *ero@usccr.gov.* Persons who desire additional information may contact the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://database.faca.gov/committee/meetings.aspx?cid=279,* click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meetings. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number, email or street address.

Agenda: Wednesday, November 28, 2018

I. Rollcall
II. Welcome
III. Project Panning Discussion
IV. Other Business
V. Adjourn

Dated: November 7, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–24754 Filed 11–13–18; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Pennsylvania Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission), and the Federal Advisory Committee Act (FACA) that a meeting of the Pennsylvania Advisory Committee to the Commission will convene by conference call at 11:30 a.m. (EST) on Tuesday, November 20, 2018. The Committee is considering and will discuss possible topics for its civil rights project.

DATES: Tuesday, November 20, 2018, at 11:30 a.m. (EDT).

Public Call-In Information: Conference call-in number: 800–949–2175 and conference call ID: 8426059.

FOR FURTHER INFORMATION CONTACT: Ivy Davis at *ero@usccr.gov* or by phone at 202–376–7533.

SUPPLEMENTARY INFORMATION: Interested members of the public may listen to the discussion by calling the following toll-free conference call-in number: 800–949–2175 and conference call ID: 8426059. Please be advised that before placing them into the conference call, the conference call operator will ask callers to provide their names, their organizational affiliations (if any), and email addresses (so that callers may be notified of future meetings). Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free conference call-in number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service at 1–800–877–8339 and providing the operator with the toll-free conference call-in number: 800–949–2175 and conference call ID: 8426059.

Members of the public are invited to submit written statements for the record. The statements must be received in the regional office approximately 30 days after the scheduled meeting. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, or emailed to Corrine Sanders at *ero@usccr.gov.* Persons who desire additional information may phone the Eastern Regional Office at (202) 376–7533.

Records and documents discussed during the meeting will be available for public viewing as they become available at *https://database.faca.gov/committee/meetings.aspx?cid=279,* click the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's website, *www.usccr.gov,* or to contact the Eastern Regional Office at the above phone number, email or street address.

Agenda: Tuesday, November 20, 2018

I. Rollcall
II. Welcome and Introductions
III. Project Planning

—Discuss Possible Topics for Civil Rights Project
IV. Other Business
V. Adjourn

Dated: November 7, 2018.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2018–24752 Filed 11–13–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–70–2018]

Foreign-Trade Zone (FTZ) 52—Suffolk County, New York; Notification of Proposed Production Activity; LNK International, Inc. (Pharmaceutical Products), Hauppauge, New York

Suffolk County, New York, grantee of FTZ 52, submitted a notification of proposed production activity to the FTZ Board on behalf of LNK International, Inc. (LNK), located at sites in Hauppauge, New York. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on November 5, 2018.

The LNK facilities are located within Subzone 52B. The facilities are used for the production of over-the-counter (OTC) analgesic pharmaceutical products. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status materials and components and specific finished products described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt LNK from customs duty payments on the foreign-status components used in export production. On its domestic sales, for the foreign-status materials/components noted below, LNK would be able to choose the duty rates during customs entry procedures that apply to dosage form ibuprofen, aspirin and acetaminophen pharmaceutical products (duty-free). LNK would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The components and materials sourced from abroad include: Ibuprofen active pharmaceutical ingredient; o-acetylsalicylic acid (aspirin) active pharmaceutical ingredient; diphenhydramine citrate; acetaminophen active pharmaceutical ingredient; caffeine; and, bulk mixture of acetaminophen (duty rates range from duty-free to 6.5%).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is December 24, 2018.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: November 7, 2018.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2018–24797 Filed 11–13–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–830]

Carbon and Certain Alloy Steel Wire Rod From Mexico: Preliminary Results of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that sales of carbon and certain alloy steel wire rod (wire rod) from Mexico were made at less than normal value during the period of review (POR), October 1, 2016, through September 30, 2017. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: Jolanta Lawska, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–8362.

Background

On October 29, 2002 Commerce published the *Wire Rod Order* in the **Federal Register**.[1] On December 7, 2017, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), Commerce initiated an administrative review of the *Wire Rod Order*[2] covering Deacero S.A.P.I. de C.V. (Deacero), ArcelorMittal Las Truchas, S.A. de C.V. (AMLT), ArcelorMittal Mexico S.A. de C.V. (AMM) (successor-in-interest to AMLT),[3] and Ternium Mexico S.A. de C.V. (Ternium). On May 31, 2018, Commerce extended the deadline for the preliminary results to November 5, 2018.[4] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[5]

Scope of the Order

The product covered by the *Wire Rod Order* is wire rod, in coils, of approximately round cross section, 5.00 mm or more, but less than 19.00 mm, in solid cross-sectional diameter. The subject merchandise is currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 7213.91.3000, 7213.91.3010, 7213.91.3011, 7213.91.3015, 7213.91.3020, 7213.91.3090, 7213.91.3091, 7213.91.3092, 7213.91.3093, 7213.91.4500, 7213.91.4510, 7213.91.4590, 7213.91.6000, 7213.91.6010, 7213.91.6090, 7213.99.0030, 7213.99.0031, 7213.99.0038, 7213.99.0090, 7227.20.0000, 7227.20.0010, 7227.20.0020, 7227.20.0030, 7227.20.0080, 7227.20.0090, 7227.20.0095, 7227.90.6010, 7227.90.6020, 7227.90.6030, 7227.90.6035, 7227.90.6050, 7227.90.6051, 7227.90.6053, 7227.90.6058, 7227.90.6059, 7227.90.6080, and 7227.90.6085. The HTSUS subheadings are provided for convenience and customs purposes only; the written product description remains dispositive. A full description

[1] *See Notice of Antidumping Duty Orders: Carbon and Certain Alloy Steel Wire Rod from Brazil, Indonesia, Mexico, Moldova, Trinidad and Tobago, and Ukraine,* 67 FR 65945 (October 29, 2002) (*Wire Rod Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 82 FR 57705, 57707 (December 7, 2017).

[3] *See Final Results of Changed Circumstances Review: Antidumping Duty Order on Carbon and Certain Alloy Steel Wire Rod from Mexico,* 82 FR 53456 (November 16, 2017) (Final Results of Changed Circumstances Review), in which Commerce determined that AMM is the successor-in-interest to AMLT.

[4] *See* Memorandum, ''Carbon and Certain Alloy Steel Wire Rod from Mexico: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated May 31, 2018.

[5] *See* ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Carbon and Certain Alloy Steel Wire Rod from Mexico; 2016–2017,'' dated concurrently and hereby adopted by this notice (Preliminary Decision Memorandum).

of the scope of the *Wire Rod Order* is contained in the Preliminary Decision Memorandum.

Preliminary Determination of No Shipments

On December 12, 2017, we received a timely-filed submission on behalf of AMM and its predecessor-in-interest AMLT that AMM/AMLT made no exports, sales, or entries of subject merchandise to the United States during the POR. To confirm AMM's no shipment claim, Commerce issued a no-shipment inquiry to U.S. Customs and Border Protection (CBP) requesting that it confirm AMM/AMLT had no shipments during the POR. CBP did not report that it had any information to contradict the claim of no shipments during the POR.

Given that AMM certified that AMM/AMLT made no shipments of subject merchandise to the United States during the POR, and there is no information calling its claims into question, we preliminarily determine that AMM/AMLT did not have any shipments during the POR. Consistent with Commerce's practice, we will not rescind the review with respect to AMM/AMLT but, rather, will complete the review and issue instructions to CBP based on the final results.[6]

Application of Adverse Facts Available With Regard to Ternium

Because Ternium failed to response to Commerce's questionnaire, we preliminarily find that necessary information is not on the record and that Ternium failed to cooperate to the best of its ability to comply with a request for information from Commerce in this review. As a result, we have preliminarily based Ternium's dumping margin on facts otherwise available with an adverse inference (AFA), in accordance with sections 776(a) and (b) of the Act and 19 CFR 351.308. As AFA, we have preliminarily assigned Ternium a dumping margin of 40.52 percent. For further discussion, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Act. Export and constructed export price were calculated in accordance with section 772 of the Act. Normal value was calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically *via* Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov* and is available 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 accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content. A list of topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

Preliminary Results of the Review

As a result of this review, we preliminarily determine the following weighted-average dumping margins exist for the POR:

Exporter/producer	Weighted-average dumping margins (percent)
Deacero S.A.P.I de C.V	17.65
Ternium Mexico S.A. de C.V (Ternium)	40.52

Assessment Rates

Upon issuance of the final results, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. If the weighted-average dumping margin for Deacero is not zero or *de minimis* (*i.e.,* less than 0.5 percent), we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1).[7] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer- specific assessment rate calculated in the final results of this review is above *de minimis* (*i.e.,* 0.5 percent). Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review where applicable.

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by each respondent for which they did not know that their merchandise was destined for the United States, we will instruct CBP to liquidate entries not reviewed at the all-others rate of 20.11 percent[8] if there is no rate for the intermediate company(ies) involved in the transaction. We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of wire rod from Mexico entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results, as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for the firms listed above will be equal to the dumping margins established in the final results of this review, except if the ultimate rates are *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rates will be zero; (2) for merchandise exported by producers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the producer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value investigation but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of the proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other

[6] *See, e.g., Certain Frozen Warmwater Shrimp from Thailand; Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Review, Preliminary Determination of No Shipments; 2012–2013,* 79 FR 15951, 15952 (March 24, 2014), unchanged in *Certain Frozen Warmwater Shrimp from Thailand: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Partial Rescission of Review; 2012–2013,* 79 FR, at 51306–51307 (August 28, 2014).

[7] In the preliminary results, Commerce applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

[8] *See Wire Rod Order,* 67 FR at 65947.

producers or exporters will continue to be 20.11 percent, the all-others rate established in the antidumping duty investigation.[9] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed in these preliminary results to parties in this proceeding within five days of the date of publication of this notice.[10]

Public Comment

Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.[11] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[12] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the established deadline.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

We intend to issue the final results of this administrative review, including the results of our analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

[9] *Id.*

[10] *See* 19 CFR 351.224(b).

[11] *See* 19 CFR 351.309(d).

[12] *See* 19 CFR 351.309(c)(2) and (d)(2) and 19 CFR 351.303 (for general filing requirements).

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(1).

Dated: November 5, 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

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2018–24801 Filed 11–13–18; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–821–802]

Agreement Suspending the Antidumping Duty Investigation on Uranium From the Russian Federation: Preliminary Results of 2016–2017 Administrative Review and Postponement of Final Results

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review of the Agreement Suspending the Antidumping Duty Investigation on Uranium from the Russian Federation (the Agreement). We preliminarily find that the State Atomic Energy Corporation ''ROSATOM'' (ROSATOM), its affiliates Joint Stock Company ''TENEX'' (TENEX) and TENAM Corporation (TENAM), and TENEX's unaffiliated reseller, Centrus Energy Corp. and United States Enrichment Corporation (collectively, Centrus), are in compliance with the Agreement.

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: Sally C. Gannon or Jill Buckles, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0162 or (202) 482–6230, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 16, 1992, Commerce signed an agreement with the Russian Federation's Ministry for Atomic Energy (MINATOM), the predecessor to ROSATOM, under section 734(l) of the Tariff Act of 1930, as amended (the Act), suspending the antidumping duty investigation on uranium from the Russian Federation.[1] There have been five amendments to the Agreement, the most recent of which was signed on February 1, 2008.[2] Section 8118 of the

[1] *See Antidumping; Uranium from Kazakhstan, Kyrgyzstan, Russia, Tajikistan, Ukraine, and Uzbekistan; Suspension of Investigations and Amendment of Preliminary Determinations,* 57 FR 49220, 49235 (October 30, 1992) (*1992 Suspension Agreement*).

[2] *See Amendment to Agreement Suspending the Antidumping Investigation on Uranium from the Russian Federation,* 59 FR 15373 (April 1, 1994) (*1994 Amendment*); *Amendments to the Agreement Suspending the Antidumping Investigation on Uranium from the Russian Federation,* 61 FR 56665 (November 4, 1996) (*1996 Amendments*); *Amendment to Agreement Suspending the*

Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, codified at 42 U.S.C. 2297h *et seq.* (2008) (Domenici Amendment) established import limitations through 2020 that in large part mirror the export limits instituted in the 2008 amendment to the Agreement. On February 2, 2010, Commerce issued its Statement of Administrative Intent (SAI) which provided implementation guidance related to the 2008 amendment.

On October 4, 2017, Commerce notified interested parties of the opportunity to request an administrative review of the Agreement.[3] On October 30, 2017, domestic interested party Louisiana Energy Services LLC (LES) submitted a request for an administrative review of the Agreement. On December 7, 2017, Commerce published in the **Federal Register** a notice initiating an administrative review of the Agreement.[4] The period of review (POR) is October 1, 2016, through September 30, 2017. On April 27, 2018, Commerce issued questionnaires to ROSATOM, TENEX, and any other affiliated or unaffiliated exporters and resellers, as applicable. For a complete description of the events that followed the initiation of this administrative review, *see* the Preliminary Decision Memorandum.[5] 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 accessed directly 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 Review

The product covered by this Agreement is natural uranium in the form of uranium ores and concentrates; natural uranium metal and natural uranium compounds; alloys, dispersions (including cermets), ceramic products, and mixtures containing natural uranium or natural uranium compounds; uranium enriched in U^{235} and its compounds; alloys, dispersions (including cermets), ceramic products, and mixtures containing uranium enriched in U^{235} or compounds of uranium enriched in U^{235}; and any other forms of uranium within the same class or kind.

Imports of uranium ores and concentrates, natural uranium compounds, and all forms of enriched uranium are currently classifiable under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 2612.10.00, 2844.10.20, 2844.20.00, respectively. Imports of natural uranium metal and forms of natural uranium other than compounds are currently classifiable under HTSUS subheadings: 2844.10.10 and 2844.10.50. HTSUS subheadings are provided for convenience and Customs purposes. The written description of the scope of this proceeding is dispositive. A full description of the scope of the order is contained in the Preliminary Decision Memorandum.

Methodology and Preliminary Results

Commerce is conducting this review in accordance with section 751(a)(1)(C) of the Act, which specifies that Commerce shall ''review the current status of, and compliance with, any agreement by reason of which an investigation was suspended.'' In this case, Commerce and MINATOM (the predecessor to ROSATOM) signed the Agreement, under section 734(l) of the Act, suspending the underlying antidumping duty investigation on October 16, 1992, which was subsequently amended on March 11, 1994, October 3, 1996, May 7, 1997, and February 1, 2008. Section 734(l) provides that Commerce may suspend an investigation upon acceptance of an agreement with a non-market-economy country[6] to restrict the volume of imports into the United States, if Commerce determines that such an agreement is in the public interest, effective monitoring is possible, and the agreement ''will prevent the suppression or undercutting of price levels of domestic products by imports of the merchandise under investigation.''

After reviewing the information submitted in initial questionnaire responses and related new factual information and comments from interested parties in this administrative review, we preliminarily find no evidence that the Agreement's export limits have not been complied with, or evidence of any violation of the Agreement, during the POR. For example, Commerce reviewed the contract, contract amendment, shipment approval request documentation, and Master Export Schedules submitted on the record of the administrative review by the respondents for completeness and compliance. We found no discrepancies in the respondents' utilization of the export limits during the POR, *i.e.,* the overall export limits were not exceeded nor were approved contract quantities exceeded. However, in examining respondents' individual contracts, contract amendments, and shipment documentation filed on the record of the review, we found certain inconsistencies that required further examination and clarification. Consequently, Commerce issued supplemental questionnaires to TENEX, TENAM, and Centrus regarding, in part, certain contracts in force and shipments executed during the POR. We have not yet received all of the supplemental questionnaire responses and/or had the opportunity to undertake a fulsome review of the responses to these supplemental questionnaires. In addition, based on Commerce's review to date of the record information, we do not yet find a sufficient basis to make a complete determination as to whether the Agreement continues to meet the relevant statutory requirements set forth in Section 734(l) of the Act.

In light of parties' comments and due to the complex nature of the issues of price suppression and undercutting and public interest, we find that we require additional time and information in order to complete our examination of whether the Agreement continues to meet the statutory requirements referenced above. Commerce also needs to obtain additional information and needs additional time to evaluate information received, and to be received, from respondents and interested parties in order to complete its examination of the current status of

Antidumping Investigation on Uranium from the Russian Federation, 62 FR 37879 (July 15, 1997) (*1997 Amendment*); *and Amendment to the Agreement Suspending the Antidumping Investigation on Uranium from the Russian Federation,* 73 FR 7705 (February 11, 2008) (*2008 Amendment*).

[3] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 82 FR 46217 (October 4, 2017).

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 82 FR 57705 (December 7, 2017).

[5] *See* Memorandum to Gary Taverman, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance, re ''Decision Memorandum for the Preliminary Results of the Administrative Review of the Agreement Suspending the Antidumping Investigation on Uranium from the Russian Federation,'' dated concurrently with and adopted by this notice.

[6] Because Commerce determined that the Russian Federation was a non-market economy at the time the Agreement was signed, the Agreement was entered into under section 734(l) of the Act, which applies to non-market-economy countries.

the Agreement. Therefore, we intend to continue our examination after the issuance of these preliminary results as to whether the Agreement has been complied with during the POR and whether the Agreement continues to meet the statutory requirements set forth in section 734(l) of the Act and intend to issue a post-preliminary analysis as soon as practicable. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Disclosure and Public Comment

As discussed above, Commerce needs additional information and additional time to review the information received before making a definitive preliminary finding. Therefore, we intend to issue a post-preliminary analysis on these issues as soon as practicable. The comment period on these preliminary results as well as the post-preliminary analysis will be stated with the release of the post-preliminary analysis. At that time, interested parties will have the opportunity to submit case and rebuttal briefs.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically filed document must be received successfully in its entirety by Commerce's electronic records system ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.[7]

Postponement of Final Results

Section 751(a)(3)(A) of the Act, requires Commerce to complete the final results of an administrative review within 120 days after the date on which the preliminary results are published. If it is not practicable to complete the review within this time period, section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(2) allow Commerce to extend the time limit for the final results to a maximum of 180 days after the date on which the preliminary results are published.

[7] *See* 19 CFR 351.310(c).

We determine that it is not practicable to complete the final results of this administrative review within 120 days from the date of publication of these preliminary results. Commerce requires additional time to analyze supplemental questionnaire responses, complete our examination, issue our post-preliminary analysis, conduct verification of questionnaire responses, and allow for case briefs and rebuttal briefs on our preliminary and post-preliminary results. Accordingly, Commerce is extending the deadline for the final results of this administrative review by 60 days. The final results of the review will now be due no later than 180 days from the date of publication of these preliminary results.

We are issuing and publishing these preliminary results of review in accordance with sections 751(a)(l) and 777(i)(l) of the Act and 19 CFR 351.213.

Dated: November 5, 2018.

Gary Taverman,

Deputy Assistant Secretary for Antidumping Duty and Countervailing Duty Operations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2018–24799 Filed 11–13–18; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–078]

Countervailing Duty Investigation of Large Diameter Welded Pipe From the People's Republic of China: Final Affirmative Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers/exporters of large diameter welded pipe from the People's Republic of China (China).

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: Justin Neuman at (202) 482–0486 or Benito Ballesteros at (202) 482–7425, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On June 29, 2018, Commerce published in the **Federal Register** the *Preliminary Determination* of this countervailing duty (CVD) investigation and invited interested parties to comment.[1] We received no comments from any interested parties.

Period of Investigation

The period of investigation is January 1, 2017, through December 31, 2017.

Scope of the Investigation

The product covered by this investigation is large diameter welded pipe from China. For a full description of the scope of this investigation, *see* the ''Scope of the Investigation,'' at the Appendix to this notice.

Scope Comments

During the course of this investigation and the concurrent LTFV investigations of large diameter welded pipe from Canada, Greece, Korea, China and Turkey, and the concurrent countervailing duty investigations of large diameter welded pipe from India, Korea and Turkey, Commerce received numerous scope comments from interested parties. We issued a Preliminary Scope Decision Memorandum [2] to address these comments. Further, in the *Preliminary Determination,* we set aside a period of time for parties to address scope issues in scope case and rebuttal briefs. No interested parties submitted scope comments in case or rebuttal briefs. Therefore, for this final determination, the scope of this investigation remains unchanged from that published in the *Preliminary Determination.*

Use of Adverse Facts Available

As noted above, we received no comments pertaining to the *Preliminary Determination.* As stated in the *Preliminary Determination,* we found that the mandatory respondents in this investigation, Hefei Zijin Steel Tube Manufacturing Co., Hefei Ziking Steel Pipe, and Panyu Chu Kong Steel Pipe Co. Ltd., did not cooperate to the best of their abilities and, accordingly, we determined it appropriate to apply facts otherwise available with adverse inferences, in accordance with section 776(a)–(b) of the Tariff Act of 1930, as amended (the Act).[3] For this final determination, Commerce has made no

[1] *See Large Diameter Welded Pipe from the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Determination,* 83 FR 30695 (June 29, 2018) (*Preliminary Determination*).

[2] *See* Memorandum, ''Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated June 19, 2018 (Preliminary Scope Decision Memorandum).

[3] *See Preliminary Determination.*

changes to the *Preliminary Determination.*

All-Others Rate

As discussed in the *Preliminary Determination,* Commerce based the selection of the ''All-Others'' rate on the countervailable subsidy rate established for the mandatory respondents in accordance with section 705(c)(5)(A)(ii) of the Act.[4] We made no changes to the selection of this rate for this final determination.

Final Determination

Commerce determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent)
Hefei Zijin Steel Tube Manufacturing Co	198.49
Hefei Ziking Steel Pipe	198.49
Panyu Chu Kong Steel Pipe Co. Ltd	198.49
All-Others	198.49

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination* and pursuant to section 703(d)(1)(B) and (d)(2) of the Act, Commerce directed U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the Scope of the Investigation section, entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. In accordance with section 703(d) of the Act, we issued instructions to CBP to discontinue the suspension of liquidation for CVD purposes for subject merchandise entered, or withdrawn from warehouse, on or after October 27, 2018, but to continue the suspension of liquidation of all entries from June 29, 2018, through October 26, 2018.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order, reinstate the suspension of liquidation under section 706(a) of the Act, and will require a cash deposit of estimated countervailing duties for such entries of subject merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated, and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

[4] *Id.*

International Trade Commission Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Notification Regarding Administrative Protective Orders

This notice will serve as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of propriety information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act and 19 CFR 351.210(c).

Dated: November 5, 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 welded carbon and alloy steel pipe (including stainless steel pipe), more than 406.4 mm (16 inches) in nominal outside diameter (large diameter welded pipe), regardless of wall thickness, length, surface finish, grade, end finish, or stenciling. Large diameter welded pipe may be used to transport oil, gas, slurry, steam, or other fluids, liquids, or gases. It may also be used for structural purposes, including, but not limited to, piling. Specifically, not included is large diameter welded pipe produced only to specifications of the American Water Works Association (AWWA) for water and sewage pipe.

Large diameter welded pipe used to transport oil, gas, or natural gas liquids is normally produced to the American Petroleum Institute (API) specification 5L. Large diameter welded pipe may also be produced to American Society for Testing and Materials (ASTM) standards A500, A252, or A53, or other relevant domestic specifications, grades and/or standards. Large diameter welded pipe can be produced to comparable foreign specifications, grades and/or standards or to proprietary specifications, grades and/or standards, or can be non-graded material. All pipe meeting the physical description set forth above is covered by the scope of this investigation, whether or not produced according to a particular standard.

Subject merchandise also includes large diameter welded pipe that has been further processed in a third country, including but not limited to coating, painting, notching, beveling, cutting, punching, welding, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the in-scope large diameter welded pipe.

The large diameter welded pipe that is subject to this investigation is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7305.11.1030, 7305.11.1060, 7305.11.5000, 7305.12.1030, 7305.12.1060, 7305.12.5000, 7305.19.1030, 7305.19.1060, 7305.19.5000, 7305.31.4000, 7305.31.6010, 7305.31.6090, 7305.39.1000 and 7305.39.5000. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

[FR Doc. 2018–24805 Filed 11–13–18; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–826]

Certain Hot-Rolled Steel Flat Products From Republic of Turkey: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Colakoglu Metalurji A.S. and Colakoglu Dis Ticaret A.S. (collectively, Colakoglu) did not sell subject merchandise in the United States at prices below normal value during the period of review (POR). Additionally, Commerce preliminarily determines that three other companies for which we initiated reviews had no shipments during the POR. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: Lingjun Wang, 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) 482–2316.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty order on certain hot-rolled steel flat products (hot-rolled steel) from the Republic of Turkey (Turkey). The notice of initiation of this administrative review was published on December 7, 2017.[1] This review covers 11 producers or exporters of the subject merchandise. The POR is March 22, 2016, through September 30, 2017. Commerce selected Colakoglu as the mandatory respondent in this administrative review.[2]

Scope of the Order

The merchandise covered by the order is certain hot-rolled steel flat products. For a complete description of the scope of the order, *see* the Preliminary Decision Memorandum.[3]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). Export price and constructed export price are calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and it is available 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 accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Preliminary Decision Memorandum are identical in content. A list of the topics discussed in the Preliminary Decision Memorandum is attached as the Appendix to this notice.

Preliminary Determination of No Shipments

Among the companies under review, three companies, Gazi Metal Mamulleri Sanayi Ve Ticaret A.S. (Gazi), Toscelik Profile and Sheet Ind. Co. (a.k.a. Toscelik Profil ve Sac endustrisi A.S.) and Tosyali Holding A.S. (collectively, Toscelik), and Eregli Demir ve Celik Fabrikalari T.A.S. and Iskenderun Iron and Steel Works Ltd. (a.k.a. Iskenderun Demir ve Celik A.S.) (collectively, Erdemir), each properly filed statements reporting that they made no shipments of subject merchandise to the United States during the POR. Based on the certifications submitted and our analysis of Customs and Border Protection (CBP) information, we preliminarily determine that Gazi, Toscelik, and Erdemir had no shipments during the POR.[4] Consistent with its practice, Commerce finds that it is not appropriate to preliminarily rescind the review with respect to these companies but, rather, to complete the review and issue appropriate instructions to CBP based on the final results of this review.

Preliminary Results of the Review

As a result of this review, we preliminarily determine the following weighted-average dumping margins for the period March 22, 2016, through September 30, 2017:

Exporter or producer	Weighted-average dumping margin (percent)
Colakoglu Metalurji A.S. and Colakoglu Dis Ticaret A.S	0
Agir Haddecilik A.S	0
Habas Industrial and Medical Gases Production Industries Inc	0
Habas Sinai ve Tibbi Gazlar Istihsal Endustrisi	0
MMK Atakas Metalurji	0
Ozkan Iron and Steel Ind	0

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries.

Pursuant to 19 CFR 351.212(b)(1), we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales. Where the mandatory respondents did not report entered value, we calculated the entered value in order to calculate the *ad valorem* assessment rate. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For the companies which were not selected for individual review, we will assign an assessment rate based on the weighted-average dumping margins calculated for the mandatory respondents. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated antidumping duties, where applicable.[5]

We intend to issue liquidation instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for each specific company listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated companies not participating in this review, the cash deposit will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, or the underlying investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 82 FR 57705 (December 7, 2017).

[2] *See Memorandum,* ''Respondent Selection for the Administrative Review of the Antidumping Duty Order of Certain Hot-Rolled Steel Flat Products from Turkey,'' dated January 16, 2018.

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Certain Hot-Rolled Steel Flat Products from the Republic of Turkey; 2016–2017,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See* Preliminary Decision Memorandum.

[5] *See* section 751(a)(2)(C) of the Act.

deposit rate for all other manufacturers or exporters will continue to be 6.41 percent, the all-others rate established in the underlying investigation.[6] These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

Commerce intends to disclose the calculations performed in connection with these preliminary results to interested parties within five days after the date of publication of this notice.[7] Interested parties may submit case briefs not later than 30 days after the date of publication of this notice.[8] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the time limit for filing case briefs.[9] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[10] Case and rebuttal briefs should be filed using ACCESS.[11]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed request for a hearing must be received successfully in its entirety by ACCESS by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.[12] Hearing requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.[13]

Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the publication of these preliminary results in the **Federal Register,** unless otherwise extended.[14]

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 1, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2018–24795 Filed 11–13–18; 8:45 am]

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[6] *See Certain Hot-Rolled Steel Flat Products from Australia, Brazil, Japan, the Republic of Korea, the Netherlands, the Republic of Turkey, and the United Kingdom: Amended Final Affirmative Antidumping Determinations for Australia, the Republic of Korea, and the Republic of Turkey and Antidumping Duty Orders,* 81 FR 67962 (October 3, 2016).

[7] *See* 19 CFR 351.224(b).

[8] *See* 19 CFR 351.309(c)(1)(ii).

[9] *See* 19 CFR 351.309(d)(1).

[10] *See* 19 CFR 351.309(c)(2) and (d)(2).

[11] *See* 19 CFR 351.303.

[12] *See* 19 CFR 351.310(c); 19 CFR 351.303(b)(1).

[13] *See* 19 CFR 351.310(c).

[14] *See* Section 751(a)(3)(A) of the Act.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–560–829]

Certain Uncoated Paper From Indonesia: Amended Final Results of Countervailing Duty Administrative Review; 2015–2016

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is amending its final results of the administrative review of the countervailing duty (CVD) order on certain uncoated paper from Indonesia to correct ministerial errors in the calculation of the countervailable subsidy rates for PT Anugrah Kertas Utama, PT Riau Andalan Kertas, APRIL Fine Paper Macao Commercial Offshore Limited, and their cross-owned affiliates (collectively APRIL). As a result of the correction of these errors, we calculated a revised subsidy rate for APRIL for 2015; however we did not revise APRIL's subsidy rate for 2016. The amended final 2015 countervailable subsidy rate is listed below in the section entitled, ''Amended Final Results.''

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: David Goldberger or Darla Brown, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4136 or 202–482–1791, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 17, 2018, Commerce published the Final Results of the 2015–2016 administrative review in the **Federal Register**.[1] On October 16, 2018, domestic interested parties [2] timely filed ministerial error allegations with respect to the calculation of the countervailable subsidy rates in the Final Results for the respondent in the review, APRIL.[3]

[1] *See Certain Uncoated Paper From Indonesia: Final Results of Countervailing Duty Administrative Review; 2015–2016,* 83 FR 52383 (October 17, 2018) (*Final Results*), and accompanying Issues and Decision Memorandum (IDM).

[2] These parties are the Packaging Corporation of America (PCA), and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL–CIO, CLC (USW).

[3] *See* The Domestic Interested Parties' Letter, ''First Administrative Review of the Countervailing Duty Order on Uncoated Paper from Indonesia—

Continued

Scope of the Order

The merchandise covered by the order is certain uncoated paper from Indonesia.[4] Imports of the subject merchandise are provided for under Harmonized Tariff Schedule of the United States (HTSUS) categories 4802.56.1000, 4802.56.2000, 4802.56.3000, 4802.56.4000, 4802.56.6000, 4802.56.7020, 4802.56.7040, 4802.57.1000, 4802.57.2000, 4802.57.3000, and 4802.57.4000. Some imports of subject merchandise may also be classified under 4802.62.1000, 4802.62.2000, 4802.62.3000, 4802.62.5000, 4802.62.6020, 4802.62.6040, 4802.69.1000, 4802.69.2000, 4802.69.3000, 4811.90.8050 and 4811.90.9080. While HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope is dispositive.

Ministerial Error

Section 751(h) of the Tariff Act of 1930, as amended (the Act), defines ''ministerial errors'' as including ''errors in addition, subtraction, or other arithmetic function, clerical errors resulting from inaccurate copying, duplication, or the like, and any other type of unintentional error which the administering authority considers ministerial.'' [5] The domestic interested parties allege that we made ministerial errors in our calculation of the 2015 and 2016 countervailable subsidy rates for APRIL by: (1) Correcting the freight adjustments for one of the benchmark prices used to calculate the 2015 Log Export Ban benefit; (2) correcting the inland freight adjustments for two benchmark prices used to calculate the 2015 and 2016 Provision of Standing Timber for Less Than Adequate Remuneration (Stumpage) benefit; and (3) incorporating all of the revised 2015 harvesting cost data provided at verification to calculate the benefit under the Stumpage program.[6] After analyzing these comments, we find that we made the alleged ministerial errors in the Final Results, within the meaning of section 751(h) of the Act and 19 CFR 351.224(f).[7] Correction of these errors in APRIL's benefit calculations results in a revised countervailable subsidy rate for 2015, but no change in the 2016 countervailable subsidy rate. For a detailed discussion of these ministerial errors, see the Ministerial Error Memorandum.

Amended Final Results of the Review

As a result of correcting the ministerial errors decribed above, we determine the following countervailable subsidy rates for 2015 and 2016:

Company	2015 *Ad valorem* rate (%)	2016 *Ad valorem* rate [8] (%)
APRIL Fine Paper Macao Commercial Offshore Limited/PT Anugrah Kertas Utama/PT Riau Andalan Kertas/ PT Intiguna Primatama/PT Riau Andalan Pulp & Paper/PT Esensindo Cipta Cemerlang/PT Sateri Viscose International/ PT ITCI Hutani Manunggal	11.73	5.13

Assessment Rates

In accordance with 19 CFR 351.212(b)(2), Commerce intends to issue appropriate instructions to U.S. Customs and Border Protection (CBP) in accordance with the amended final results of this review.

Cash Deposit Requirements

Commerce instructed CBP to collect cash deposits of estimated countervailing duties at the 2016 *ad valorem* rate shown above for APRIL, on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. After correcting the ministerial errors noted above, the 2016 *ad valorem* rate calculated for APRIL did not change; therefore, we will not issue revised cash deposit intructions to CBP because the cash deposit rate for APRIL remains unchanged from the *Final Results*.

For all non-reviewed firms, Commerce instructed CBP to continue to collect cash deposits at the most recent company-specific or all-others rate applicable to the company, as appropriate. Accordingly, the cash deposit requirements applied to companies covered by this order, but not examined in this administrative review, are those established in the most recently completed segment of the proceeding for each company. These cash deposit requirements shall remain in effect until further notice.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

These amended final results are issued and published in accordance with sections 751(h) and 777(i) of the Act and 19 CFR 351.224(e).

Dated: November 7, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–24800 Filed 11–13–18; 8:45 am]

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PCA and the USW's Ministerial Error Comments,'' dated October 16, 2018 (Ministerial Error Allegation).

[4] For a complete description of the scope of the order, *see* IDM.

[5] *See also* 19 CFR 351.224(f).

[6] *See* Ministerial Error Allegation.

[7] *See* Memorandum, ''Ministerial Error Allegations,'' dated concurrently with this notice (Ministerial Error Memorandum).

[8] The 2016 *ad valorem* rate for APRIL is unchanged from the *Final Results*.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–842; A–580–868; C–580–869]

Preliminary Results of Changed Circumstances Reviews of the Antidumping Duty Orders on Large Residential Washers From the Republic of Korea and Mexico, and the Countervailing Duty Order on Large Residential Washers From the Republic of Korea

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines not to revoke the antidumping duty (AD) orders on large residential washers (LRWs) from the Republic of Korea (Korea) and Mexico and the countervailing duty (CVD) order on large residential washers from Korea, in part, with respect to LRWs that (1) have a horizontal rotational axis; (2) are front loading; and (3) have a drive train consisting, *inter alia,* of (a) a controlled induction motor and (b) a belt drive (hereinafter, FL CIM/Belt washers), because Whirlpool Corporation (Whirlpool), the requestor, does not account for substantially all of the production of domestic like product to which these orders pertain.

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: William Miller or Ajay Menon, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–3906 or (202) 482–1993, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 11, 2018, in response to a request by Whirlpool, a domestic producer of the subject merchandise, Commerce published a notice of initiation of changed circumstances reviews to consider the possible revocation, in part, of the AD orders on LRWs from Korea and Mexico and the CVD order on large residential washers from Korea (collectively, the *Orders* [1]) with respect to FL CIM/Belt washers.[2] In the *Initiation Notice,* we invited comments from: (1) Members of the domestic industry, including their domestic production data of LRWs for 2017; and (2) other interested parties regarding industry support.[3]

On May 21, 2018, we received comments from Haier U.S. Appliance Solutions, Inc., d/b/a GE Appliances (GE); [4] LG Electronics USA, Inc., LG Electronics Alabama, Inc., and LG Electronics, Inc. (collectively, LGE); [5] Samsung Electronics Co., Ltd., Samsung Electronics America, and Samsung Electronics Home Appliances America (collectively, Samsung); [6] and Whirlpool.[7] Samsung opposed Whirlpool's request, noting that the U.S. International Trade Commission defined FL CIM/Belt washers as part of the domestic like product.[8] LGE also opposed Whirlpool's request, and argued that partially revoking the *Orders* would harm domestic producers.[9] Additionally, Samsung and LGE each argued that their potential 2018 and 2019 production should be included in Commerce's analysis because they started producing LRWs in the United States in 2018.[10] GE also opposed Whirlpool's request and provided its 2017 production data.[11] Finally, Whirlpool submitted additional comments in support of its request and provided its 2017 production data.[12]

On May 29, 2018, we received rebuttal comments from LGE,[13] Samsung,[14] and Whirlpool.[15] In their rebuttal comments, LGE and Samsung reiterated that Whirlpool does not account for substantially all of the domestic industry.[16] Conversely, in its rebuttal comments, Whirlpool argued that Commerce should use 2017 production data in determining industry support and not speculative future production.[17] Whirlpool further asserted that Commerce should disregard GE's 2017 production data and exercise its discretion to find that Whirlpool constitutes ''substantially all'' of the domestic industry.[18]

Scope of the Orders

The products covered by the *Orders* are all large residential washers and certain subassemblies thereof from Mexico and Korea.

For purposes of these *Orders,* the term ''large residential washers'' denotes all automatic clothes washing machines, regardless of the orientation of the rotational axis, except as noted below, with a cabinet width (measured from its widest point) of at least 24.5 inches (62.23 cm) and no more than 32.0 inches (81.28 cm).

Also covered are certain subassemblies used in large residential washers, namely: (1) All assembled cabinets designed for use in large residential washers which incorporate, at a minimum: (a) At least three of the six cabinet surfaces; and (b) a bracket; (2) all assembled tubs [19] designed for use in large residential washers which incorporate, at a minimum: (a) a tub; and (b) a seal; (3) all assembled baskets [20] designed for use in large residential washers which incorporate, at a minimum: (a) A side wrapper; [21] (b) a base; and (c) a drive hub; [22] and (4) any combination of the foregoing subassemblies.

Excluded from the scope are stacked washer-dryers and commercial washers. The term ''stacked washer-dryers'' denotes distinct washing and drying machines that are built on a unitary frame and share a common console that controls both the washer and the dryer. The term ''commercial washer'' denotes an automatic clothes washing machine designed for the ''pay per use'' market meeting either of the following two definitions:

[1] *See Large Residential Washers from Mexico and the Republic of Korea: Antidumping Duty Orders,* 78 FR 11148 (February 15, 2013); and *Large Residential Washers from the Republic of Korea: Countervailing Duty Order,* 78 FR 11154 (February 15, 2013) (the *Orders*).

[2] *See Large Residential Washers from the Republic of Korea and Mexico: Initiation of Changed Circumstances Reviews, and Consideration of Revocation, in Part, of the Antidumping Duty Orders on Large Residential Washers from the Republic of Korea and Mexico and the Countervailing Duty Order on Large Residential Washers from the Republic of Korea,* 83 FR 22006 (May 11, 2018) (*Initiation Notice*).

[3] *Id.,* 83 FR at 22007.

[4] *See* GE's Letter, ''Large Residential Washers from the Republic of Korea and Mexico—GE Appliances Entry of Appearance and Substantive Response,'' (GE's Comments) dated May 21, 2018, at 2.

[5] *See* LGE's Letter, ''LGE's Comments on Initiation of Changed Circumstances Review (CCR) Large Residential Washers from Korea,'' (LGE's Comments) dated May 21, 2018, at 2–11.

[6] *See* Samsung's Letter, ''Large Residential Washers from Korea and Mexico: Belt Drive CCR Response to Request for Information and Comments,'' (Samsung's Comments) dated May 21, 2018, at 2–7.

[7] *See* Whirlpool Corporation's (Whirlpool) Letter, ''Large Residential Washers from Korea and Mexico: Response of Whirlpool Corporation to U.S. Department of Commerce Request for 2017 Production Data to Support Partial Revocation of AD/CVD Orders,'' (Whirlpool's Comments) dated May 21, 2018, at 2.

[8] *See* Samsung's Comments at 3.

[9] *See* LGE's Comments at 6.

[10] *Id.* at 3; *see also* Samsung's Comments at 6.

[11] *See* GE's Comments at 2.

[12] *See* Whirlpool's Comments at 2.

[13] *See* LGE's Letter, ''LG Electronics' Rebuttal Comments (Changed Circumstances Review) Large Residential Washers from Korea and Mexico,'' (LGE's Rebuttal Comments) dated May 29, 2018, at 2–5.

[14] *See* Samsung's Letter, ''Large Residential Washers from Korea and Mexico: Belt Drive CCR Response to Comments and Information,'' (Samsung's Rebuttal Comments) dated May 29, 2018.

[15] *See* Whirlpool's Letter, ''Large Residential Washers (''LRWs'') from Korea and Mexico: Rebuttal Comments of Whirlpool Corporation,'' (Whirlpool's Rebuttal Comments) dated May 29, 2018.

[16] *See* LGE's Rebuttal Comments at 4; *see also* Samsung's Rebuttal Comments at 2.

[17] *See* Whirlpool's Rebuttal Comments at 2.

[18] *Id.* at 6.

[19] A ''tub'' is the part of the washer designed to hold water.

[20] A ''basket'' (sometimes referred to as a ''drum'') is the part of the washer designed to hold clothing or other fabrics.

[21] A ''side wrapper'' is the cylindrical part of the basket that actually holds the clothing or other fabrics.

[22] A ''drive hub'' is the hub at the center of the base that bears the load from the motor.

(1) (a) it contains payment system electronics; [23] (b) it is configured with an externally mounted steel frame at least six inches high that is designed to house a coin/token operated payment system (whether or not the actual coin/token operated payment system is installed at the time of importation); (c) it contains a push button user interface with a maximum of six manually selectable wash cycle settings, with no ability of the end user to otherwise modify water temperature, water level, or spin speed for a selected wash cycle setting; and (d) the console containing the user interface is made of steel and is assembled with security fasteners; [24] *or*

(2) (a) it contains payment system electronics; (b) the payment system electronics are enabled (whether or not the payment acceptance device has been installed at the time of importation) such that, in normal operation,[25] the unit cannot begin a wash cycle without first receiving a signal from a *bona fide* payment acceptance device such as an electronic credit card reader; (c) it contains a push button user interface with a maximum of six manually selectable wash cycle settings, with no ability of the end user to otherwise modify water temperature, water level, or spin speed for a selected wash cycle setting; and (d) the console containing the user interface is made of steel and is assembled with security fasteners.

Also excluded from the scope are automatic clothes washing machines with a vertical rotational axis and a rated capacity of less than 3.7 cubic feet, as certified to the U.S. Department of Energy pursuant to 10 CFR 429.12 and 10 CFR 429.20, and in accordance with the test procedures established in 10 CFR Part 430.

The products subject to these *Orders* are currently classifiable under subheadings 8450.20.0040 and 8450.20.0080 of the Harmonized Tariff System of the United States (HTSUS). Products subject to these *Orders* may also enter under HTSUS subheadings 8450.11.0040, 8450.11.0080, 8450.90.2000, and 8450.90.6000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to this scope is dispositive.

[23] ''Payment system electronics'' denotes a circuit board designed to receive signals from a payment acceptance device and to display payment amount, selected settings, and cycle status. Such electronics also capture cycles and payment history and provide for transmission to a reader.

[24] A ''security fastener'' is a screw with a non-standard head that requires a non-standard driver. Examples include those with a pin in the center of the head as a ''center pin reject'' feature to prevent standard Allen wrenches or Torx drivers from working.

[25] ''Normal operation'' refers to the operating mode(s) available to end users (*i.e.,* not a mode designed for testing or repair by a technician).

Scope of Changed Circumstances Reviews

Whirlpool requests that Commerce revoke the *Orders,* in part, with respect to FL CIM/Belt washers.[26] Should Commerce determine to revoke the *Orders,* in part, Whirlpool proposes that Commerce amend the scope language as follows: ''{A}lso excluded from the scope are automatic clothes washing machines that meet all of the following conditions: (1) have a horizontal rotational axis; (2) are front loading; and (3) have a drive train consisting, *inter alia,* of (a) a controlled induction motor and (b) a belt drive.'' [27]

Preliminary Results of Changed Circumstances Reviews

Pursuant to sections 751(d)(1) and 782(h) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.222(g), Commerce may revoke an AD or CVD order, in whole or in part, based on a review under section 751(b) of the Act (*i.e.,* a changed circumstances review). Section 751(b)(1) of the Act requires that a changed circumstances review be conducted upon receipt of a request which shows changed circumstances sufficient to warrant a review. Section 782(h)(2) of the Act gives Commerce the authority to revoke an order if producers accounting for substantially all of the production of the domestic like product have expressed a lack of interest in the order. Section 351.222(g) of Commerce's regulations provides that Commerce will conduct a changed circumstances review under 19 CFR 351.216, and may revoke an order (in whole or in part), if it concludes that: (i) Producers accounting for substantially all of the production of the domestic like product to which the order pertains have expressed a lack of interest in the relief provided by the order, in whole or in part, or (ii) if other changed circumstances sufficient to warrant revocation exist. Both the Act and Commerce's regulations require that ''substantially all'' domestic producers express a lack of interest in the order for Commerce to revoke the order, in whole or in part.[28] Commerce has interpreted ''substantially all'' to represent producers accounting for at least 85 percent of U.S. production of the domestic like product.[29]

Record evidence indicates that Whirlpool does not account for at least 85 percent of the production of the domestic like product, and therefore, does not account for ''substantially all'' of the production of the domestic like product.[30] We based our analysis on actual 2017 production volumes, the most recent complete year for which we have actual production data.[31] Information on the record of this proceeding shows that in 2017, only GE and Whirlpool had actual domestic production of LRWs.[32] GE opposed Whirlpool's request. We find no basis to disregard GE's 2017 production volume for purposes of our preliminary analysis, as suggested by Whirlpool.

Therefore, based on our analysis of the 2017 production volumes of the domestic industry, we preliminarily determine not to revoke the *Orders,* in part, with respect to FL/CIM Belt washers.

Public Comment

Interested parties may submit case briefs no later than 21 days after the date of publication of this notice.[33] Rebuttals briefs, limited to arguments raised in the case briefs, may be submitted no later than seven days after the deadline for case briefs.[34] Parties who submit case or rebuttal briefs are requested to submit, as part of that submission, (a) a statement of the issues, (b) a summary of the arguments, and (c) a table of authorities.[35]

Any interested party may request a hearing within 30 days of publication of this notice.[36] Hearing requests should

[26] *See* Whirlpool's Comments at 2.

[27] Whirlpool proposes that the following words be defined as follows: (1) ''front loading'' means that ''access to the basket is from the front of the washer;'' and (3) a ''controlled induction motor'' is ''an asynchronous, alternating current, polyphase induction motor.''

[28] *See* Section 782(h) of the Act and 19 CFR 351.222(g).

[29] *See, e.g., Honey from Argentina; Antidumping and Countervailing Duty Changed Circumstances Reviews; Preliminary Intent to Revoke Antidumping and Countervailing Duty Orders,* 77 FR 67790, 67791 (November 14, 2012), unchanged in *Honey from Argentina; Final Results of Antidumping and Countervailing Duty Changed Circumstances Reviews; Revocation of Antidumping and Countervailing Duty Orders,* 77 FR 77029 (December 31, 2012).

[30] *See* Memorandum, ''Analysis of U.S. Production Data for the Preliminary Results of the Changed Circumstances Reviews: Large Residential Washers from the Republic of Korea and Mexico'' (Analysis Memorandum), dated concurrently with this notice, at 1.

[31] LGE and Samsung argue that we should base our determination on projected production data for 2018 and 2019. However, we need not reach this issue, given that even the 2017 data demonstrate that Whirlpool did not account for ''substantially all'' of the domestic production.

[32] The data on each company's 2017 production volumes and values are business proprietary information that cannot be discussed here. For more information, *see* Analysis Memorandum.

[33] *See* 19 CFR 351.309(c)(1)(ii).

[34] *See* 19 CFR 351.309(d).

[35] *See* 19 CFR 351.309(c)(2) and (d)(2).

[36] *See* 19 CFR 351.310(c).

contain the following information: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the case and rebuttal briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.[37]

All submissions, with limited exceptions, must be filed electronically using Enforcement and Compliance's AD and CVD Centralized Electronic Service System (ACCESS).[38] ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, Room B8024 of the main Department of Commerce building. An electronically filed document must be received successfully in its entirety by ACCESS, by 5 p.m. Eastern Time (ET) on the due date. Documents excepted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with the APO/Dockets Unit in Room 18022 and stamped with the date and time of receipt by 5 p.m. ET on the due date.[39]

Commerce will issue the final results of these changed circumstances reviews, which will include its analysis of any written comments, no later than 270 days after the date on which this review was initiated.

The current requirement for cash deposits of estimated antidumping and countervailing duties on all entries of subject merchandise will continue unless until they are modified pursuant to the final results of these changed circumstances reviews.

This notice is published in accordance with sections 751(b) and 777(i) of the Act.

Dated: November 5, 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. 2018–24798 Filed 11–13–18; 8:45 am]

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[37] *See* 19 CFR 351.310(d).

[38] *See generally* 19 CFR 351.303.

[39] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–881]

Large Diameter Welded Pipe From India: Final Determination of Sales at Less Than Fair Value; 2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of large diameter welded pipe from India are being, or are likely to be, sold in the United States at less than fair value (LTFV) for the period of investigation January 1, 2017, through December 31, 2017

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: Kate Johnson at (202) 482–4929 or Jaron Moore at (202) 482–3640, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On August 27, 2018, Commerce published in the **Federal Register** the *Preliminary Determination* of sales at LTFV of large diameter welded pipe from India and invited interested parties to comment.[1] We received comments from the petitioners,[2] agreeing with our affirmative preliminary determination to apply total adverse facts available (AFA) to the non-responsive companies.[3] No other interested party submitted comments. Accordingly, we made no changes to the *Preliminary Determination.*

Period of Investigation

The period of investigation is January 1, 2017, through December 31, 2017.

Scope of the Investigation

The product covered by this investigation is large diameter welded pipe from India. For a full description of the scope of this investigation, *see* the ''Scope of the Investigation,'' at the Appendix to this notice.

Scope Comments

During the course of this investigation and the concurrent LTFV investigations of large diameter welded pipe from Canada, Greece, Korea, the People's Republic of China (China) and Turkey, and the concurrent countervailing duty investigations of large diameter welded pipe from China, India, Korea and Turkey, Commerce received scope comments from interested parties. Commerce issued a Preliminary Scope Decision Memorandum [4] to address these comments. In the *Preliminary Determination,* Commerce set aside a period of time for parties to address scope issues in scope case and rebuttal briefs. No interested parties submitted scope comments in scope case or scope rebuttal briefs. Therefore, for this final determination, the scope of this investigation remains unchanged from that published in the *Preliminary Determination.*

Use of Adverse Facts Available

The mandatory respondents Bhushan Steel (Bhushan) and Welspun Trading Limited (Welspun) failed to participate in this investigation.[5] Therefore, in the *Preliminary Determination,* pursuant to sections 776(a)(1), 776(a)(2)(A)–(C), and 776(b) of the Act, we determined for Bhushan and Welspun an estimated dumping rate based on AFA. No parties filed comments in opposition to our *Preliminary Determination* with respect to Bhushan and Welspun and there are no comments or information on the record that would cause us to revisit our preliminary AFA determinations. Accordingly, we continue to find that the application of AFA pursuant to sections 776(a) and (b) of the Act is warranted with respect to Bhushan and Welspun. In applying total AFA, we have determined for Bhushan's and Welspun's exports of the subject merchandise an estimated dumping margin of 50.55 percent, which is the only dumping margin alleged in the Petition [6] and which has been corroborated to the extent practicable

[1] *See Large Diameter Welded Pipe from India: Preliminary Determination of Sales at Less Than Fair Value,* 83 FR 43653 (August 27, 2018) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum.

[2] The petitioners are American Cast Iron Pipe Company, Berg Steel Pipe Corp., Berg Spiral Pipe Corp., Dura-Bond Industries, and Stupp Corporation, individually and as members of American Line Pipe Producers Association; Greens Bayou Pipe Mill, LP; JSW Steel (USA) Inc.; Skyline Steel; and Trinity Products LLC.

[3] *See* Petitioners Letter, ''Case Brief of Petitioners,'' dated September 26, 2018.

[4] *See* Memorandum, ''Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated June 19, 2018 (Preliminary Scope Decision Memorandum).

[5] *See* Preliminary Determination Memorandum at 4–8.

[6] *See* Petitions for the Imposition of Antidumping and Countervailing Duties: Large Diameter Welded Pipe from Canada, Greece, India, the People's Republic of China, the Republic of Korea, and the Republic of Turkey, dated January 17, 2018 (Petition).

within the meaning of section 776(c) of the Act.[7]

All-Others Rate

As discussed in the *Preliminary Determination,* Commerce based the ''All-Others'' rate on the only dumping margin alleged in the Petition,[8] in accordance with section 735(c)(5)(B) of the Act. We made no changes to the selection of this rate for this final determination.

Final Determination

The final estimated dumping margins are as follows:

Exporter/producer	Dumping margin (percent)	Cash deposit rate (adjusted for export subsidies offset) (percent)
Bhushan Steel	50.55	16.85
Welspun Trading Limited	50.55	16.85
All-Others	50.55	16.85

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, for this final determination, we will direct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of large diameter welded pipe from India, as described in the Appendix to this notice, which are entered, or withdrawn from warehouse, for consumption on or after August 27, the date of publication in the **Federal Register** of the affirmative *Preliminary Determination.*

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), Commerce will instruct CBP to require a cash deposit for such entries of merchandise equal to the estimated dumping margin, as follows: (1) The cash deposit rate for the respondents listed above will be equal to the respondent-specific estimated dumping margin determined in this final determination; (2) if the exporter is not a respondent identified above but the producer is, then the cash deposit rate will be equal to the respondent-specific estimated weighted-average dumping margin established for that producer of the subject merchandise; and (3) the cash deposit rate for all other producers or exporters will be equal to the estimated dumping margin for all other producers or exporters. These suspension-of-liquidation instructions will remain in effect until further notice.

Commerce normally adjusts the estimated weighted-average dumping margin by the amount of export subsidies countervailed in a companion countervailing duty (CVD) proceeding, when CVD provisional measures are in effect. Accordingly, where Commerce has made a final affirmative determination for countervailable export subsidies,[9] Commerce offsets the estimated weighted-average dumping margin by the appropriate CVD rate. Any such adjusted rates may be found in the ''Final Determination'' section, above. However, provisional measures expired in the companion countervailing duty investigation on October 26, 2018. Accordingly, we will direct CBP to collect the estimated antidumping cash deposits unadjusted for countervailed export subsidies. In the event of an affirmative determination by the International Trade Commission (ITC), Commerce will issue antidumping and countervailing duty orders and direct CBP to collect the cash deposit rate, as adjusted for export subsidies.

Disclosure

The dumping margins assigned to the mandatory respondents in this investigation are based on AFA. As these margins are based on the dumping margin alleged in the Petition, and because we made no changes to the *Preliminary Determination,* there are no calculations to disclose for this final determination.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify ITC of the final affirmative determination of sales at LTFV. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of large diameter welded pipe, no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all cash deposits posted will be refunded. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Notification Regarding Administrative Protective Orders

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials, or conversion to judicial protective order,

[7] *See* Preliminary Determination Memorandum at 7–8.

[8] *See* Petition; *see also* Preliminary Determination Memorandum at 8–9.

[9] *See* the unpublished **Federal Register** notice, *Large Diameter Welded Pipe from India: Final Affirmative Countervailing Duty Determination,* dated concurrently with this notice.

is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act and 19 CFR 351.210(c).

Dated: November 5, 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 welded carbon and alloy steel pipe (including stainless steel pipe), more than 406.4 mm (16 inches) in nominal outside diameter (large diameter welded pipe), regardless of wall thickness, length, surface finish, grade, end finish, or stenciling. Large diameter welded pipe may be used to transport oil, gas, slurry, steam, or other fluids, liquids, or gases. It may also be used for structural purposes, including, but not limited to, piling. Specifically, not included is large diameter welded pipe produced only to specifications of the American Water Works Association (AWWA) for water and sewage pipe.

Large diameter welded pipe used to transport oil, gas, or natural gas liquids is normally produced to the American Petroleum Institute (API) specification 5L. Large diameter welded pipe may also be produced to American Society for Testing and Materials (ASTM) standards A500, A252, or A53, or other relevant domestic specifications, grades and/or standards. Large diameter welded pipe can be produced to comparable foreign specifications, grades and/or standards or to proprietary specifications, grades and/or standards, or can be non-graded material. All pipe meeting the physical description set forth above is covered by the scope of this investigation, whether or not produced according to a particular standard.

Subject merchandise also includes large diameter welded pipe that has been further processed in a third country, including but not limited to coating, painting, notching, beveling, cutting, punching, welding, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the in-scope large diameter welded pipe.

The large diameter welded pipe that is subject to this investigation is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7305.11.1030, 7305.11.1060, 7305.11.5000, 7305.12.1030, 7305.12.1060, 7305.12.5000, 7305.19.1030, 7305.19.1060, 7305.19.5000, 7305.31.4000, 7305.31.6010, 7305.31.6090, 7305.39.1000 and 7305.39.5000. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

[FR Doc. 2018–24806 Filed 11–13–18; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–588–874]

Certain Hot-Rolled Steel Flat Products From Japan: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Nippon Steel & Sumitomo Metal Corporation (Nippon Steel) and Tokyo Steel Manufacturing Co., Ltd. (Tokyo Steel), the two companies selected for individual examination, sold subject merchandise in the United States at prices below normal value during the period of review (POR). Additionally, Commerce preliminarily determines that three other companies for which we initiated reviews had no shipments during the POR. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: Myrna Lobo or Jack Zhao, 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) 482–2371 or (202) 482–1396, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty order on certain hot-rolled steel flat products (hot-rolled steel) from Japan. The notice of initiation of this administrative review was published on December 7, 2017.[1] This review covers 20 producers and exporters of the subject merchandise. The POR is March 22, 2016, through September 30, 2017. Commerce selected two mandatory respondents for individual examination: Nippon Steel and Tokyo Steel.

Scope of the Order

The merchandise covered by the order is certain hot-rolled steel flat products. For a complete description of the scope of the order, *see* the Preliminary Decision Memorandum.[2]

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Export price and constructed export price are calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and 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 accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Preliminary Decision Memorandum are identical in content. A list of the topics discussed in the Preliminary Decision Memorandum is attached as the Appendix to this notice.

Preliminary Determination of No Shipments

Among the companies under review, four companies, Hitachi Metals, Ltd. (Hitachi), Honda Trading Canada, Inc. (Honda), Mitsui & Co. Ltd. (Mitsui), and Panasonic Corporation (Panasonic) properly filed statements reporting that they made no shipments of subject merchandise to the United States during the POR. Based on the certifications submitted and our analysis of Customs and Border Protection (CBP) information, we preliminarily determine that Hitachi, Honda, and Panasonic had no shipments during the POR.[3]

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 82 FR 57705 (December 7, 2017).

[2] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments: Certain Hot-Rolled Steel Flat Products from Japan; 2016–2017,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[3] *See* Hitachi Letter, ''Antidumping Duty Administrative Review of Certain Hot-Rolled Steel Flat Products: Hitachi No Shipment Letter,'' dated December 18, 2017; *see also* Honda Letter, ''Administrative Review of Certain Hot-Rolled Steel

Continued

Consistent with its practice, Commerce finds that it is not appropriate to preliminarily rescind the review with respect to these companies but, rather, to complete the review and issue appropriate instructions to CBP based on the final results of this review. We intend to solicit more information and comments with respect to Mitsui's no shipment certification.[4]

Preliminary Results of the Review

As a result of this review, we preliminarily determine the following weighted-average dumping margins for the period March 22, 2016, through September 30, 2017:

Exporter/producer	Weighted-average dumping margin (percent)	
Nippon Steel & Sumitomo Metal Corporation[5]	0.54.	
Nisshin Steel Co., Ltd.[6]	3/22/2016 to 3/12/2017 1.46[7]	3/13/2017 to 9/30/2017. 0.54.[8]
Tokyo Steel Manufacturing Co., Ltd	7.64	

Review-Specific Average Rate Applicable to the Following Companies:[9]

Exporter/producer	Weighted-average dumping margin (percent)
Hanwa Co., Ltd	1.46
JFE Steel Corporation[10]	1.46
JFE Shoji Trade America	1.46
Kanematsu Corporation	1.46
Kobe Steel, Ltd.	1.46
Mitsui & Co., Ltd.	1.46
Miyama Industry Co., Ltd.	1.46
Nippon Steel & Sumikin Logistics Co., Ltd.	1.46
Okaya & Co. Ltd.	1.46
Saint-Gobain KK	1.46
Shinsho Corporation	1.46
Sumitomo Corporation	1.46
Suzukaku Corporation	1.46
Toyota Tsusho Corporation Nagoya	1.46

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries.

Pursuant to 19 CFR 351.212(b)(1), where the mandatory respondents reported the entered value for their U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales for which entered value was reported. Where the mandatory respondents did not report entered value, we calculated the entered value

Flat Products from Japan: Honda Trading Canada, Inc.'s No Shipment Certification,'' dated December 22, 2017; *see also* Mitsui Letter, ''Antidumping Administrative Review of Certain Hot-Rolled Steel Flat Products: Mitsui No Shipment Notification,'' dated January 5, 2018; *see also* Panasonic Letter, ''Administrative Review of Certain Hot-Rolled Steel Flat Products from Japan: Panasonic Corporation No Shipment Certification,'' dated January 5, 2018. *See also* Public Memorandum, ''Re: No shipment inquiry with respect to the companies below during the period 03/22/2016 through 09/30/2017,'' dated October 23, 2018.

[4] *See* Business Proprietary Memorandum, ''Re: No shipment inquiry with respect to the companies below during the period 03/22/2016 through 09/30/2017,'' dated October 23, 2018.

[5] We collapsed Nippon Steel & Sumikin Bussan Corporation with Nippon Steel & Sumitomo Metal Corporation in the underlying investigation. *See Certain Hot-Rolled Steel Flat Products from Japan: Preliminary Determination of Sales at Less than Fair Value and Postponement of Final Determination,* 81 FR 15222 (March 22, 2016) and accompanying Preliminary Decision Memorandum at 6–7.

[6] We have collapsed Nisshin Steel Co., Ltd. and Nippon Steel & Sumitomo Metal Corporation as of March 13, 2017. *See* Preliminary Decision Memorandum at 9.

[7] Entries of subject merchandise produced/exported by Nisshin Steel Co., Ltd. made prior to March 13, 2017 are subject to the all others rate calculated in this administrative review. S*ee* Memorandum re: Calculation of the Review-Specific Average Rate for the Preliminary Results, dated concurrently with this notice.

[8] Entries of subject merchandise produced/exported by Nisshin Steel Co., Ltd. made on/or after March 13, 2017 are subject to the AD rate assigned to Nippon Steel in this administrative review.

[9] This rate is based on the weighted-average margin using the publicly-ranged sales value of mandatory respondents, and is the best proxy of the actual weighted-average margin determined for the mandatory respondents. Due to requests to protect business proprietary information, we cannot apply our normal methodology of calculating a weighted-average margin. *See Ball Bearings and Parts Thereof from France, et al.: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010); *see also* Memorandum re: Calculation of the Review-Specific Average Rate for the Preliminary Results, dated concurrently with this notice.

[10] We collapsed JFE Shoji Trade Corporation with JFE Steel Corporation in the underlying investigation. *See Certain Hot-Rolled Steel Flat Products from Japan: Preliminary Determination of Sales at Less than Fair Value and Postponement of Final Determination,* 81 FR 15222 (March 22, 2016) and accompanying Preliminary Decision Memorandum at 8–9.

in order to calculate the assessment rate. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For the companies which were not selected for individual review, we will assign an assessment rate based on the average [11] of the cash deposit rates calculated for the two mandatory respondents. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[12]

We intend to issue liquidation instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for each specific company listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated companies not participating in this review, the cash deposit will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, or the underlying investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 5.58 percent, the all-others rate established in the underlying investigation.[13] These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

Commerce intends to disclose the calculations performed in connection with these preliminary results to interested parties within five days after the date of publication of this notice.[14] Interested parties may submit case briefs not later than 30 days after the date of publication of this notice.[15] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than five days after the time limit for filing case briefs.[16] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[17] Case and rebuttal briefs should be filed using ACCESS.[18]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed request for a hearing must be received successfully in its entirety by ACCESS by 5 p.m. Eastern Time within 30 days after the date of publication of this notice.[19] Hearing requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing to be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.[20]

Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the publication of these preliminary results in the **Federal Register**, unless otherwise extended.[21]

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 1, 2018.

James Maeder,

Associate Deputy Assistant Secretary, for Antidumping and Countervailing Duty Operations, performing the duties of Deputy Assistant Secretary, for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2018–24794 Filed 11–13–18; 8:45 am]

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[11] This rate was calculated as discussed in footnote 8, above.

[12] *See* section 751(a)(2)(C) of the Act.

[13] *See Certain Hot-Rolled Steel Flat Products from Australia, Brazil, Japan, the Republic of Korea, the Netherlands, the Republic of Turkey, and the United Kingdom: Amended Final Affirmative Antidumping Determinations for Australia, the Republic of Korea, and the Republic of Turkey and Antidumping Duty Orders,* 81 FR 67962 (October 3, 2016).

[14] *See* 19 CFR 351.224(b).

[15] *See* 19 CFR 351.309(c)(1)(ii).

[16] *See* 19 CFR 351.309(d)(1).

[17] *See* 19 CFR 351.309(c)(2) and (d)(2).

[18] *See* 19 CFR 351.303.

[19] *See* 19 CFR 351.310(c); 19 CFR 351.303(b)(1).

[20] *See* 19 CFR 351.310(c).

[21] *See* Section 751(a)(3)(A) of the Act.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–077]

Large Diameter Welded Pipe From the People's Republic of China: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that imports of large diameter welded pipe from the People's Republic of China (China) are being, or are likely to be, sold in the United States at less than fair value (LTFV).

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: Rachel Greenberg at (202) 482–0652 or Ryan Mullen at (202) 482–5260, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On August 27, 2018, Commerce published in the **Federal Register** the *Preliminary Determination* of sales at LTFV of large diameter welded pipe from China and invited interested parties to comment.[1] We only received comments from the petitioners,[2] who agreed with our preliminary determination to apply total adverse facts available (AFA) to the China-wide entity.[3] Accordingly, we made no changes to the *Preliminary Determination.*

Period of Investigation

The period of investigation is July 1, 2017 through December 31, 2017.

Scope of the Investigation

The product covered by this investigation is large diameter welded pipe from China. For a full description of the scope of this investigation, *see* the ''Scope of the Investigation,'' at the Appendix to this notice.

Scope Comments

During the course of this investigation and the concurrent antidumping duty investigations of large diameter welded pipe from Canada, Greece, India, Korea and Turkey, and the concurrent countervailing duty investigations of large diameter welded pipe from China, India, Korea and Turkey, Commerce received scope comments from interested parties. We issued a Preliminary Scope Decision Memorandum [4] to address these comments. Further, in the *Preliminary Determination,* we set aside a period of time for parties to address scope issues in scope case and rebuttal briefs. No interested parties submitted scope comments in case or rebuttal briefs. Therefore, for this final determination, the scope of this investigation remains unchanged from that published in the *Preliminary Determination.*

Use of Adverse Facts Available

We continue to find the companies which did not respond to our requests for information to be part of the China-wide entity. Further, we found these companies, which comprise part of the China-wide entity, failed to provide necessary information, withheld requested information, significantly impeded this investigation, and did not cooperate in submitting the requested Q&V information, as detailed in the *Preliminary Determination* and accompanying Preliminary Decision Memorandum.[5] Accordingly, we have applied facts otherwise available, with an adverse inference, in accordance with sections 776(a)–(b) of the Act.[6]

China-Wide Rate

In selecting the AFA rate for the China-wide entity, Commerce's practice is to select a rate that is sufficiently adverse to ensure that the uncooperative party does not obtain a more favorable result by failing to cooperate than if it had fully cooperated. Specifically, it is Commerce's practice to select, as an AFA rate, the higher of: (a) The highest dumping margin alleged in the petition; or, (b) the highest calculated dumping margin of any respondent in the investigation. As AFA, Commerce has assigned to the China-wide entity the rate of 132.63 percent, which is the highest dumping margin alleged in the Petition.[7]

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.[8] Because Commerce continues to use facts otherwise available with an adverse inference in determining the rate for the China-wide entity and there were no respondents that demonstrated eligibility for a separate rate in this investigation, Commerce did not calculate producer/exporter combination rates for specific companies.

Final Determination

The final estimated weighted-average dumping margins are as follows:

Exporter or producer	Estimated weighted-average dumping margin (percent)
China-wide entity	132.63 percent

Continuation of Suspension of Liquidation

In accordance with section 735(c)(1)(B) of the Act, for this final determination, we will direct U.S. Customs and Border Protection (CBP) to continue to suspend liquidation of all entries of large diameter welded pipe from China, as described in the Appendix to this notice, which are entered, or withdrawn from warehouse, for consumption on or after August 27, the date of publication in the **Federal Register** of the affirmative *Preliminary Determination.*

Pursuant to section 735(c)(1)(B)(ii) of the Act and 19 CFR 351.210(d), Commerce will instruct CBP to require

[1] *See Large Diameter Welded Pipe from the People's Republic of China: Preliminary Determination of Sales at Less Than Fair Value,* 83 FR 43644 (August 27, 2018) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum.

[2] The petitioners are American Cast Iron Pipe Company, Berg Steel Pipe Corp.; Berg Spiral Pipe Corp.; Dura-Bond Industries; Skyline Steel; Stupp Corporation; Greens Bayou Pipe Mill, LP; JSW Steel (USA) Inc.; and Trinity Products LLC.

[3] *See* Petitioners' Letter, ''Case Brief,'' dated September 26, 2018.

[4] *See* Memorandum, ''Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated June 19, 2018 (Preliminary Scope Decision Memorandum).

[5] *See Preliminary Determination,* 83 FR at 43644; *see also* Preliminary Decision Memorandum at 4–5.

[6] Preliminary Decision Memorandum at 5–6.

[7] *See Large Diameter Welded Pipe from Canada, Greece, India, the People's Republic of China, the Republic of Korea, and the Republic of Turkey: Initiation of Less-Than-Fair-Value Investigations,* 83 FR 7154 (February 20, 2018); *see also* Petitioners' Letter, ''Large Diameter Welded Pipe from Canada, Greece, India, the People's Republic of China, the Republic of Korea, and the Republic of Turkey: Petition for Imposition of Antidumping and Countervailing Duties,'' dated January 17, 2018 (Petition); *see also* Petitioners' Letter, ''Response to the Department's January 23, 2018, Supplemental Questions Regarding Volume VIII of the Petition for the Imposition of Antidumping and Countervailing Duties,'' dated January 25, 2018, at Exhibit AD-CN-Supp-3.

[8] *See Large Diameter Welded Pipe from Canada, Greece, India, the People's Republic of China, the Republic of Korea, and the Republic of Turkey: Initiation of Less-Than-Fair-Value Investigations,* 83 FR 7154 (February 20, 2018) *(Initiation Notice).*

a cash deposit for such entries of merchandise equal to the estimated weighted-average dumping margin or the estimated all-others rate, as follows: (1) The rate for the exporters listed in the chart above will be the rate we have determined in this final determination; (2) for all Chinese exporters of subject merchandise which have not received their own rate, the cash-deposit rate will be the China-wide rate; and (3) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash-deposit rate will be the 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. Additionally, Commerce is making no adjustments for export subsidies to the antidumping cash deposit rate in this investigation because we have made no findings in the companion countervailing duty investigation that any of the programs are export subsidies.

Disclosure

The estimated weighted-average dumping margin assigned to the China-wide entity in this investigation is based on AFA. As the margin is based on the rate calculated in the Petition, and because we made no changes to this margin since the *Preliminary Determination,* there are no calculations to disclose for this final determination.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the International Trade Commission (ITC) of the final affirmative determination of sales at LTFV. Because Commerce's final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of large diameter welded pipe, no later than 45 days after this final determination. If the ITC determines that such injury does not exist, this proceeding will be terminated, and all cash deposits posted will be refunded. If the ITC determines that such injury does exist, Commerce will issue an antidumping duty order directing CBP to assess, upon further instruction by Commerce, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation, as discussed above in the ''Continuation of Suspension of Liquidation'' section.

Notification Regarding Administrative Protective Orders

This notice will serve as a reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of propriety information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with sections 735(d) and 777(i)(1) of the Act and 19 CFR 351.210(c).

Dated: November 5, 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 welded carbon and alloy steel pipe (including stainless steel pipe), more than 406.4 mm (16 inches) in nominal outside diameter (large diameter welded pipe), regardless of wall thickness, length, surface finish, grade, end finish, or stenciling. Large diameter welded pipe may be used to transport oil, gas, slurry, steam, or other fluids, liquids, or gases. It may also be used for structural purposes, including, but not limited to, piling. Specifically, not included is large diameter welded pipe produced only to specifications of the American Water Works Association (AWWA) for water and sewage pipe.

Large diameter welded pipe used to transport oil, gas, or natural gas liquids is normally produced to the American Petroleum Institute (API) specification 5L. Large diameter welded pipe may also be produced to American Society for Testing and Materials (ASTM) standards A500, A252, or A53, or other relevant domestic specifications, grades and/or standards. Large diameter welded pipe can be produced to comparable foreign specifications, grades and/or standards or to proprietary specifications, grades and/or standards, or can be non-graded material. All pipe meeting the physical description set forth above is covered by the scope of this investigation, whether or not produced according to a particular standard.

Subject merchandise also includes large diameter welded pipe that has been further processed in a third country, including but not limited to coating, painting, notching, beveling, cutting, punching, welding, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the in-scope large diameter welded pipe.

The large diameter welded pipe that is subject to this investigation is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7305.11.1030, 7305.11.1060, 7305.11.5000, 7305.12.1030, 7305.12.1060, 7305.12.5000, 7305.19.1030, 7305.19.1060, 7305.19.5000, 7305.31.4000, 7305.31.6010, 7305.31.6090, 7305.39.1000 and 7305.39.5000. While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

[FR Doc. 2018–24807 Filed 11–13–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–602–809]

Certain Hot-Rolled Steel Flat Products From Australia: Preliminary Results of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that sales of certain hot-rolled steel flat products from Australia were made at less than normal value during the period of review (POR), March 22, 2016, through September 30, 2017. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: Amanda Brings, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3927.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2017, Commerce initiated the antidumping duty administrative review on certain hot-rolled steel flat products from Australia.[1] This review covers one producer/exporter of the subject merchandise, the collapsed entity BlueScope Steel Ltd., BlueScope Steel (AIS) Pty Ltd., and BlueScope Steel Distribution Pty Ltd. (collectively,

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 82 FR 57705 (December 7, 2017).

BlueScope).[2] For a detailed description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum, dated concurrently with these preliminary results and hereby adopted by this notice.[3]

Scope of the Order

The product covered by this review is certain hot-rolled steel flat products from Australia. For a full description of the scope, see the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) and (a)(2) of the Tariff Act of 1930, as amended (the Act). For a full description of the methodology underlying our administrative review preliminary results, *see* the Preliminary Decision Memorandum. A list of the topics included in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed at *http://enforcement.trade.gov/frn/index.html.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

Adverse Facts Available

Because mandatory respondent BlueScope has failed to provide requested information and has failed to cooperate by not acting to the best of its ability to comply with the requests for information from Commerce in this review, we preliminarily determine to apply facts otherwise available with an adverse inference (AFA) to this respondent, in accordance with sections 776(a) and (b) of the Act and 19 CFR 351.308. For a complete explanation of the analysis underlying the preliminary application of AFA, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

We preliminarily determine that, for the period of March 22, 2016, through September 30, 2017, the following dumping margin exists:

Exporter/producer	Dumping margin (percent)
BlueScope Steel Ltd., BlueScope Steel (AIS) Pty Ltd., and BlueScope Steel Distribution Pty Ltd	99.20

Disclosure and Public Comment

Normally, Commerce discloses to interested parties the calculations performed in connection with the preliminary results within five days of the date of publication of the notice of preliminary results in the **Federal Register,** in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily applied AFA to BlueScope, the only individually examined company in this administrative review, in accordance with section 776 of the Act, there are no calculations to disclose.

Interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.[4] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[5] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Case and rebuttal briefs should be filed using ACCESS.[6]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed document must be received successfully in its entirety by ACCESS by 5 p.m. Eastern Standard Time within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; (3) whether any participant is a foreign national; and (4) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined.[7] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

All submissions, with limited exceptions, must be filed electronically using ACCESS.[8] An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time, on the due dates established above (or, where applicable, to be established by Commerce at a later date). Documents excepted from the electronic submission requirements must be filed manually, (*i.e.,* in paper form) with the APO/Dockets Unit in Room 18022 and stamped with the date and time of receipt by on the due date.[9]

Commerce intends to issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the date of publication of this notice, unless the deadline is extended.[10]

Assessment Rates

Upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[11] The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[12] We intend to issue instructions to CBP 15 days after the date of publication of the final results of this review.

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this

[2] In the investigation, Commerce found that BlueScope Steel Ltd., BlueScope Steel (AIS) Pty Ltd., and BlueScope Steel Distribution Pty Ltd. (collectively, BlueScope) are a single entity and, because there were no changes to the facts which supported that decision since that determination was made, we continue to find that these companies are a single entity for this administrative review. *See Certain Hot-Rolled Steel Flat Products from Australia: Final Determination of Sales at Less Than Fair Value,* 81 FR 53406, 53407 (August 12, 2016).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Certain Hot-Rolled Steel Flat Products from Australia; 2016–2017,'' dated concurrently with this notice (Preliminary Decision Memorandum).

[4] *See* 19 CFR 351.309(c)(1)(ii).

[5] *See* 19 CFR 351.309(d).

[6] *See* 19 CFR 351.303.

[7] *See* 19 CFR 351.310(c).

[8] *See* 19 CFR 351.303.

[9] *Id.*

[10] *See* section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

[11] *See* 19 CFR 351.212(b).

[12] *See* section 751(a)(2)(C) of the Act.

administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for BlueScope will be the rate established in the final results of this review; (2) for previously reviewed or investigated companies not participating in this review, the cash deposit rate will continue to be the company-specific rate published for the most recently-completed segment of this proceeding in which the company was reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair value (LTFV) investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the manufacturer of subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 29.58 percent, the all-others rate established in the LTFV investigation.[13] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

The preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: November 1, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2018–24793 Filed 11–13–18; 8:45 am]

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[13] *See Antidumping Duty Order.*

DEPARTMENT OF COMMERCE

International Trade Administration

Correction To Notice of Opportunity To Request Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

SUPPLEMENTARY INFORMATION: On November 1, 2018, the Department of Commerce (''Commerce'') published its opportunity to request administrative review of the antidumping duty orders for November 2018 anniversary cases. Commerce inadvertently stated parties may request an administrative review not later than the last day of October 2018. The last day to submit a request review request for November cases is the last day of November 2018. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 83 FR 54912 (November 1, 2018). This notice serves as a correction notice.

Dated: November 7, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–24792 Filed 11–13–18; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–882]

Large Diameter Welded Pipe From India: Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that countervailable subsidies are being provided to producers/exporters of large diameter welded pipe welded pipe from India.

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: Robert Palmer at (202) 482–9068 or Suzanne Lam at (202) 482–0783, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On June 29, 2018, Commerce published in the **Federal Register** its affirmative *Preliminary Determination* of this countervailing duty (CVD) investigation and invited interested parties to comment.[1] A summary of the events that occurred since Commerce published the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for this final determination, may be found in the Issues and Decision Memorandum issued concurrently with this notice.[2] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov,* and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Period of Investigation

The period of investigation is January 1, 2017, through December 31, 2017.

Scope of the Investigation

The product covered by this investigation is large diameter welded pipe from India. For a full description of the scope of this investigation, *see* the ''Scope of the Investigation'' in Appendix I of this notice.

Scope Comments

During the course of this investigation and the concurrent LTFV investigations

[1] *See Large Diameter Welded Pipe from India: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Determination with Final Antidumping Duty Determination,* 83 FR 30690 (June 29, 2018) (*Preliminary Determination*) and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Affirmative Determination of the Countervailing Duty Investigation of Large Diameter Welded Pipe from India'' (Issues and Decision Memorandum), dated concurrently with this determination and hereby adopted by this notice.

of large diameter welded pipe from Canada, Greece, Korea, the People's Republic of China (China) and Turkey, and the concurrent countervailing duty investigations of large diameter welded pipe from China, India, Korea and Turkey, Commerce received scope comments from interested parties. Commerce issued a Preliminary Scope Decision Memorandum [3] to address these comments. In the *Preliminary Determination,* Commerce set aside a period of time for parties to address scope issues in scope case and rebuttal briefs.[4] No interested parties submitted scope comments in scope case or scope rebuttal briefs. Therefore, for this final determination, the scope of this investigation remains unchanged from that published in the *Preliminary Determination.*

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs by parties in this investigation are discussed in the Issues and Decision Memorandum. A list of the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, is attached to this notice at Appendix II.

Methodology

Commerce conducted this investigation in accordance with section 701 of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, Commerce determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[5] For a full description of the methodology underlying our final determination, *see* the Issues and Decision Memorandum.

In making these findings, Commerce relied, in part, on facts otherwise available and, because it finds that both respondents and the Government of India did not act to the best of their ability to respond to Commerce's requests for information, it drew an adverse inference where appropriate in selecting from among the facts otherwise available.[6] For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Issues and Decision Memorandum.

Final Determination

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated an individual rate for each producer/exporter of the subject merchandise individually investigated. In accordance with section 705(c)(5)(A) of the Act, for companies not individually investigated, we apply an ''all-others'' rate, which is normally calculated by weighting the subsidy rates of the individual companies selected as mandatory respondents by those companies'' exports of the subject merchandise to the United States. Under section 705(c)(5)(A)(i) of the Act, the all-others rate excludes zero and *de minimis* rates calculated for the exporters and producers individually investigated, as well as rates based entirely on facts otherwise available. Section 705(c)(5)(A)(ii) of the Act provides that if the countervailable subsidy rate established for all exporters and producers individually investigated are zero, *de minimis,* or determined entirely in accordance with section 776 of the Act, Commerce may use any reasonable method to establish an all-others rate for exporters and producers not individually investigated. In this case, the estimated countervailable subsidy rate calculated for the investigated companies is based entirely on facts available under section 776 of the Act. There is no other information on the record upon which to determine an all-others rate. As a result, we have used the rate assigned to Bhushan Steel and Welspun Trading Limited as the all-others rate. This method is consistent with the Department's past practice.[7]

Commerce determines that the following estimated countervailable subsidy rates exist:

Company	Subsidy rate (percent)
Bhushan Steel	541.15
Welspun Trading Limited	541.15
All-Others	541.15

Continuation of Suspension of Liquidation

As a result of our *Preliminary Determination* and pursuant to section 703(d)(1)(B) and (d)(2) of the Act, Commerce instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication in the **Federal Register**. In accordance with section 703(d) of the Act, we issued instructions to CBP to discontinue the suspension of liquidation for countervailing duty (CVD) purposes for subject merchandise entered, or withdrawn from warehouse, on or after October 27, 2018, but to continue the suspension of liquidation of all entries from June 29, 2018, through October 26, 2018.

If the U.S. International Trade Commission (ITC) issues a final affirmative injury determination, we will issue a CVD order, will reinstate the suspension of liquidation under section 706(a) of the Act, and will require a cash deposit of estimated countervailing duties for such entries of subject merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

Disclosure

Normally, Commerce discloses calculations performed for a final determination within five days of its public announcement, or if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). However, Commerce applied AFA in determining the estimated countervailable subsidy rate for the individually examined companies (Bhushan Steel and Welspun Trading Limited) in this investigation, in accordance with section 776 of the Act. Because our calculation of the AFA subsidy rate is outlined in Appendix I of the Preliminary Decision Memorandum, and because we made no changes to the *Preliminary Determination,* there are no further calculations to disclose.

International Trade Commission Notification

In accordance with section 705(d) of the Act, Commerce will notify the ITC of its determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose

[3] *See* Memorandum, ''Scope Comments Decision Memorandum for the Preliminary Determinations,'' dated June 19, 2018 (Preliminary Scope Decision Memorandum).

[4] *See Large Diameter Welded Pipe from India: Preliminary Determination of Sales at Less Than Fair Value,* 83 FR 43653 (August 27, 2018).

[5] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[6] *See* sections 776(a), (b), and 782(d) of the Act.

[7] *See, e.g., Certain Carbon and Alloy Steel Cut-to-Length Plate from the People's Republic of China: Final Affirmative Countervailing Duty Determiniation,* 82 FR 8507, 8508 (January 26, 2017).

such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance. Because Commerce's final determination is affirmative, in accordance with section 705(b) of the Act, the ITC will make its final determination as to whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports of large diameter welded pipe from India no later than 45 days after this final determination.

Notification Regarding Administrative Protective Orders

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act and 19 CFR 351.210(c).

Dated: November 1, 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 welded carbon and alloy steel pipe (including stainless steel pipe), more than 406.4 mm (16 inches) in nominal outside diameter (large diameter welded pipe), regardless of wall thickness, length, surface finish, grade, end finish, or stenciling. Large diameter welded pipe may be used to transport oil, gas, slurry, steam, or other fluids, liquids, or gases. It may also be used for structural purposes, including, but not limited to, piling. Specifically, not included is large diameter welded pipe produced only to specifications of the American Water Works Association (AWWA) for water and sewage pipe.

Large diameter welded pipe used to transport oil, gas, or natural gas liquids is normally produced to the American Petroleum Institute (API) specification 5L. Large diameter welded pipe may also be produced to American Society for Testing and Materials (ASTM) standards A500, A252, or A53, or other relevant domestic specifications, grades and/or standards. Large diameter welded pipe can be produced to comparable foreign specifications, grades and/or standards or to proprietary specifications, grades and/or standards, or can be non-graded material. All pipe meeting the physical description set forth above is covered by the scope of this investigation, whether or not produced according to a particular standard.

Subject merchandise also includes large diameter welded pipe that has been further processed in a third country, including but not limited to coating, painting, notching, beveling, cutting, punching, welding, or any other processing that would not otherwise remove the merchandise from the scope of the investigation if performed in the country of manufacture of the in-scope large diameter welded pipe.

The large diameter welded pipe that is subject to this investigation is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheadings 7305.11.1030, 7305.11.1060, 7305.11.5000, 7305.12.1030, 7305.12.1060, 7305.12.5000, 7305.19.1030, 7305.19.1060, 7305.19.5000, 7305.31.4000, 7305.31.6010, 7305.31.6090, 7305.39.1000 and 7305.39.5000. While the 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 Issues and Decision Memorandum

[FR Doc. 2018–24804 Filed 11–13–18; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–883]

Certain Hot-Rolled Steel Flat Products From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2016–2017

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Hyundai Steel Company (Hyundai) and POSCO/POSCO Daewoo Co., Ltd. (collectively POSCO/PDW), the two companies selected for individual examination, sold subject merchandise in the United States at prices below normal value during the POR. We invite interested parties to comment on these preliminary results.

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: Benito Ballesteros or Justin Neuman, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) (202) 482–7425 or (202) 482–0486, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2017, Commerce initiated the antidumping duty administrative review on certain hot-rolled steel flat products (hot-rolled steel) from the Republic of Korea (Korea).[1] Commerce selected two respondents for individual examination, POSCO/PDW and Hyundai Steel Company. For a detailed description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum, dated concurrently with these preliminary results and hereby adopted by this notice.[2]

The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). Access to ACCESS is available to registered users at *http://access.trade.gov* and is available 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 accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.* A list of the topics discussed in the Preliminary Decision Memorandum is attached at the Appendix to this notice. The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 82 FR 21513 (May 9, 2017).

[2] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review: Certain Cold Rolled Steel Flat Products from the Republic of Korea; 2016–2017,'' dated October 3, 2018 (Preliminary Decision Memorandum).

Scope of the Order

The product covered by this review is hot-rolled steel from Korea. For a full description of the scope see the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Export price and constructed export price are calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Rates for Non-Examined Companies

The statute and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a market economy investigation, for guidance when calculating the rate for companies which were not selected for individual examination in an administrative review. Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.''

In this review, we have preliminarily calculated weighted-average dumping margins for Hyundai and POSCO/PDW that are not zero, *de minimis,* or determined entirely on the basis of facts available. Accordingly, we have preliminarily assigned to the companies not individually examined in this review [3] a margin of 5.95 percent, which is the weighted average of Hyundai and POSCO/PDW calculated weighted-average dumping margins.[4]

[3] The non-examined companies subject to this review are: Daewoo International Corp., Dongbu Steel Co., Ltd., Dongkuk Industries Co., Ltd., Marubeni-Itochu Steel Korea, Soon Hong Trading Co., and Sungjin Co.

[4] For more information regarding the calculation of this margin, *see* Memorandum, ''Calculation of the Margin for Non-Examined Companies,'' dated November 2, 2018. As the weighting factor, we relied on the publicly ranged sales data reported in Hyundai's and POSCO/PDW's quantity and value charts.

Preliminary Results of Review

We preliminarily determine that the following weighted-average dumping margins exist for the period March 22, 2016, through September 30, 2017.

Exporter/producer	Weighted-average margin (percent)
POSCO/POSCO Daewoo Co., Ltd.	7.67
Hyundai Steel Company	3.95
Non-Examined Companies	5.95

Disclosure, Public Comment, and Opportunity To Request a Hearing

We intend to disclose the calculations performed for these preliminary results of review to interested parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, the content of which is limited to issues raised in the case briefs, may be filed no later than five days after the date for filing case briefs.[5] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[6] Case and rebuttal briefs should be filed using ACCESS [7] and must be served on interested parties.[8] Executive summaries should be limited to five pages total, including footnotes.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically *via* Commerce's electronic records system, ACCESS. An electronically filed request must be received successfully in its entirety by 5:00 p.m. Eastern Time within 30 days of the date of publication of this notice.[9] Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a date and time to be determined.[10] Parties should confirm the date, time, and location of the hearing two days before the scheduled date.

Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any case or rebuttal briefs, no later than 120 days after the date of publication of this notice, unless extended.[11]

Assessment Rates

Upon completion of this administrative review, Commerce shall determine, and Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. We intend to issue liquidation instructions to CBP 15 days after publication of the final results of this review.

For any individually examined respondent whose weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review and the respondent reported reliable entered values, we will calculate importer-specific *ad valorem* assessment rates for the merchandise based on the ratio of the total amount of dumping calculated for the examined sales made during the period of review to each importer and the total entered value of those same sales, in accordance with 19 CFR 351.212(b)(1). If the respondent has not reported reliable entered values, we will calculate a per-unit assessment rate for each importer by dividing the total amount of dumping calculated for the examined sales made to that importer by the total sales quantity associated with those transactions. Where an importer-specific *ad valorem* assessment rate is zero or *de minimis* in the final results of review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties in accordance with 19 CFR 351.106(c)(2). If a respondent's weighted-average dumping margin is zero or *de minimis* in the final results of review, we will instruct CBP not to assess duties on any of its entries in accordance with the *Final Modification for Reviews, i.e.,* ''{w}here the weighted-average margin of dumping for the exporter is determined to be zero or *de minimis,* no antidumping duties will be assessed.'' [12]

[5] *See* 19 CFR 351.309(d).

[6] *See* 19 CFR 351.309(c)(2) and (d)(2).

[7] *See generally* 19 CFR 351.303.

[8] *See* 19 CFR 351.303(f).

[9] *See* 19 CFR 351.310(c).

[10] *See* 19 CFR 351.310(d).

[11] *See* section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

[12] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8102 (February 14, 2012) (*Final Modification for Reviews*).

For entries of subject merchandise during the POR produced by Hyundai and POSCO/PDW for which the producer did not know its merchandise was destined for the United States, or for any respondent for which we have a final determination of no shipments, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company (or companies) involved in the transaction.[13]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Hyundai and POSCO/PDW in the final results of review will be equal to the weighted-average dumping margin established in the final results of this administrative review; (2) for merchandise exported by producers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which they were reviewed; (3) if the exporter is not a firm covered in this review or the original investigation but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will continue to be 5.55 percent,[14] the all-others rate established in the less-than-fair-value investigation. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

Commerce is issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: November 2, 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

List of Topics Discussed in the Preliminary Decision Memorandum

[FR Doc. 2018–24796 Filed 11–13–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–560–829]

Certain Uncoated Paper From Indonesia: Rescission of 2017 Countervailing Duty Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty (CVD) order on certain uncoated paper from Indonesia for the period of review (POR) January 1, 2017, through December 31, 2017.

DATES: Applicable November 14, 2018.

FOR FURTHER INFORMATION CONTACT: David Goldberger or Darla Brown, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4136 or (202) 482–1791, respectively.

Background

On March 5, 2018, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the CVD order on certain uncoated paper from Indonesia for the POR.[1] On April 2, 2018, Commerce received a timely request from PT Anugerah Kertas Utama, PT Riau Andalan Kertas, and APRIL Fine Paper Macao Offshore Limited (collectively, APRIL), in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.213(b), to conduct an administrative review of this CVD order.[2]

On May 2, 2018, Commerce published in the **Federal Register** a notice of initiation with respect to APRIL.[3] On July 13, 2018, APRIL timely withdrew its request for an administrative review.[4]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), the Secretary will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review. As noted above, APRIL withdrew its request for review by the 90-day deadline, and no other party requested an administrative review of this order. Therefore, we are rescinding the administrative review of the CVD order on certain uncoated paper from Indonesia covering the period January 1, 2017, through December 31, 2017.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties on all appropriate entries. Countervailing duties shall be

[13] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[14] *See Certain Hot-Rolled Steel Flat Products from Australia, Brazil, Japan, the Republic of Korea, the Netherlands, the Republic of Turkey, and the United Kingdom: Amended Final Affirmative Antidumping Determinations for Australia, the Republic of Korea, and the Republic of Turkey and Antidumping Duty Orders,* 81 FR 67962 (October 3, 2016) (*Order*).

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 83 FR 9284 (March 5, 2018).

[2] *See* Letter from APRIL, ''Uncoated Paper from Indonesia,'' dated April 2, 2018.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 19215 (May 2, 2018).

[4] *See* Letter from APRIL, ''Certain Uncoated Paper from Indonesia: APRIL—Withdraw of Request for Administrative Review,'' dated July 13, 2018.

assessed at rates equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions directly to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification Regarding Administrative Protective Orders

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

This notice is issued and published in accordance with section 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

Dated: November 7, 2018.

James Maeder,

Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations performing the duties of Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2018–24791 Filed 11–13–18; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket Number 181101997–8997–01]

Developing a Privacy Framework

AGENCY: National Institute of Standards and Technology, U.S. Department of Commerce.

ACTION: Notice; request for information (RFI).

SUMMARY: The National Institute of Standards and Technology (NIST) is developing a framework that can be used to improve organizations' management of privacy risk for individuals arising from the collection, storage, use, and sharing of their information.[1] The NIST Privacy Framework: An Enterprise Risk Management Tool (''Privacy Framework''), is intended for voluntary use and is envisioned to consist of outcomes and approaches that align policy, business, technological, and legal approaches to improve organizations' management of processes for incorporating privacy protections into products and services. This notice requests information to help identify, understand, refine, and guide development of the Privacy Framework. The Privacy Framework will be developed through a consensus-driven, open, and collaborative process that will include workshops and other opportunities to provide input.

DATES: Comments in response to this notice must be received by 5:00 p.m. Eastern time on December 31, 2018.

ADDRESSES: Written comments may be submitted by mail to Katie MacFarland, National Institute of Standards and Technology, 100 Bureau Drive, Stop 2000, Gaithersburg, MD 20899. Electronic submissions may be sent to *privacyframework@nist.gov,* and may be in any of the following formats: HTML, ASCII, Word, RTF, or PDF. Please cite ''Developing a Privacy Framework'' in all correspondence. Comments received by the deadline will be posted at *http://www.nist.gov/privacyframework* without change or redaction, so commenters should not include information they do not wish to be posted (*e.g.,* personal or confidential business information). Comments that contain profanity, vulgarity, threats, or other inappropriate language or content will not be posted or considered.

FOR FURTHER INFORMATION CONTACT: For questions about this RFI contact: Naomi Lefkovitz, U.S. Department of Commerce, NIST, MS 2000, 100 Bureau Drive, Gaithersburg, MD 20899, telephone (301) 975–2924, email *privacyframework@nist.gov.* Please direct media inquiries to NIST's Public Affairs Office at (301) 975–NIST.

SUPPLEMENTARY INFORMATION:

Genesis for the Privacy Framework's Development

It is a challenge to design, operate, or use technologies in ways that are mindful of diverse privacy needs in an increasingly connected and complex environment. Current and cutting-edge technologies such as mobile devices, social media, the Internet of Things and artificial intelligence are giving rise to increased concerns about their impacts on individuals' privacy. Inside and outside the U.S., there are multiple visions for how to address these concerns. Accordingly, the U.S. Department of Commerce (DOC) is developing a forward-thinking approach that supports both business innovation and strong privacy protections. As part of this effort, NIST is developing a voluntary Privacy Framework to help organizations: better identify, assess, manage, and communicate privacy risks; foster the development of innovative approaches to protecting individuals' privacy; and increase trust in products and services.[2] The Privacy Framework is intended to be a tool that would assist with enterprise risk management.

Privacy Framework Development and Attributes

While good cybersecurity practices help manage privacy risk through the protection of personally identifiable information (PII),[3] privacy risks also can arise from how organizations collect, store, use, and share PII to meet their mission or business objective, as well as how individuals interact with products and services. NIST seeks to understand whether organizations that design, operate, or use these products and services would be better able to address the full scope of privacy risk with more tools to support better implementation of privacy protections.

NIST will develop the Privacy Framework in a manner consistent with its mission to promote U.S. innovation and industrial competitiveness, and is seeking input from all interested stakeholders. NIST intends for the Framework to provide a prioritized, flexible, risk-based, outcome-based, and cost-effective approach that can be compatible with existing legal and regulatory regimes in order to be the most useful to organizations and enable widespread adoption. NIST expects that the Privacy Framework development process will involve several iterations to

[1] While NIST requests information about how organizations define privacy risk in topic #3 below, for the purposes of this RFI, NIST references the privacy risk model set forth in NISTIR 8062, *An Introduction to Privacy Engineering and Risk Management in Federal Systems* at *https://csrc.nist.gov/publications/detail/nistir/8062/final,* which analyzes the problems that individuals might experience as a result of the processing of their information, and the impact if they were to occur.

[2] In parallel with this effort, the DOC's National Telecommunications and Information Administration is developing a set of privacy principles in support of a domestic policy approach that advances consumer privacy protections while protecting prosperity and innovation, in coordination with DOC's International Trade Administration to ensure consistency with international policy objectives: *https://www.ntia.doc.gov/federal-register-notice/2018/request-comments-developing-administration-s-approach-consumer-privacy.*

[3] For the purposes of this RFI, NIST is using the definition from the Office of Management and Budget Circular A–130. PII is defined as ''information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual.''

allow for continuing engagement with interested stakeholders. This will include interactive workshops, along with other forms of outreach.

On October 16, 2018, NIST held its first workshop in Austin, Texas to launch the framework development process.[4] NIST heard from panelists from industry, civil society and academia, as well as audience participants about the needs the Privacy Framework should address and some key desired characteristics. As a consequence, NIST believes that in order to be effective, the Privacy Framework should have the following minimum attributes:

1. Consensus-driven and developed and updated through an open, transparent process. All stakeholders should have the opportunity to contribute to the Privacy Framework's development. NIST has a long track record of successfully and collaboratively working with stakeholders to develop guidelines and standards. NIST will model the approach for the Privacy Framework on the successful, open, transparent, and collaborative approach used to develop the Framework for Improving Critical Infrastructure Cybersecurity (''Cybersecurity Framework'').[5]

2. Common and accessible language. The Privacy Framework should be understandable by a broad audience, including senior executives and those who are not privacy professionals. The Privacy Framework can then facilitate communications among various stakeholders by promoting use of this common language.

3. Adaptable to many different organizations, technologies, lifecycle phases, sectors, and uses. The Privacy Framework should be scalable to organizations of all sizes, public or private, in any sector, and operating within or across domestic borders. It should be platform- and technology-agnostic and customizable.

4. Risk-based, outcome-based, voluntary, and non-prescriptive. The Privacy Framework should provide a catalog of privacy outcomes and approaches to be used voluntarily, rather than a set of one-size-fits-all requirements, in order to: Foster innovation in products and services; inform education and workforce development; and promote research on and adoption of effective privacy solutions. The Privacy Framework should assist organizations to better manage privacy risks within their diverse environments without prescribing the methods for managing privacy risk.

5. Readily usable as part of any enterprise's broader risk management strategy and processes. The Privacy Framework should be consistent with, or reinforce, other risk management efforts within the enterprise, recognizing that privacy is one of several major areas of risk that an organization needs to manage.

6. Compatible with or may be paired with other privacy approaches. The Privacy Framework should take advantage of existing privacy standards, methodologies, and guidance. It should be compatible with and support organizations' ability to operate under applicable domestic and international legal or regulatory regimes.

7. A living document. The Privacy Framework should be updated as technology and approaches to privacy protection change and as stakeholders learn from implementation.

Although the goal of the Privacy Framework is to help organizations better identify, assess, manage, and communicate privacy risks, NIST expects there may be aspects of privacy practices that are not sufficiently developed for inclusion in the Privacy Framework. When developing the Cybersecurity Framework, NIST produced a related roadmap that identified focus areas that still needed more research and understanding before they were mature enough for widespread adoption, but that could potentially inform future revisions of the Cybersecurity Framework. With respect to the Privacy Framework, NIST anticipates that a roadmap may be needed for similar reasons.

As noted below, NIST solicits comments on the desired attributes of a Privacy Framework, as well as high-priority gaps in organizations' ability to manage privacy risk, as part of this RFI.

Goals of This Request for Information

Based upon discussions that took place during the October 16, 2018 workshop, this RFI seeks further information about the topics discussed by stakeholders, as elaborated in the sections below. The RFI invites stakeholders to submit ideas, based on their experience as well as their mission and business needs, to assist in prioritizing elements and development of the Privacy Framework. NIST invites industry, civil society groups, academic institutions, Federal agencies, state, local, territorial, tribal, and foreign governments, standard-setting organizations, and other interested stakeholders to respond.

The goals of the Privacy Framework development process, generally, and this RFI, specifically, are:

(i) To better understand common privacy challenges in the design, operation, and use of products and services that might be addressed through a voluntary Privacy Framework,

(ii) to gain a greater awareness about the extent to which organizations are identifying and communicating privacy risk or have incorporated privacy risk management standards, guidelines, and best practices, into their policies and practices; and

(iii) to specify high-priority gaps for which privacy guidelines, best practices, and new or revised standards are needed and that could be addressed by the Privacy Framework or a related roadmap.

Details About Responses to This Request for Information

When addressing the topics below, commenters may address the practices of their organization or a group of organizations with which they are familiar. If desired, commenters may provide information about the type, size, and location of the organization(s). Provision of such information is optional and will not affect NIST's full consideration of the comment.

Comments containing references, studies, research, and other empirical data that are not widely published (*e.g.,* available on the internet) should include copies of or electronic links to the referenced materials. Beyond that, responses should not include additional information. Do not include in comments or otherwise submit information deemed to be proprietary, private, or in any way confidential, as all comments relevant to this RFI topic area that are received by the deadline will be made available publicly at *http://www.nist.gov/privacyframework.*

Request for Information

The following list of topics covers the major areas about which NIST seeks information. The listed areas are not intended to limit the topics that may be addressed by respondents so long as they address privacy and how a useful Privacy Framework might be developed. Responses may include any topic believed to have implications for the development of the Privacy Framework, regardless of whether the topic is included in this document.

Risk Management

NIST solicits information about how organizations assess risk; how privacy

[4] *https://www.nist.gov/news-events/events/2018/10/kicking-nist-privacy-framework-workshop-1.*

[5] *https://www.nist.gov/cyberframework/framework.*

considerations factor into that risk assessment; the current usage of existing privacy standards, frameworks, models, methodologies, tools, guidelines, and principles; and other risk management practices related to privacy. In addition, NIST is interested in understanding whether particular frameworks, standards, guidelines, and/or best practices are mandated by legal or regulatory requirements and the challenges organizations perceive in meeting such requirements. This will assist in achieving NIST's goal of developing a framework that includes and identifies common practices across contexts and environments and is structured to help organizations achieve positive privacy outcomes. Accordingly, NIST is requesting information related to the following topics:

Organizational Considerations

1. The greatest challenges in improving organizations' privacy protections for individuals;
2. The greatest challenges in developing a cross-sector standards-based framework for privacy;
3. How organizations define and assess risk generally, and privacy risk specifically;
4. The extent to which privacy risk is incorporated into different organizations' overarching enterprise risk management;
5. Current policies and procedures for managing privacy risk;
6. How senior management communicates and oversees policies and procedures for managing privacy risk;
7. Formal processes within organizations to address privacy risks that suddenly increase in severity;
8. The minimum set of attributes desired for the Privacy Framework, as described in the *Privacy Framework Development and Attributes* section of this RFI, and whether any attributes should be added, removed or clarified;
9. What an outcome-based approach to privacy would look like;
10. What standards, frameworks, models, methodologies, tools, guidelines and best practices, and principles organizations are aware of or using to identify, assess, manage, and communicate privacy risk at the management, operational, and technical levels, and whether any of them currently meet the minimum attributes described above;
11. How current regulatory or regulatory reporting requirements (*e.g.,* local, state, national, international) relate to the use of standards, frameworks, models, methodologies, tools, guidelines and best practices, and principles;
12. Any mandates to use specific standards, frameworks, models, methodologies, tools, guidelines and best practices, and principles or conflicts between requirements and desired practices;
13. The role(s) national/international standards and organizations that develop national/international standards play or should play in providing confidence mechanisms for privacy standards, frameworks, models, methodologies, tools, guidelines, and principles;
14. The international implications of a Privacy Framework on global business or in policymaking in other countries; and
15. How the Privacy Framework could be developed to advance the recruitment, hiring, development, and retention of a knowledgeable and skilled workforce necessary to perform privacy functions within organizations.

Structuring the Privacy Framework

NIST is interested in understanding how to structure the Privacy Framework to achieve the desired set of attributes and improve integration of privacy risk management processes with the organizational processes for developing products and services for better privacy outcomes. NIST is seeking any input from the public regarding options for structuring the Privacy Framework, and is particularly interested in receiving comment on the following issues, if applicable:

16. Please describe how your organization currently manages privacy risk. For example, do you structure your program around the information life cycle (*i.e.,* the different stages—from collection to disposal—through which PII is processed), around principles such as the fair information practice principles (FIPPs), or by some other construct?
17. Whether any aspects of the Cybersecurity Framework could be a model for this Privacy Framework, and what is the relationship between the two frameworks.
18. Please describe your preferred organizational construct for the Privacy Framework. For example, would you like to see a Privacy Framework that is structured around:
    a. The information life cycle;
    b. Principles such as FIPPs;
    c. The NIST privacy engineering objectives of predictability, manageability, and disassociability[6] or other objectives;
    d. Use cases or design patterns;
    e. A construct similar to the Cybersecurity Framework functions, categories, and subcategories; or
    f. Other organizing constructs?

    Please elaborate on the benefits or challenges of your preferred approach with respect to integration with organizational processes for managing enterprise risk and developing products or services. If you provided information about topic 10 above, please identify any supporting examples of standards, frameworks, models, methodologies, tools, guidelines and best practices, and principles.

Specific Privacy Practices

In addition to the approaches above, NIST is interested in identifying core privacy practices that are broadly applicable across sectors and organizations. NIST is interested in information on the degree of adoption of the following practices regarding products and services:

- De-identification;
- Enabling users to have a reliable understanding about how information is being collected, stored, used, and shared;
- Enabling user preferences;
- Setting default privacy configurations;
- Use of cryptographic technology to achieve privacy outcomes—for example, the disassociability privacy engineering objective;
- Data management, including:
  - Tracking permissions or other types of data tracking tools,
  - Metadata,
  - Machine readability,
  - Data correction and deletion; and
- Usable design or requirements.

19. Whether the practices listed above are widely used by organizations;
20. Whether, in addition to the practices noted above, there are other practices that should be considered for inclusion in the Privacy Framework;
21. How the practices listed above or other proposed practices relate to existing international standards and best practices;
22. Which of these practices you see as being the most critical for protecting individuals' privacy;
23. Whether some of these practices are inapplicable for particular sectors or environments;
24. Which of these practices pose the most significant implementation challenge, and whether the challenges vary by technology or other factors such as size or workforce capability of the organization;

[6] NISTIR 8062, *An Introduction to Privacy Engineering and Risk Management in Federal Systems* at *https://csrc.nist.gov/publications/detail/nistir/8062/final.*

25. Whether these practices are relevant for new technologies like the Internet of Things and artificial intelligence; and

26. How standards or guidelines are utilized by organizations in implementing these practices.

Authority: 15 U.S.C. 272(b), (c), & (e); 15 U.S.C. 278g–3.

Kevin A. Kimball,

Chief of Staff.

[FR Doc. 2018–24714 Filed 11–13–18; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Proposed Voluntary Product Standard 2–10, Performance Standard for Wood-Based Structural-Use Panels

AGENCY: National Institute of Standards and Technology (NIST), Commerce.

ACTION: Notice and request for comments.

SUMMARY: The National Institute of Standards and Technology (NIST) is soliciting public comment on a proposed revision to Voluntary Product Standard (PS) 2–10, Performance Standard for Wood-Based Structural-Use Panels. The standard, prepared by the Standing Committee for PS 2, establishes requirements for those who choose to adhere to the standard, for the structural criteria to assess the acceptability of wood-based structural-use panels for construction sheathing and single-floor applications. It also provides a basis for common understanding among the producers, distributors, and the users of these products. Interested parties are invited to review the proposed standard and submit comments to NIST.

DATES: Written comments regarding the proposed revision to PS 2–10 should be submitted to the Standards Services Division, NIST, no later than December 14, 2018.

ADDRESSES: An electronic copy (an Adobe Acrobat File) of the proposed revision to the standard, PS 2–10, can be obtained at the following website: *https://www.nist.gov/standardsgov/voluntary-product-standards-program.* This site also includes an electronic copy of PS 2–10 (the existing standard) and a summary of the significant changes. Written comments on the proposed revision should be submitted to David F. Alderman, Standards Coordination Office, NIST, 100 Bureau Drive, Stop 2100, Gaithersburg, MD 20899–2100. Electronic comments may be submitted to *david.alderman@nist.gov.*

FOR FURTHER INFORMATION CONTACT: David F. Alderman, Standards Coordination Office, National Institute of Standards and Technology, telephone (301) 975–4019; fax: (301) 975–4715, email: *david.alderman@nist.gov.*

SUPPLEMENTARY INFORMATION: The proposed revision of the standard has been developed and is being processed in accordance with Department of Commerce provisions in 15 CFR part 10, *Procedures for the Development of Voluntary Product Standards,* as amended (published June 20, 1986). The Standing Committee for PS 2 is responsible for maintaining, revising, and interpreting the standard, and is comprised of producers, distributors, users, and others with an interest in the standard. Committee members voted on the revision, which was approved unanimously. The Committee then submitted a report to NIST along with the voting results and the draft revised standard. NIST has determined that the revised standard should be issued for public comment.

Voluntary Product Standard PS 2–10 establishes structural criteria for assessing the acceptability of wood-based structural-use panels for construction sheathing and single-floor application and provides a basis for common understanding among the producers, distributors, and the users of these products. After conducting a review of the current standard, PS 2–10, the Standing Committee for PS 2 determined that updates were needed to reflect current industry practices and developed the proposed revision to the standard through meetings to review the standard and propose needed changes.

The proposed revision includes the following changes: Change of title, editorial corrections, new and revised definitions, updated references, and changes to Section 5 Requirements. A complete list of proposed changes can be found at *https://www.nist.gov/standardsgov/voluntary-product-standards-program.* All public comments will be reviewed and considered.

Attachments will be accepted in plain text, Microsoft Word, or Adobe PDF formats. Comments containing references, studies, research, and other empirical data that are not widely published should include copies or electronic links of the referenced materials.

All submissions, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. NIST reserves the right to publish comments publicly, unedited and in their entirety. Sensitive personal information, such as account numbers or Social Security numbers, or names of other individuals, should not be included. Submissions will not be edited to remove any identifying or contact information. Do not submit confidential business information, or otherwise sensitive or protected information. Comments that contain profanity, vulgarity, threats, or other inappropriate language or content will not be considered.

Written comments should be submitted in accordance with the **DATES** and **ADDRESSES** sections of this notice. The Standing Committee for PS 2 and NIST will consider all responsive comments received and may revise the standard accordingly.

Authority: 15 U.S.C. 272.

Kevin A. Kimball,

Chief of Staff.

[FR Doc. 2018–24713 Filed 11–13–18; 8:45 am]

BILLING CODE 3510–13–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Renew Collection 3038–0043, Rules Relating To Review of National Futures Association Decisions in Disciplinary, Membership Denial, Registration, and Member Responsibility Actions

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'') is announcing an opportunity for public comment on the renewal of a collection of certain information by the agency. Under the Paperwork Reduction Act (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments on rules relating to review of National Futures Association decisions in disciplinary, membership denial, registration, and member responsibility actions.

DATES: Comments must be submitted on or before January 14, 2019.

ADDRESSES: You may submit comments, identified by ''OMB Control No. 3038–0043'' by any of the following methods:

• The Agency's website, at *http://comments.cftc.gov/.* Follow the instructions for submitting comments through the website.

• *Mail:* Christopher J. Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

• *Hand Delivery/Courier:* Same as Mail above.

Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Melissa Chiang, Assistant General Counsel, Office of General Counsel, Commodity Futures Trading Commission, (202) 418–5578; email: *mchiang@cftc.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.,* Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below.

Title: Rules Relating to Review of National Futures Association Decisions in Disciplinary, Membership Denial, Registration, and Member Responsibility Actions (OMB Control No. 3038–0043). This is a request for extension of a currently approved information collection.

Abstract: 17 CFR part 171 require a registered futures association to provide fair and orderly procedures for membership and disciplinary actions. The Commission's review of decisions of registered futures associations in disciplinary, membership denial, registration, and member responsibility actions is governed by Section 17(h)(2) of the Commodity Exchange Act, 7 U.S.C. 21(h)(2). The rules establish procedures and standards for Commission review of such actions, and the reporting requirements included in the procedural rules are either directly required by Section 17 of the Commodity Exchange Act or are necessary to the type of appellate review role Congress intended the Commission to undertake when it adopted that provision. 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 OMB control numbers for the CFTC's regulations were published on December 30, 1981. *See* 46 FR 63035 (Dec. 30, 1981).

With respect to the collection of information, the CFTC invites comments on:

• Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;

• The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Ways to enhance the quality, usefulness, and clarity of the information to be collected; and

• Ways to minimize 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.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

Burden Statement: The respondent burden for this collection is estimated to average 1 hour per response. This estimate includes the time needed to transmit decisions of disciplinary, membership denial, registration, and member responsibility actions to the Commission for review. The total estimated burden of 3 hours is determined by the following:

Respondents/Affected Entities: Individuals or entities filing appeals from disciplinary and membership decisions by National Futures Association.

Estimated number of respondents per year: 1.

Estimated number of responses: 3.

Estimated total annual burden on respondents: 3 hours (1 hour/each response × 3).

Frequency of collection: On occasion.

There are no capital costs or operating and maintenance costs associated with this collection.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: November 8, 2018.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2018–24770 Filed 11–13–18; 8:45 am]

BILLING CODE 6351–01–P

[1] 17 CFR 145.9.

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Notice of Intent To Extend Collection 3038–0094; Clearing Member Risk Management

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (CFTC) is announcing an opportunity for public comment on the extension of a collection of certain information by the agency. Under the Paperwork Reduction Act (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment. This notice solicits comments on the obligation to maintain records related to clearing documentation between the customer and the customer's clearing member.

DATES: Comments must be submitted on or before January 14, 2019.

ADDRESSES: You may submit comments, identified by OMB Control No. 3038–0094, by any of the following methods:

• The Agency's website, at *http://comments.cftc.gov/.* Follow the instructions for submitting comments through the website.

• *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW, Washington, DC 20581.

• *Hand Delivery/Courier:* Same as Mail above. Please submit your comments using only one method. All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov.*

FOR FURTHER INFORMATION CONTACT: Jocelyn Partridge, Special Counsel, Division of Clearing and Risk, Commodity Futures Trading Commission, (202) 418–5926; email: *jpartridge@cftc.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA, 44 U.S.C. 3501 *et seq.,* Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice for the extension of the collection of information listed below. 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.

Title: Clearing Member Risk Management (OMB Control No. 3038–0094). This is a request for extension of a currently approved information collection.

Abstract: Section 3(b) of the Commodity Exchange Act (''Act'' or ''CEA'') provides that one of the purposes of the Act is to ensure the financial integrity of all transactions subject to the Act and to avoid systemic risk. Section 8a(5) authorizes the Commission to promulgate such regulations that it believes are reasonably necessary to effectuate any of the provisions or to accomplish any of the purposes of the Act. Risk management systems are critical to the avoidance of systemic risks.

Section 4s(j)(2) requires each Swap Dealer (''SD'') and Major Swap Participant (''MSP'') to have risk management systems adequate for managing its business. Section 4s(j)(4) requires each SD and MSP to have internal systems and procedures to perform any of the functions set forth in Section 4s.

Section 4d requires FCMs to register with the Commodity Futures Trading Commission (''Commission''). It further requires Futures Commission Merchants (''FCMs'') to segregate customer funds. Section 4f requires FCMs to maintain certain levels of capital. Section 4g establishes reporting and recordkeeping requirements for FCMs.

Pursuant to these provisions, the Commission adopted § 1.73 which applies to clearing members that are FCMs and § 23.609 which applies to clearing members that are SDs or MSPs. These provisions require these clearing members to have procedures to limit the financial risks they incur as a result of clearing trades and liquid resources to meet the obligations that arise. The regulations require clearing members to: (1) Establish credit and market risk-based limits based on position size, order size, margin requirements, or similar factors; (2) use automated means to screen orders for compliance with the risk-based limits; (3) monitor for adherence to the risk-based limits intra-day and overnight; (4) conduct stress tests of all positions in the proprietary account and all positions in any customer account that could pose material risk to the futures commission merchant at least once per week; (5) evaluate its ability to meet initial margin requirements at least once per week; (6) evaluate its ability to meet variation margin requirements in cash at least once per week; (7) evaluate its ability to liquidate the positions it clears in an orderly manner, and estimate the cost of the liquidation at least once per month; and (8) test all lines of credit at least once per quarter.

Each of these items has been observed by Commission staff as an element of an existing sound risk management program at an SD, MSP, or FCM. The Commission regulations require each clearing member to establish written procedures to comply with this regulation and to keep records documenting its compliance. The information collection obligations imposed by the regulations are necessary to implement certain provisions of the CEA, including ensuring that registrants exercise effective risk management and for the efficient operation of trading venues among SDs, MSPs, and FCMs. 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.[1]

With respect to the collection of information, the CFTC invites comments on:

• Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;

• The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

• Ways to enhance the quality, usefulness, and clarity of the information to be collected; and

• Ways to minimize 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.

You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[2]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the ICR will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

Burden Statement: The respondent burden for this collection is estimated to average 2 hours per response for an estimated annual burden of 504 hours per respondent. This estimate includes the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or

[1] The OMB control numbers for the CFTC's regulations were published on December 30, 1981. *See* 46 FR 63035 (Dec. 30, 1981).

[2] 17 CFR 145.9.

provide information to or for a federal agency.

Respondents/Affected Entities: Clearing member Swap Dealers, Major Swap Participants, and Futures Commission Merchants.

Estimated Number of Respondents: 166 (101 Clearing Member Swap Dealers and 65 Clearing Member Futures Commission Merchants).

Estimated Average Burden Hours per Respondent: 504.

Estimated Total Annual Burden Hours: 83,664 hours.

Frequency of Collection: As needed.

There are no capital costs or operating and maintenance costs associated with this collection.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: November 8, 2018.

Robert Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2018–24761 Filed 11–13–18; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2018–OS–0090]

Proposed Collection; Comment Request

AGENCY: Office of the General Counsel/Defense Legal Services Agency, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of Defense, Office of the General Counsel/Defense Legal Services Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: 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; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 14, 2019.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal e-Rulemaking 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, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Department of Defense, Office of the General Counsel/Defense Legal Services Agency, 1600 Defense Pentagon, ATTN: Standard of Conduct Office, Washington, DC, or email: *OSD.SOCO@MAIL.MIL.* Call +1 (703) 571–9446.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Office of the Secretary of Defense Confidential Conflict-of-Interest Statement for Office of the Secretary of Defense Advisory Committee Members; SD Form 830; OMB Control Number 0704–0551.

Needs and Uses: The information requested on this form is required by Title I of the Ethics in Government Act of 1978 (5 U.S.C. App.), Executive Order 12674, and 5 CFR part 2634, subpart I, of the Office of Government Ethics regulations. The requested information is necessary to prevent conflicts of interest and to identify potential conflicts of individuals serving on certain Office of the Secretary of Defense (OSD) Advisory Committees.

Affected Public: Individuals or households.

Annual Burden Hours: 125.

Number of Respondents: 125.

Responses per Respondent: 1.

Annual Responses: 125.

Average Burden per Response: 1 hour.

Frequency: Annually.

Respondents are members of or potential members of Office of the Secretary of Defense Advisory Committees. SD Form 830 will assist in identifying potential conflicts of interest due to personal financial interests or affiliations. The collection of requested information will satisfy a Federal regulatory requirement and assist the Department of Defense in complying with applicable Federal conflict of interest laws and regulations.

Dated: November 7, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2018–24744 Filed 11–13–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Administrative Suspension of Department of Defense Federal Advisory Committee

AGENCY: Department of Defense.

ACTION: Administrative suspension of Federal Advisory Committee.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that it is administratively suspending the charter for the Lake Eufaula Advisory Committee (''the Committee'').

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The DoD, pursuant to section 3133(b)(1) of the Water Resources Development Act of 2007 (''the 2007 WRDA'') (Pub. L. 110–114) and in accordance with the Federal Advisory Committee Act (5 U.S.C., Appendix), established the Committee on August 28, 2015. After careful consideration, the DoD has determined that the Committee's stated objectives have been accomplished and, therefore, the DoD is administratively suspending the Committee pending rescission of section 3133(b) of the 2007 WRDA. Information concerning the Committee, to include contact information for the Committee's Designated Federal Officer, can be found at *https://gsageo.force.com/FACA/FACAPublicPage.*

Dated: November 7, 2018.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2018–24742 Filed 11–13–18; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket ID ED–2017–IES–0131]

Privacy Act of 1974; System of Records–National Center for Education Statistics (NCES) Longitudinal and Cross-Sectional Studies

AGENCY: National Center for Education Statistics, Institute of Education Sciences, Department of Education.

ACTION: Notice of a modified system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended (Privacy Act), the Department of Education (Department) publishes this notice of a modified system of records entitled ''National Center for Education Statistics (NCES) Longitudinal and Cross-sectional Studies'' (18–13–01). This system is used to fulfill NCES's legislative mandate to collect, report, analyze, and disseminate statistical data on the condition and progress of education in the United States and other nations at the early childhood, preschool, elementary, secondary, postsecondary, and adult levels, including data on the critical influences, contexts, and transitions of: Students in elementary, secondary, postsecondary, and graduate education, and into employment and adult experiences; children at early childhood stage; homeschooled students; the general adult population; and participants in career training.

DATES: The Department seeks comment on the modified system of records described in this notice in accordance with the requirements of the Privacy Act. We must receive your comments on or before December 14, 2018.

This modified system of records will become applicable upon publication in the **Federal Register** on November 14, 2018, unless the modified system of records notice needs to be changed as a result of public comment. Modified routine uses (1) and (2) in the ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES section will become applicable upon the expiration of the 30-day period of public comment on December 14, 2018, unless any of the modified routine uses in the system of records notice need to be changed as a result of public comment. The Department will publish any significant changes resulting from public comment.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail, commercial delivery, or hand delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to *www.regulations.gov* to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under the ''help'' tab.
- *Postal Mail, Commercial Delivery, or Hand Delivery:* If you mail or deliver your comments about this modified system of records, address them to: Commissioner, National Center for Education Statistics, Institute of Education Sciences, U.S. Department of Education, Potomac Center Plaza (PCP), 550 12th Street SW, 4th Floor, Washington, DC 20202–4160.

Privacy Note: The Department's policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at *www.regulations.gov.* Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

Assistance to Individuals With Disabilities in Reviewing the Rulemaking Record: On request, we will supply an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

FOR FURTHER INFORMATION CONTACT: Kashka Kubzdela, National Center for Education Statistics, Institute of Education Sciences, U.S. Department of Education, PCP, 550 12th Street SW, 4th Floor, Washington, DC 20202–4160. Telephone: (202) 245–7377. Email: *NCES.Information.Collections@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or text telephone (TTY), you may call the Federal Relay Service (FRS) toll free at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: This system of records is used to fulfill NCES's legislative mandate to collect, report, analyze, and disseminate statistical data on the condition and progress of education in the United States and other nations at the early childhood, preschool, elementary, secondary, postsecondary, and adult levels. These data must be timely, objective, and non-ideological; free of political influence and bias; and relevant and useful to practitioners, researchers, policymakers, and the public.

The Department previously published the NCES Longitudinal Studies and the School and Staffing Surveys system of records in the **Federal Register** on June 4, 1999 (64 FR 30181–82). This modified system of records notice is updating:

(a) The name of the system and the system's security classification to indicate that it is unclassified.

(b) The system location to provide the current address of the Department's Institute of Education Sciences' National Center for Education Statistics office and the locations of its contractors and subcontractors serving as additional system locations;

(c) The system manager to reflect the location of the National Center for Education Statistics;

(d) The section entitled ''AUTHORITY FOR MAINTENANCE OF THE SYSTEM'' to reflect the updated authorizing law for collecting and maintaining the records in this system of records;

(e) The section entitled ''PURPOSES(S) OF THE SYSTEM'' to align the purpose with the legislative mandate set in the Education Sciences Reform Act of 2002 (ESRA) (20 U.S.C. 9541 and 9543);

(f) The section entitled ''CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM'' to provide a streamlined description and updated list of studies for which records are maintained (the categories of individuals in the system were neither expanded nor reduced), and to add that minors' participation in the listed studies is subject to ''implicit or explicit parental or legal guardian consent to participate . . . depending on school or school district requirements and on the Department's Protection of Human Subjects regulations (34 CFR part 97).'';

(g) The section entitled ''CATEGORIES OF RECORDS IN THE SYSTEM'' to provide a streamlined description of the collected records;

(h) The section entitled ''RECORD SOURCE CATEGORIES'' to clarify and update the description to reflect that information in the records comes from responses to survey and assessment instruments and from administrative records maintained by K–12 schools and school districts, postsecondary institutions, the Department, and third-parties, including State and Federal

agencies, as well as vendors, such as the National Student Clearinghouse (NSC);

(i) The section entitled ''ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES'' to modify both of the routine uses (Contract Disclosure and Research Disclosure) to replace the statement: ''will be required to maintain safeguards under the Privacy Act of 1974 and under section 406(d)(4) of [the General Education Provisions Act] GEPA (20 U.S.C. 1221e–1(d)(4)) with respect to such records'' with: ''must agree to safeguards to protect the security and confidentiality of the records disclosed from this system, consistent with ESRA (20 U.S.C. 9573);'' to add a citation for ''the Individuals with Disabilities Education Act (IDEA) (20 U.S.C. 1417(c); 34 CFR 300.610–300.611, 300.613–300.623, and 300.625–300.627)'' as applicable to the disclosure of records in this system by NCES; and to clarify for the Research Disclosure routine use that directly personally identifiable respondent information, such as name and contact information, is stored separately from the rest of the data collected in this system, and is not made available as part of a research disclosure, and add that the researcher must agree to use the information for statistical purposes only, not redisclose any data in identifiable form, and permit NCES' periodic inspection;

(j) The section entitled ''POLICIES AND PRACTICES FOR STORAGE OF RECORDS'' to reflect updated electronic storage practices on secure servers and other secure electronic storage media, and to state that directly personally identifiable contact information is stored separately from the rest of the data collected in this system;

(k) The section entitled ''POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS'' to include that records are retrieved by title of survey and the unique number, and are indexed by a unique number assigned to each individual, which can be cross-referenced when needed with the separately stored direct personal identifiers to allow the records to be retrieved by name and contact information;

(l) The section entitled ''POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS'' to indicate that the Department will submit a retention and disposition schedule to the National Archives and Records Administration (NARA) for review; and, that the records contained in this system will not be destroyed until NARA approves said schedule;

(m) The section entitled ''ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS'' to more accurately describe the various safeguards NCES and the Department employ to protect the data in this system; and

(n) The sections entitled ''RECORD ACCESS PROCEDURES'' and ''NOTIFICATION PROCEDURES'' to specify which necessary particulars are required for an individual to provide when requesting to be notified if the system of records contains a record pertaining to him or her or when accessing a record.

(o) A new section entitled ''HISTORY'' also has been added to the system of records notice to comply with the requirements of Office of Management and Budget Circular No. A–108.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of the Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: November 7, 2018.

Mark Schneider,

Director, Institute of Education Sciences.

SYSTEM NAME AND NUMBER:

National Center for Education Statistics (NCES) Longitudinal and Cross-sectional Studies (18–13–01).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

National Center for Education Statistics (NCES), Institute of Education Sciences, U.S. Department of Education (Department), Potomac Center Plaza (PCP), 550 12th Street SW, 4th Floor, Washington, DC 20202–4160. See the Appendix at the end of this system notice for additional system locations.

SYSTEM MANAGER(S):

Commissioner, National Center for Education Statistics, Institute of Education Sciences, U.S. Department of Education, PCP, 550 12th Street SW, 4th Floor, Washington, DC 20202.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The data collections being administered and their maintenance are authorized under the Education Sciences Reform Act of 2002 (ESRA) (20 U.S.C. 9541–9547 and 9571–9576).

PURPOSE(S) OF THE SYSTEM:

This system is used to fulfill NCES's legislative mandate to collect, report, analyze, and disseminate statistical data on the condition and progress of education in the United States and other nations at the early childhood, preschool, elementary, secondary, postsecondary, and adult levels. These data must be timely, objective, and non-ideological; free of political influence and bias; and relevant and useful to practitioners, researchers, policymakers, and the public.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system maintains records about individuals randomly selected from their respective populations of particular subgroups of children and adults (pre-Kindergarten children, pre-Kindergarten through graduate school students, parents or legal guardians, teachers, administrators, service providers, and general population adults) who voluntarily agree to participate (with implicit or explicit parental or legal guardian consent to participate for minors, depending on school or school district requirements and on the Department's Protection of Human Subjects regulations (34 CFR part 97)) in one of the NCES studies categorized below (with example studies provided for each category):

1. National household studies [*e.g.,* National Household Education Survey (NHES) including the current Early Childhood Education/Program Participation (ECPP) and Parent and Family Involvement in Education (PFI), and with past PFI-Enrolled and PFI-Homeschooled modules, the Adult Training and Education Survey (ATES)

studies, and the past Adult Education (AE), Adult Education for Work-Related Reasons (AEWR), Adult Education and Lifelong Learning (AELL), Before- and After-School Programs and Activities (ASPA), School Readiness (SR), Civic Engagement (CE), School Safety and Discipline (SS&D), and Household and Library Use (HHL)];

2. National and international K–12 school and staff studies [*e.g.,* Schools and Staffing Survey (SASS) and its follow-ups Teacher Follow-Up Survey (TFS), Principal Follow-Up Survey (PFS), and Beginning Teacher Longitudinal Study (BTLS); redesigned SASS—National Teacher and Principal Surveys (NTPS); and studies not related to SASS, such as Teacher Compensation Survey (TCS)*, Teacher Pilot Study (TPS), School Survey of Crime and Safety (SSOCS), Teaching and Learning International Survey (TALIS) and its associated Video Studies, and ED School Climate Surveys (EDSCLS)];

3. National early childhood longitudinal studies [*e.g.,* Early Childhood Longitudinal Study, Birth Cohort (ECLS–B); and Early Childhood Longitudinal Study, Kindergarten Class studies (ECLS–K)];

4. International K–12 assessments studies [*e.g.,* International Early Learning Study (IELS); Progress in International Reading Literacy Study (PIRLS); Civic Education Study (CivEd); Program for International Student Assessment (PISA); Program for International Student Assessment (PISA) Young Adult Follow-up (YAF) Study; Trends in International Mathematics and Science Study (TIMSS) and its associated Video Studies; and International Computer and Information Literacy Study (ICILS)];

5. National middle grades longitudinal studies [*e.g.,* Middle Grades Longitudinal Study (MGLS)];

6. National high school longitudinal studies [*e.g.,* National Longitudinal Study of the High School Class of 1972 (NLS); National Education Longitudinal Study of 1988 (NELS); Education Longitudinal Study of 2002 (ELS); High School Longitudinal Study of 2009 (HSLS); and High School and Beyond Longitudinal studies (HS&B)];

7. National postsecondary studies [*e.g.,* Recent College Graduates (RCG); National Postsecondary Student Aid Study (NPSAS) and its follow-ups Beginning Postsecondary Students Longitudinal Study (BPS) and Baccalaureate and Beyond Longitudinal Study (B&B); National Postsecondary Student Aid Study, Administrative Collection (NPSAS–AC); National Postsecondary Education Cooperative—Sample Surveys (NPEC–S); National Study of Postsecondary Faculty (NSOPF); and National Center for Education Research NCER–NPSAS Grant Studies];

8. National and international adult assessment studies [*e.g.,* International Adult Literacy Survey (IALS); Adult Literacy and Lifeskills Survey (ALL); National Assessment of Adult Literacy (NAAL); and Program for the International Assessment of Adult Competencies (PIAAC)];

9. National quick response studies [*e.g.,* Quick Response Information System (QRIS) made up of pre-postsecondary Fast Response Survey System (FRSS) and Postsecondary Education Quick Information System (PEQIS)]; and

10. NCES national and international developmental studies [*e.g.,* cognitive interviews, focus groups, feasibility studies, usability tests, pilot tests, web tests, etc., utilized to develop new or to improve current data collection methodologies and instruments for particular existing or multiple current and future data collection programs].

* TCS is an administrative records survey that collected between Fiscal Years (FY) 2007–2011 total compensation, teacher status, and demographic data about all teachers from multiple States.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system consists of responses from students, their parents or legal guardians, teachers, administrators, service providers, and other adults to data collection instruments including information such as background and demographic data, functional measures (reports of children's functioning in cognitive, social, emotional, and physical domains), family characteristics, education and/or employment experiences, finances, aspirations, plans, and attitudes. Cognitive assessment scores, administrative and financial aid records, and high school and college transcripts are also appended to the records. The appended administrative records contain data such as attendance, program participation, and other information.

The records for service providers, schools/institutions, and local educational agencies contain information on numbers and characteristics of students, teaching staff, and administrators; data on facilities, programs, services, and finances; and information related to student enrollment, persistence, completion, and performance. The records related to teachers and administrators contain, in addition to the above, data on certifications, training, experience, staff evaluations, salary, benefits, and attitudes and opinions related to various aspects of education and operations.

RECORD SOURCE CATEGORIES:

Information in the records comes from responses to survey and assessment instruments and from administrative records maintained by K–12 schools and school districts, postsecondary institutions, the Department, and third-parties, including State and Federal agencies, as well as vendors, such as the National Student Clearinghouse (NSC).

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

The Department may disclose information contained in a record in this system of records under the routine uses listed in this system of records without the consent of the individual if the disclosure is compatible with the purpose for which the record was collected. Any disclosure of individually identifiable information from a record in this system must also comply with the requirements of Section 183 of the ESRA (20 U.S.C. 9573) and its confidentiality standards that apply to all collection, reporting, and publication of data by NCES. Any disclosure of personally identifiable information (PII) from students' education records that were obtained from schools, school districts, postsecondary institutions, and other sources must also comply with the requirements of the Individuals with Disabilities Education Act (IDEA) (20 U.S.C. 1417(c); 34 CFR 300.610–300.611, 300.613–300.623, and 300.625–300.627) and the Family Educational Rights and Privacy Act (20 U.S.C. 1232g; 34 CFR part 99), which protect the privacy of student education records and the PII contained therein.

(1) *Contract Disclosure.* When NCES contracts with a private firm for the purpose of collating, analyzing, aggregating, maintaining, appending, or otherwise refining records in this system, the Commissioner of Education Statistics may release relevant records to the contractor. The contractor must agree to safeguards to protect the security and confidentiality of the records disclosed from this system, consistent with Section 183 of the ESRA (20 U.S.C. 9573).

(2) *Research Disclosure.* Where the Commissioner of Education Statistics determines that an individual or organization is qualified to carry out specific research, the Commissioner may disclose information from the

system of records to that researcher solely for the purpose of carrying out that research. Directly personally identifiable respondent information, such as name and contact information, are stored separately from the rest of the data collected in this system, and are not made available as part of a research disclosure. The researcher must agree to safeguards to protect the security and confidentiality of the records disclosed from this system, consistent with Section 183 of the ESRA (20 U.S.C. 9573). Furthermore, the researcher must agree to use the information for statistical purposes only, not redisclose any data in identifiable form, and permit NCES' periodic inspection.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in a database on NCES' or its contractors' or subcontractors' secure servers and in other secure electronic storage media. Directly personally identifiable respondent information, such as name and contact information, is stored separately from the rest of the data collected in this system.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records in the location file are indexed by a unique number assigned to each individual, which can be cross-referenced when needed with the separately stored direct personal identifiers. Records are retrieved by title of survey and the unique number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The Department shall submit a retention and disposition schedule that covers the records contained in this system to the National Archives and Records Administration (NARA) for review. The records will not be destroyed until such time as NARA approves said schedule.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to the records is limited to authorized personnel who are briefed regarding confidentiality of the data, are required to sign a written statement attesting to their understanding of the significance of the confidentiality requirement and penalties for non-compliance, and have received Department security clearances.

All physical access to the NCES, contractor, and subcontractor sites where this system of records is maintained, is controlled and monitored by security personnel who check each individual entering the buildings for his or her employee or visitor badge.

The computer systems employed offer a high degree of resistance to tampering and circumvention. Security systems limit data access to contract staff on a ''need to know'' basis, and control each individual user's ability to access and alter records within the system.

The NCES, contractor, and subcontractor employees who ''maintain'' (including collect, maintain, use, or disseminate) data in this system of records must comply with the requirements of the confidentiality standards under Section 183 of the ESRA (20 U.S.C. 9573).

RECORD ACCESS PROCEDURES:

If you wish to gain access to a record that exists regarding you in this system of records, contact the system manager at the address listed above. You must provide necessary particulars such as the study in question, your name, current address, the date and place of your birth, and any other identifying information requested by the Department, while processing the request, to distinguish between individuals with the same name. Your request must meet the requirements in 34 CFR 5b.5, including proof of identity.

CONTESTING RECORD PROCEDURES:

If you wish to contest content of a record regarding you in this system of records, contact the system manager. Your request must meet the requirements in 34 CFR 5b.7.

NOTIFICATION PROCEDURES:

If you wish to determine whether a record exists regarding you in this system of records, contact the system manager at the address listed above. You must provide necessary particulars such as the study in question, your name, current address, the date and place of your birth, and any other identifying information requested by the Department, while processing the request, to distinguish between individuals with the same name. Your request must meet the requirements in 34 CFR 5b.5, including proof of identity.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

The system of records previously entitled ''National Center for Education Statistics Longitudinal Studies and the School and Staffing Surveys'' (18–13–01) was last published in the **Federal Register** at 64 FR 30181–30182 (June 4, 1999).

Appendix to 18–13–01 Additional System Locations

- ABT Associates, 4550 Montgomery Ave., Suite 800 North, Bethesda, MD 20815–3343
- Activate Research, 1001 Connecticut Ave. NW, #515, Washington, DC 20036
- American Institutes for Research (AIR), 1000 and 1025 Thomas Jefferson St. NW, Washington, DC 20007
- Branch Associates, 1628 John F. Kennedy Blvd., #800, Philadelphia, PA 19103
- Child Trends, 7315 Wisconsin Ave., #1200w, Bethesda, MD 20814
- Educational Testing Service (ETS), 660 Rosedale Rd., Princeton, NJ 08541
- EurekaFacts, 51 Monroe St., Plaza East 10, Rockville, MD 20850
- Fors Marsh Group, 1010 N Glebe Rd., #510, Arlington, VA 22201
- Hager Sharp, 1030 15th St. NW, Suite 600E, Washington, DC 20005
- Mathematica Policy Research, 1100 First St. NE, #1200, Washington, DC 20002
- National Opinion Research Center (NORC), 1155 E 60th St., Chicago, Illinois 60637; 55 E Monroe, Suite 3000, Chicago, IL 60603; 4350 East-West Hwy., 8th Fl., Bethesda, MD 20814
- Pearson Inc., 2510 N Dodge St., Iowa City, Iowa 52245
- Research Support Services, 906 Ridge Ave., Evanston, IL 60202
- RTI International, 3040 E Cornwallis Rd., Research Triangle Park, NC 27709–2194
- Sanametrix, 1120 20th St. NW, South Tower, Suite 200, Washington, DC 20036; 506 Wonderwood Drive, Charlotte, NC 28211; 24574 Spriggs Court, Hollywood, MD 20636
- Shugoll Research, 7475 Wisconsin Ave., #200, Bethesda, MD 20814; 1800 Diagonal Rd., #300, Alexandria, VA 22314
- SRI International, 1100 Wilson Boulevard, #2800, Arlington, VA 22209
- Strategic Analytics Inc., 6503 Shipyard Place, Falls Church, VA 22043
- Synergy Enterprises, 8757 Georgia Ave., Silver Spring, MD 20910
- U.S. Census Bureau, 4600 Silver Hill Rd., Suitland, MD 20746; 1201 E 10th St., Jeffersonville, IN 47190
- WESTAT, 1600 Research Blvd., Rockville, MD 20850.

[FR Doc. 2018–24847 Filed 11–13–18; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Hanford

AGENCY: Department of Energy (DOE).

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Hanford. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES:

Wednesday, December 5, 2018—8:30 a.m.–4:30 p.m.

Thursday, December 6, 2018—8:30 a.m.–11:30 a.m.

ADDRESSES: Red Lion Hanford House, 802 George Washington Way, Richland, WA 99352.

FOR FURTHER INFORMATION CONTACT: Kristen Holmes, Federal Coordinator, Department of Energy Richland Operations Office, P.O. Box 550, H5–20, Richland, WA 99352; Phone: (509) 376–5803; or Email: *kristen.l.holmes@rl.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

- Potential Draft Advice
  - DOE's Interpretation of the Definition of High-Level Radioactive Waste
- Discussion Topics
  - Tri-Party Agreement Agencies' Updates
  - Consideration of a System Plan Assumptions White Paper
  - New Board Member Orientation
  - Hanford Advisory Board Committee Reports
  - Board Business

Public Participation: The meeting is open to the public. The EM SSAB, Hanford, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kristen Holmes at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Kristen Holmes at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Kristen Holmes' office at the address or phone number listed above. Minutes will also be available at the following website: *http://www.hanford.gov/page.cfm/hab/FullBoardMeetingInformation.*

Signed in Washington, DC on November 8, 2018.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2018–24811 Filed 11–13–18; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Sunshine Act Meeting Notice

The following notice of meeting is published pursuant to section 3(a) of the government in the Sunshine Act (Pub. L. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

TIME AND DATE: November 15, 2018 10:00 a.m.

PLACE: Room 2C, 888 First Street NE, Washington, DC 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

* Note—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: Kimberly D. Bose, Secretary, Telephone (202) 502–8400.

For a recorded message listing items struck from or added to the meeting, call (202) 502–8627.

This is a list of matters to be considered by the Commission. It does not include a listing of all documents relevant to the items on the agenda. All public documents, however, may be viewed on line at the Commission's website at *http://ferc.capitolconnection.org/* using the eLibrary link, or may be examined in the Commission's Public Reference Room.

1049TH MEETING—OPEN MEETING

[November 15, 2018, 10:00 a.m.]

Item No.	Docket No.	Company
	Administrative	
A–1	AD19–1–000	Agency Administrative Matters.
A–2	AD19–2–000	Customer Matters, Reliability, Security and Market Operations.
A–3	AD07–13–012	FY2018 Report on Enforcement.
	Electric	
E–1	RM19–5–000	Public Utility Transmission Rate Changes to Address Accumulated Deferred Income Taxes.
E–2	RM19–4–000	Implementation of Amended Section 203(a)(1)(B) of the Federal Power Act.
E–3	RM18–8–000	Geomagnetic Disturbance Reliability Standard.
	RM15–11–003	Reliability Standard for Transmission System Planned Performance for Geomagnetic Disturbance Events.
E–4	PL19–2–000	Accounting and Ratemaking Treatment of Accumulated Deferred Income Taxes and Treatment Following the Sale or Retirement of an Asset.
E–5	EL18–62–000	AEP Appalachian Transmission Company, Inc.; AEP Indiana Michigan Transmission Company, Inc.; AEP Kentucky Transmission Company, Inc.; AEP Ohio Transmission Company, Inc.; AEP West Virginia Transmission Company, Inc.

1049TH MEETING—OPEN MEETING—Continued

[November 15, 2018, 10:00 a.m.]

Item No.	Docket No.	Company
	ER18–1546–000	PJM Interconnection, L.L.C.; AEP Appalachian Transmission Company, Inc.; AEP Indiana Michigan Transmission Company, Inc.; AEP Kentucky Transmission Company, Inc.; AEP Ohio Transmission Company, Inc.; AEP West Virginia Transmission Company, Inc.
	EL18–63–000	AEP Oklahoma Transmission Company, Inc.; AEP Southwestern Transmission Company, Inc.
	ER18–1541–000	Southwest Power Pool, Inc.
	EL18–65–000; ER18–1583–000	Black Hills Power, Inc.
	EL18–70–000	Transource West Virginia, LLC.
	ER18–1544–000 (not consolidated)	PJM Interconnection, L.L.C.; Transource West Virginia, LLC.
E–6	EL14–12–003	Association of Businesses Advocating Tariff Equity; Coalition of MISO Transmission Customers; Illinois Industrial Energy Consumers; Indiana Industrial Energy Consumers, Inc.; Minnesota Large Industrial Group; Wisconsin Industrial Energy Group v. Midcontinent Independent System Operator, Inc.; ALLETE, Inc.; Ameren Illinois Company; Ameren Missouri; Ameren Transmission Company of Illinois; American Transmission Company LLC; Cleco Power LLC; Duke Energy Business Services, LLC; Entergy Arkansas, Inc.; Entergy Gulf States Louisiana, LLC; Entergy Louisiana, LLC; Entergy Mississippi, Inc.; Entergy New Orleans, Inc.; Entergy Texas, Inc.; Indianapolis Power & Light Company; International Transmission Company; ITC Midwest LLC; Michigan Electric Transmission Company, LLC; MidAmerican Energy Company; Montana-Dakota Utilities Co.; Northern Indiana Public Service Company; Northern States Power Company—Minnesota; Northern States Power Company—Wisconsin; Otter Tail Power Company; Southern Indiana Gas & Electric Company.
	EL15–45–000	Arkansas Electric Cooperative Corporation; Mississippi Delta Energy Agency; Clarksdale Public Utilities Commission; Public Service Commission of Yazoo City; Hoosier Energy Rural Electric Cooperative, Inc. v. ALLETE, Inc.; Ameren Illinois Company; Ameren Missouri; Ameren Transmission Company of Illinois; American Transmission Company LLC; Cleco Power LLC; Duke Energy Business Services, LLC; Entergy Arkansas, Inc.; Entergy Gulf States Louisiana, LLC; Entergy Louisiana, LLC; Entergy Mississippi, Inc.; Entergy New Orleans, Inc.; Entergy Texas, Inc.; Indianapolis Power & Light Company; International Transmission Company; ITC Midwest LLC; Michigan Electric Transmission Company, LLC; MidAmerican Energy Company; Montana—Dakota Utilities Co.; Northern Indiana Public Service Company; Northern States Power Company—Minnesota; Northern States Power Company—Wisconsin; Otter Tail Power Company; Southern Indiana Gas & Electric Company.
E–7	EL18–71–000; EL18–71–001	UNS Electric, Inc.
E–8	EL18–72–000	Alcoa Power Generating Inc.—Long Sault Division.
	EL18–73–000	Alcoa Power Generating Inc.—Tapoco Division.
	ER18–1600–000; ER18–1601–000	Alcoa Power Generating Inc.
	EL18–76–000; ER18–1580–000	Black Hills/Colorado Electric Utility Company, LP.
	EL18–90–000; ER18–1602–000	Cube Yadkin Transmission LLC.
	EL18–97–000	Essential Power Rock Springs, LLC.
	ER18–1566–000	PJM Interconnection, L.L.C.; Essential Power Rock Springs, LLC.
	EL18–101–000	Monongahela Power Company; Potomac Edison Company; West Penn Power Company.
	ER18–1595–000	PJM Interconnection, L.L.C.; Monongahela Power Company; Potomac Edison Company; West Penn Power Company.
	EL18–102–000	Nevada Power Company; Sierra Pacific Power Company.
	ER18–1603–000	Nevada Power Company.
	EL18–103–000	New York State Electric & Gas Corporation.
	EL18–110–000	Rochester Gas and Electric Corporation.
	ER18–1588–000	New York Independent System Operator, Inc.; New York State Electric & Gas Corporation; Rochester Gas and Electric Corporation.
	EL18–105–000; ER18–1599–000; ER18–1599–001.	Ohio Valley Electric Corporation.
	EL18–117–000	The Dayton Power & Light Company.
	ER18–1547–000 (not consolidated)	PJM Interconnection, L.L.C.; The Dayton Power & Light Company.
E–9	EL18–67–000	San Diego Gas & Electric Company.
E–10	EL18–68–000	Transource Maryland, LLC.
	EL18–69–000 (not consolidated)	Transource Pennsylvania, LLC.
E–11	EL18–75–000	Avista Corporation.
E–12	ER18–1596–000; EL18–112–000	Sky River LLC.
E–13	EL18–93–000	Deseret Generation and Transmission; Co-operative, Inc.
	EL18–113–000 (not consolidated)	Smoky Mountain Transmission LLC.
E–14	EL18–79–000	Cheyenne Light, Fuel and Power Company.
E–15	EL18–91–000	DATC Path 15, LLC.
E–16	EL18–66–000	Citizens Sunrise Transmission LLC.
E–17	EL18–108–000	Pacific Gas and Electric Company.
E–18	EL18–111–000	Rockland Electric Company.
	ER18–1585–000	PJM Interconnection, L.L.C.; Rockland Electric Company.
E–19	EL18–104–000	NorthWestern Corporation.

1049TH MEETING—OPEN MEETING—Continued

[November 15, 2018, 10:00 a.m.]

Item No.	Docket No.	Company
E–20	EL17–41–001	Arkansas Public Service Commission and Mississippi Public Service Commission v. System Energy Resources, Inc.
	EL18–142–000 (Consolidated)	Louisiana Public Service Commission v. System Energy Resources, Inc. and Entergy Services, Inc.
	EL17–76–001	East Texas Electric Cooperative, Inc. v. Public Service Company of Oklahoma; Southwestern Electric Power Company; AEP Oklahoma Transmission Company; and AEP Southwestern Transmission Company.
	EL18–58–000	Oklahoma Municipal Power Authority v. Oklahoma Gas and Electric Company.
	ER18–1225–000	Southwestern Electric Power Company.
	EL18–122–000 (Consolidated)	Minden, Louisiana v. Southwestern Electric Power Company.
	EL18–147–000	Alabama Municipal Electric Authority and Cooperative Energy v. Alabama Power Company; Georgia Power Company; Gulf Power Company; Mississippi Power Company; and Southern Company Services, Inc.
E–21	EL18–119–000	Tucson Electric Power Company.
E–22	EL18–64–000	Baltimore Gas and Electric Company.
E–23	EL18–115–000	Startrans IO, L.L.C.
E–24	EL18–118–000	Trans Bay Cable LLC.
E–25	EL18–183–000	Radford's Run Wind Farm, LLC v. PJM Interconnection, L.L.C.
E–26	AC18–59–000	Edison Electric Institute.
E–27	ER18–2273–000	Midcontinent Independent System Opeator, Inc.
E–28	ER18–1788–000	MATL LLP.
E–29	EL18–89–000	Consolidated Edison Company of New York, Inc.
E–30	EL18–95–000	El Paso Electric Company.
E–31	EL18–98–000	Florida Power & Light Company.
E–32	EL18–107–000	Orange & Rockland Utilities, Inc.
E–33	EL18–109–000	Portland General Electric Company.
	Gas	
G–1	RM96–1–041	Standards for Business Practices of Interstate Natural Gas Pipelines.
G–2	RP19–65–000; RP19–66–000	Millennium Pipeline Company, L.L.C.
G–3	OMITTED.	
G–4	RP19–71–000; RP19–72–000	North Baja Pipeline, LLC.
G–5	RP19–60–000; RP19–61–000	Vector Pipeline L.P.
G–6	RP19–55–000; RP19–76–000	Kern River Gas Transmission Company.
G–7	RP18–1219–000	Northern Natural Gas Company.
	Hydro	
H–1	P–2035–104	City and County of Denver, Colorado.
	Certificates	
C–1	CP18–26–000	Texas Eastern Transmission, LP.

Issued: November 8, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–24920 Filed 11–9–18; 11:15 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP19–238–000.

Applicants: Southwest Gas Transmission Company.

Description: § 4(d) Rate Filing: Stipulation in Lieu of Filing Form 501–G to be effective 11/2/2018.

Filed Date: 11/5/18.

Accession Number: 20181105–5000.

Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–239–000.

Applicants: P.H. Glatfelter Company, Pixelle Specialty Solutions LLC.

Description: Joint Petition for Temporary Waivers of Capacity Release Regulations and Policies, et al. of P.H. Glatfelter Company, et al. under RP19–239.

Filed Date: 11/2/18.

Accession Number: 20181102–5254.

Comments Due: 5 p.m. ET 11/9/18.

Docket Numbers: RP19–240–000.

Applicants: WestGas InterState, Inc.

Description: Pre-Arranged/Pre-Agreed (Petition for Approval of Prepackaged Stipulation and Settlement Agreement) Filing, et al. of WestGas InterState, Inc. under RP19–240.

Filed Date: 11/5/18.

Accession Number: 20181105–5084.

Comments Due: 5 p.m. ET 11/15/18.

Docket Numbers: RP18–1258–001.

Applicants: Kinder Morgan Louisiana Pipeline LLC.

Description: Compliance Filing—Docket No. RP18–1258 to be effective 10/29/2018.

Filed Date: 11/5/18.

Accession Number: 20181105–5179.

Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–217–001.

Applicants: Gulf Crossing Pipeline Company LLC.

Description: Tariff Amendment: Amendment to Filing in Docket No. RP19–217–000 to be effective 4/1/2019.

Filed Date: 11/5/18.

Accession Number: 20181105–5015.

Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–77–001.

Applicants: Trunkline Gas Company, LLC.

Description: Compliance filing FERC Form No. 501–G Report, Revised Exhibit A.

Filed Date: 11/5/18.

Accession Number: 20181105–5153.

Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–78–001.

Applicants: Panhandle Eastern Pipe Line Company, LP.

Description: Compliance filing FERC Form No. 501–G Report—Revised Exhibit A.

Filed Date: 11/5/18.

Accession Number: 20181105–5150.

Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–82–001.

Applicants: High Point Gas Transmission, LLC.

Description: eTariff filing per 1430: Updated 501–G Filing.

Filed Date: 11/5/18.

Accession Number: 20181105–5177.

Comments Due: 5 p.m. ET 11/19/18.

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: November 7, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–24781 Filed 11–13–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER19–289–000]

Cleco Cajun LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Cleco Cajun LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 27, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 7, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–24782 Filed 11–13–18; 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: EC19–6–000.

Applicants: NRG REMA LLC, Keystone Power Pass-Through Holders LLC, Conemaugh Power Pass-Through Holders LLC.

Description: Amendment to October 9, 2018 Joint Application for Authorization Under Section 203 of the Federal Power Act, et al. of NRG REMA LLC, et al.

Filed Date: 10/15/18.

Accession Number: 20181015–5149.

Comments Due: 5 p.m. ET 11/14/18.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–738–005; ER10–1186–008; ER10–1329–008; ER11–3097–009.

Applicants: DTE Electric Company, DTE Energy Trading, Inc., DTE Energy Supply, Inc., St. Paul Cogeneration, LLC.

Description: Supplement to June 18, 2018 Updated Market Power Analysis for the Central Region of the DTE MBR Entities.

Filed Date: 11/6/18.

Accession Number: 20181106–5073.

Comments Due: 5 p.m. ET 11/13/18.

Docket Numbers: ER18–1775–001.

Applicants: 64KT 8me LLC.

Description: Compliance filing: 64KT 8me LLC Notice of Non-Material Change in Status to be effective 11/8/2018.

Filed Date: 11/7/18.

Accession Number: 20181107–5050.

Comments Due: 5 p.m. ET 11/28/18.

Docket Numbers: ER19–298–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ISAs, SA Nos. 4682 and First Revised 4332; Queue No. AA1–139 to be effective 11/17/2017.

Filed Date: 11/6/18.

Accession Number: 20181106–5194.

Comments Due: 5 p.m. ET 11/27/18.

Docket Numbers: ER19–299–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: 3435R1 Magnet Wind Farm GIA to be effective 10/9/2018.

Filed Date: 11/7/18.

Accession Number: 20181107–5000.

Comments Due: 5 p.m. ET 11/28/18.

Docket Numbers: ER19–300–000.

Applicants: Alabama Power Company.

Description: § 205(d) Rate Filing: Hancock County Solar Project LGIA Filing to be effective 10/24/2018.

Filed Date: 11/7/18.

Accession Number: 20181107–5064.

Comments Due: 5 p.m. ET 11/28/18.

Docket Numbers: ER19–301–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2018–11–07_SA 3206 Dakota Range I & II–OTP MPFCA (J436 J437 Hankinson Ellendale) to be effective 1/7/2019.

Filed Date: 11/7/18.

Accession Number: 20181107–5096.

Comments Due: 5 p.m. ET 11/28/18.

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: November 7, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–24779 Filed 11–13–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP19–148–000.

Applicants: NEXUS Gas Transmission, LLC.

Description: § 4(d) Rate Filing: NegRates—EGD Releases eff 11–1–2018 to be effective 11/1/2018.

Filed Date: 10/30/18.

Accession Number: 20181030–5080.

Comments Due: 5 p.m. ET 11/13/18.

Docket Numbers: RP18–1193–001.

Applicants: Enable Gas Transmission, LLC.

Description: Compliance filing Fuel Tracker Compliance Filing—Eff Nov 1 2018 to be effective 11/1/2018.

Filed Date: 11/6/18.

Accession Number: 20181106–5098.

Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–241–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Nov18 Cleanup—UGI Utilities Name Change to be effective 12/6/2018.

Filed Date: 11/6/18.

Accession Number: 20181106–5024.

Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–242–000.

Applicants: Texas Eastern Transmission, LP.

Description: § 4(d) Rate Filing: Negotiated Rate—Sempra 911550 correction to be effective 11/6/2018.

Filed Date: 11/6/18.

Accession Number: 20181106–5046.

Comments Due: 5 p.m. ET 11/19/18/.

Docket Numbers: RP19–243–000.

Applicants: Southern Star Central Gas Pipeline, Inc.

Description: Compliance filing Annual Operational Flow Order Report 2018.

Filed Date: 11/6/18.

Accession Number: 20181106–5056.

Comments Due: 5 p.m. ET 11/19/18.

Docket Numbers: RP19–244–000.

Applicants: Natural Gas Pipeline Company of America.

Description: § 4(d) Rate Filing: Amendment to Negotiated Rate Agreement-Wisconsin Electric Power Company to be effective 11/6/2018.

Filed Date: 11/6/18.

Accession Number: 20181106–5157.

Comments Due: 5 p.m. ET 11/19/18.

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: November 7, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–24780 Filed 11–13–18; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER19–294–000]

GE Oleander LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of GE Oleander LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is November 27, 2018.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's

Public Reference Room in Washington, DC. There is an eSubscription link on the website that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: November 7, 2018.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2018–24783 Filed 11–13–18; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9986–41–OA]

National Environmental Justice Advisory Council; Notification of Public Teleconference and Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the U.S. Environmental Protection Agency (EPA) hereby provides notice that the National Environmental Justice Advisory Council (NEJAC) will meet on the dates and times described below. All meetings are open to the public. Members of the public are encouraged to provide comments relevant to the specific issues being considered by the NEJAC. For additional information about registering to attend the meeting or to provide public comment, please see ''REGISTRATION'' under **SUPPLEMENTARY INFORMATION**. Due to a limited number of telephone lines, attendance will be on a first-come, first served basis. Pre-registration is required.

DATES: The NEJAC will convene a public teleconference meeting on Wednesday, November 28, 2018, starting at 3:00 p.m., Eastern Time. The meeting discussion will focus on several topics including, but not limited to, the discussion and deliberation of final letters that address environmental justice concerns of communities raised during the NEJAC public meeting in Boston, MA, August 14–16, 2018, and to introduce a new charge from the Office of Land and Emergency Management focusing on the reuse and revitalization of Superfund and other contaminated sites. One public comment period relevant to the specific issues being considered by the NEJAC (see **SUPPLEMENTARY INFORMATION**) is scheduled for Wednesday, November 28, starting at 4:30 p.m., Eastern Time. Members of the public who wish to participate during the public comment period are highly encouraged to pre-register by 11:59 p.m., Eastern Time on Monday, November 26, 2018.

FOR FURTHER INFORMATION CONTACT: Questions or correspondence concerning the public meeting should be directed to Karen L. Martin, U.S. Environmental Protection Agency, by mail at 1200 Pennsylvania Avenue NW (MC2201A), Washington, DC 20460; by telephone at 202–564–0203; via email at *martin.karenl@epa.gov;* or by fax at 202–564–1624. Additional information about the NEJAC is available at *https://www.epa.gov/environmentaljustice/national-environmental-justice-advisory-council.*

SUPPLEMENTARY INFORMATION: The Charter of the NEJAC states that the advisory committee ''will provide independent advice and recommendations to the Administrator about broad, crosscutting issues related to environmental justice. The NEJAC's efforts will include evaluation of a broad range of strategic, scientific, technological, regulatory, community engagement and economic issues related to environmental justice.''

Registration

Registration for the November 28, public teleconference will be processed at *https://nejac-november-2018-public-teleconference.eventbrite.com.* Pre-registration is required. Registration closes at 11:59 p.m., Eastern Time on Monday, November 26, 2018. The deadline to sign up to speak during the public comment period, or to submit written public comments, is 11:59 p.m., Eastern Time on Monday, November 26, 2018. When registering, please provide your name, organization, city and state, email address, and telephone number for follow up. Please also indicate whether you would like to provide public comment during the meeting, and whether you are submitting written comments before the Monday, November 26, 2018, deadline.

A. Public Comment

Individuals or groups making remarks during the public comment period will be limited to three (3) minutes. To accommodate the number of people who want to address the NEJAC, only one representative of a particular community, organization, or group will be allowed to speak. Written comments can also be submitted for the record. The suggested format for individuals providing public comments is as follows: Name of speaker; name of organization/community; city and state; and email address; brief description of the concern, and what you want the NEJAC to advise EPA to do. Written comments received by registration deadline, will be included in the materials distributed to the NEJAC prior to the teleconference. Written comments received after that time will be provided to the NEJAC as time allows. All written comments should be sent to Karen L. Martin, EPA, via email at *martin.karenl@epa.gov.*

B. Information About Services for Individuals With Disabilities or Requiring English Language Translation Assistance

For information about access or services for individuals requiring assistance, please contact Karen L. Martin, at (202) 564–0203 or via email at *martin.karenl@epa.gov.* To request special accommodations for a disability or other assistance, please submit your request at least fourteen (14) working days prior to the meeting, to give EPA sufficient time to process your request. All requests should be sent to the address, email, or phone/fax number listed in the **FOR FURTHER INFORMATION CONTACT** section.

Dated: October 31, 2018.

Matthew Tejada,

Director for the Office of Environmental Justice.

[FR Doc. 2018–24818 Filed 11–13–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R08–OW–2018–0724; FRL–9986–46–Region 8]

North Dakota Pollutant Discharge Elimination System; Transfer; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability and request for comment; correction.

SUMMARY: The Environmental Protection Agency (EPA) issued a document in the **Federal Register** on October 30, 2018, providing notice of a proposed program revision to transfer the authority to implement and enforce the North Dakota Pollutant Discharge Elimination System (NDPDES) program from the North Dakota Department of Health (NDDOH) to the newly established North Dakota Department of Environmental Quality (NDDEQ).

There was an error in the Docket ID Number. This document corrects that typographical error.

DATES: November 14, 2018.

FOR FURTHER INFORMATION CONTACT: VelRey Lozano, U.S. Environmental Protection Agency, Region 8, (8WP–CWW), 1595 Wynkoop Street, Denver, Colorado 80202–1129, 303–312–6128, email *lozano.velrey@epa.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2018–23632 appearing on page 54587 in the **Federal Register** of Tuesday, October 30, 2018, the Docket number is corrected to read as follows: EPA–R08–OW–2018–0724. This correction does not affect the timing of the original comment period. Written comments and/or requests for a public hearing must be received on or before November 29, 2018.

Dated: November 7, 2018.

Darcy O'Connor,

Assistant Regional Administrator, Office of Water Protection.

[FR Doc. 2018–24769 Filed 11–13–18; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0216, 3060–0248, 3060–0404, 3060–0788]

Information Collections Being Reviewed by the Federal Communications Commission Under Delegated

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 14, 2019. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0216.

Title: Section 73.3538, Application to Make Changes in an Existing Station; Section 73.1690(e), Modification of Transmission Systems.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, Not-for-profit institutions.

Number of Respondents and Responses: 650 respondents; 650 responses.

Estimated Hours per Response: 0.50–3 hours.

Frequency of Response: On occasion reporting requirement; Recordkeeping requirement.

Total Annual Burden: 1,100 hours.

Annual Burden Cost: None.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Sections 154(i), 303(r), 308, 309(j) and 337(e) of the Communications Act of 1934, as amended.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The information collection requirements contained in Section 73.3538(b)(1) of the Commission's rules requires a broadcast station to file an informal application to modify or discontinue the obstruction marking or lighting of an antenna supporting structure.

The information collection requirements contained in Section 73.1690(e) of the Commission's rules requires AM, FM and TV station licensees to prepare an informal statement or diagram describing any electrical and mechanical modification to authorized transmitting equipment that can be made without prior Commission approval provided that equipment performance measurements are made to ensure compliance with FCC rules. This informal statement or diagram must be retained at the transmitter site as long as the equipment is in use.

OMB Control Number: 3060–0248.

Title: Section 74.751, Modification of Transmission Systems.

Form Number: Not applicable.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents and Responses: 400 respondents; 400 responses.

Estimated Time per Response: 0.50 hours.

Frequency of Response: On occasion reporting requirement; Recordkeeping requirement.

Total Annual Burden: 200 hours.

Total Annual Cost: None.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 154(i) of the Communications Act of 1934, as amended.

Nature and Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The information collection requirements contained in 47 CFR 74.751(a) and (c) require licensees of low power TV or TV translator stations to send written notification to the FCC of equipment changes which may be made at licensee's discretion without the use of a formal application. Section 74.751(d) information collection requirements require that licensees of low power TV or TV translator stations place in the station records a certification that the installation of new or replacement transmitting equipment complies in all respects with the technical requirements of this section and the station authorization. The notifications and certifications of equipment changes are used by FCC staff to ensure that the equipment changes made are in full compliance with the technical requirements of this section and the station authorizations

and will not cause interference to other authorized stations.

OMB Control Number: 3060–0404.

Title: Application for an FM Translator or FM Booster Station License, FCC Form 350.

Form Number: FCC Form 350.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, Not-for-profit institutions; State, local or Tribal government.

Number of Respondents and Reponses: 500 respondents; 500 responses.

Frequency of Response: On occasion reporting requirement.

Estimated Time per Response: 1 hour.

Total Annual Burden: 500 hours.

Total Annual Cost: $37,500.

Obligation to Respond: Required to obtain and retain benefits. The statutory authority for this collection of information is contained in Sections 154(i), 307, 308 and 309 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: Licensees and permittees of FM Translator or FM Booster stations are required to file FCC Form 350 to obtain a new or modified station license. The data is used by FCC staff to confirm that the station has been built to terms specified in the outstanding construction permit.

Data from the FCC Form 350 is extracted for inclusion in the subsequent license to operate the station.

OMB Control Number: 3060–0788.

Title: DTV Showings/Interference Agreements.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, Not-for-profit institutions.

Number of Respondents and Responses: 300 respondents; 300 responses.

Estimated Hours per Response: 5 hours.

Frequency of Response: On occasion reporting requirement, Third Party Disclosure requirement.

Total Annual Burden: 1,500 hours.

Total Annual Costs: $3,900,000.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Sections 154(i), 303 and 308 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality required with this collection of information.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The information collection requirements contained in 47 CFR 73.623 requires applicants to submit a technical showing to establish that their proposed facilities will not result in additional interference to TV broadcast operations. The Commission permits broadcasters to agree to proposed TV facilities that do not conform to the allotted parameters, even though they might be affected by potential new interference. The Commission will consider granting applications on the basis of interference agreements if it finds that such grants will serve the public interest. These agreements must be signed by all parties to the agreement. In addition, the Commission needs the following information to enable such public interest determinations: A list of parties predicted to receive additional interference from the proposed facility; a showing as to why a grant based on the agreements would serve the public interest; and technical studies depicting the additional interference. The technical showings and interference agreements will be used by FCC staff to determine if the public interest would be served by the grant of the application and to ensure that the proposed facilities will not result in additional interference.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer.

[FR Doc. 2018–24829 Filed 11–13–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1042]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 14, 2019. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–1042.

Title: Request for Technical Support—Help Request Form.

Form No.: N/A—Electronic only.

Type of Review: Revision of a currently approved collection.

Respondents: Individuals or household; business or other for-profit; not-for-profit institutions; and state, local or tribal government.

Number of Respondents: 36,300.

Estimated Time per Response: 8 minutes (0.13 hours).

Frequency of Response: On occasion reporting requirement and recordkeeping requirement.

Obligation to Respond: Required to obtain or retain benefits.

Total Annual Burden: 5,082 hours.

Total Annual Cost: $609,840.

Privacy Act Impact Assessment: Possible Impacts.

Nature and Extent of Confidentiality: In general there is no need for confidentiality. On a case by case basis,

the Commission may be required to withhold from disclosure certain information about the location, character, or ownership of a historic property, including traditional religious sites.

Needs and Uses: The Commission will submit this collection as revision to the currently approved collection. The Commission is slightly revising the electronic form to include five additional data elements, FCC Registration Number, Call Sign, Antenna Registration Number, Facility ID and File Number. Today customers are asked to include this information as part of their narrative description and often neglect to include all the necessary information to process their request. This results in customer services representatives needing to contact the customers to obtain the additional details, which slows down case resolution. We do not anticipate these changes will impact the customer burden, since they will only need to include the information applicable to their request, and it was previous requested as part of the description field. There will be no change to the estimated average burden (hours and costs) or the number of respondents.

The FCC's maintains internet software used by the public to apply for licenses, participate in auctions for spectrum, and maintain license information. In this mission, FCC has a 'help desk' that answers questions related to these systems as well as resetting and/or issuing user passwords for access to these systems. The form currently is available on the website *https://esupport.fcc.gov/request.htm* under OMB Control Number 3060–1042. This form will continue to substantially decrease public and staff burden since all the information needed to facilitate a support request will be submitted in a standard format but be available to a wider audience. This eliminates or at least minimizes the need to follow-up with the customers to obtain all the information necessary to respond to their request. This form also helps presort requests into previously defined categories to all staff to respond more quickly.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer.

[FR Doc. 2018–24832 Filed 11–13–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0422]

Information Collections Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before January 14, 2019. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email: *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0422.

Title: Section 68.5, Waivers (Application for Waivers of Hearing Aid Compatibility Requirements).

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 2 respondents; 2 responses.

Estimated Time per Response: 3 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this information collection is contained in 47 U.S.C. 610.

Total Annual Burden: 6 hours.

Total Annual Cost: None.

Nature and Extent of Confidentiality: An assurance of confidentiality is not offered because this information collection does not require the collection of personally identifiable information from individuals.

Privacy Impact Assessment: No impact(s).

Needs and Uses: Telephone manufacturers seeking a waiver of 47 CFR 68.4(a)(1), which requires that certain telephones be hearing aid compatible, must demonstrate that compliance with the rule is technologically infeasible or too costly. Information is used by FCC staff to determine whether to grant or dismiss the request. Prior to (and after) the adoption of FCC 17–135, manufacturers could request waivers for wireline telephones connected to the public switched telephone network. Pursuant to FCC 17–135, waivers may also be requested for wireline advanced communications services telephonic customer premises equipment (ACS telephonic CPE), which includes wireline telephones used for Voice over internet Protocol (VoIP).

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer.

[FR Doc. 2018–24833 Filed 11–13–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Federal Advisory Committee Act; Communications Security, Reliability, and Interoperability Council

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this

notice advises interested persons that the Federal Communications Commission's (FCC or Commission) Communications Security, Reliability, and Interoperability Council (CSRIC) VI will hold its seventh meeting.

DATES: December 13, 2018.

ADDRESSES: Federal Communications Commission, Room TW–C305 (Commission Meeting Room), 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Jeffery Goldthorp, Designated Federal Officer, (202) 418–1096 (voice) or *jeffery.goldthorp@fcc.gov* (email); or Suzon Cameron, Deputy Designated Federal Officer, (202) 418–1916 (voice) or *suzon.cameron@fcc.gov* (email).

SUPPLEMENTARY INFORMATION: The meeting will be held on December 13, 2018, from 1:00 p.m. to 5:00 p.m. in the Commission Meeting Room of the Federal Communications Commission, Room TW–C305, 445 12th Street SW, Washington, DC 20554.

The CSRIC is a Federal Advisory Committee that will provide recommendations to the FCC regarding best practices and actions the FCC can take to help ensure the security, reliability, and interoperability of communications systems. On March 19, 2017, the FCC, pursuant to the Federal Advisory Committee Act, renewed the charter for the CSRIC for a period of two years through March 18, 2019. The meeting on December 13, 2018, will be the seventh meeting of the CSRIC under the current charter. The FCC will attempt to accommodate as many attendees as possible; however, admittance will be limited to seating availability. The Commission will provide audio and/or video coverage of the meeting over the internet from the FCC's web page at *http://www.fcc.gov/live.* The public may submit written comments before the meeting to Jeffery Goldthorp, CSRIC Designated Federal Officer, by email to *jeffery.goldthorp@fcc.gov* or U.S. Postal Service Mail to Jeffery Goldthorp, Associate Bureau Chief, Public Safety and Homeland Security Bureau, Federal Communications Commission, 445 12th Street SW, Room 7–A325, Washington, DC 20554.

Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (tty). Such requests should include a detailed description of the accommodation needed. In addition, please include a way the FCC can contact you if it needs more information. Please allow at least five days' advance notice; last-minute requests will be accepted, but may be impossible to fill.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer.

[FR Doc. 2018–24834 Filed 11–13–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0700]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before January 14, 2019. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control: 3060–0700.

Title: Open Video Systems Provisions, FCC Form 1275.

Form Number: FCC Form 1275.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; and State, Local or Tribal Government.

Number of Respondents and Responses: 280 respondents; 4,672 respondents.

Frequency of Response: Recordkeeping requirement; Third party disclosure requirement; On occasion reporting requirement.

Estimated Time per Response: 0.25 to 20 hours.

Total Annual Burden: 9,855 hours.

Total Annual Costs: None.

Privacy Impact Assessment: No impact(s).

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 302 of the Communications Act of 1934, as amended.

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: Section 302 of the 1996 Telecommunications Act provides for specific entry options for telephone companies wishing to enter the video programming marketplace, one option being to provide cable service over an ''open video system'' (''OVS''). The rule sections that are covered by this collection relate to OVS.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer.

[FR Doc. 2018–24830 Filed 11–13–18; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION NOTICE OF PREVIOUS ANNOUNCEMENT: 83 FR 56079.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Wednesday, November 14, 2018 at 10:00 a.m.

CHANGES IN THE MEETING: This meeting will also discuss:

Matters relating to internal personnel decisions, or internal rules and practices.

Investigatory records compiled for law enforcement purposes and production would disclose investigative techniques.

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

* * * * *

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Laura E. Sinram,

Deputy Secretary of the Commission.

[FR Doc. 2018–24902 Filed 11–9–18; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage In or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 26, 2018.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001. Comments can also be sent electronically to *Comments.applications@ny.frb.org:*

1. Rhinebeck Bancorp, Inc., Poughkeepsie, New York; to engage in extending credit and servicing loans, pursuant to section 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, November 8, 2018.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–24802 Filed 11–13–18; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 10, 2018.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Providence Financial Corporation, South Holland, Illinois;* to acquire 100 percent of the outstanding voting shares of Urban Partnership Bank, Chicago, Illinois.

Board of Governors of the Federal Reserve System, November 8, 2018.

Yao Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2018–24803 Filed 11–13–18; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1779]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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 December 14, 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–NEW and title ''Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Disclosures of Descriptive Presentations in Professional Oncology Prescription Drug Promotion

OMB Control Number—0910–NEW

I. Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal

Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA regulated products in carrying out the provisions of the FD&C Act.

Under the FD&C Act and implementing regulations, promotional labeling and advertising about prescription drugs are generally required to be truthful, non-misleading, and to reveal facts material to the presentations made about the product being promoted (see sections 502(a) and (n), and 201(n) of the FD&C Act (21 U.S.C. 352(a) and (n), and 321(n)); see also 21 CFR 202.1). As a part of the ongoing evaluation of FDA's regulations in this area, FDA is proposing to study the impact of disclosures as they relate to presentations of preliminary and/or descriptive scientific and clinical data in promotional labeling and advertising for oncology products. The use of disclosures is one method of communicating information to healthcare professionals about scientific and clinical data, the limitations of that data, and practical utility of that information for use in treatment. These disclosures may influence prescriber comprehension and decision making and may affect how and what treatment they prescribe for their patients.

Pharmaceutical companies market directly to physicians through means that include publishing advertisements in medical journals, exhibit booths at physician meetings or events, sending unsolicited promotional materials to doctors' offices, and presentations (''detailing'') by pharmaceutical representatives (Ref. 1). Research suggests that detail aids sometimes contain carefully extracted data from clinical studies that, taken out of context, can exaggerate the benefits of a drug (Ref. 2) or contribute to physicians prescribing the drug for an inappropriate patient population.

Promotional labeling and advertising for cancer drugs deserve specific attention. Oncology drugs represented 26 percent of the 649 compounds under clinical trial investigation from 2006 to 2011 (Ref. 3). The past decade has seen a dramatic rise in the number of oncology drugs brought to market. In the past 18 months, over 22 percent of new drug approvals at FDA were new cancer drugs. In that time period, FDA approved 16 cancer drugs as new molecular entities or new therapeutic biologics out of a total of 72 (this does not include approvals of benign hematology products or biological license application approvals of blood reagents, or assays and anti-globulin products used in testing kits) (Refs. 4 and 5). Although overall survival remains the gold standard for demonstrating clinical benefit of a cancer drug, several additional endpoints including progression free survival, disease-free or recurrence-free survival, or durable response rate (including hematologic response endpoints) are accepted for either regular or accelerated approval depending on the magnitude of effect, safety profile, and disease context (Ref. 6). In addition to the endpoints upon which FDA approval of these products may be based, pharmaceutical companies typically assess many other endpoints to further explore the effects of their products. Some trials are designed to allow for formal statistical analyses of these additional endpoints; however, in many cases these endpoints are strictly exploratory and support only the reporting of descriptive results. For clinicians who are not specifically trained in clinical trial design, interpreting these endpoints may be challenging. Pharmaceutical companies invest heavily in the development and distribution of promotional materials to make oncologists aware of favorable clinical trial results.

When communicating scientific and clinical data, a specific statement that modifies or qualifies a claim (referred to for the purposes of this document as a disclosure) could be used to convey the limitations of the data and practical utility of the information for treatment. Much of the prior research on disclosures in this topic area has been limited to the dietary supplement arena with consumers (Refs. 7 to 10). Disclosures in professional pieces could influence prescriber comprehension as well as subsequent decision making; however, no published data exist regarding how prescribers use and understand scientific claims in conjunction with qualifying disclosures.

The proposed study seeks to address the following research questions:

1. Do disclosures mitigate potentially misleading presentations of preliminary and/or descriptive data in oncology drug product promotion?
2. Does the language (technical, non-technical) of the disclosure influence the effectiveness of the disclosure?
3. Does the presence of a general statement about the clinical utility of the data in addition to a specific disclosure influence processing of claims and disclosures?
4. Do primary care physicians (PCPs) and oncologists differ in their processing of claims and disclosures about preliminary and/or descriptive data?
5. Which disclosures do physicians prefer?

To address these questions, FDA has designed a study that will be conducted in three independent phases, each phase examining a data display in a promotional piece for a unique oncology or hematology product. Independent variables will include: (1) Specific disclosure (technical, non-technical, none), (2) general statement (present, absent), and (3) specialty (PCPs, oncologists). Each phase will have the following design:

Sample	General statement	Specific disclosure		
		Technical	Non-technical	No disclosure
Oncologists	Present	•	•	Control.
	Absent	•	•	
PCPs	Present	•	•	Control.
	Absent	•	•	

Specific disclosures will include material information specifically related to the particular data display in question. As such, each specific disclosure may include clinical or statistical information related to the trial design, the statistical analysis plan of the trial, or any other material statistical or clinical information necessary for evaluation or interpretation of the data. The team developing the disclosures includes social science analysts, pharmacists, oncological medical officers, statisticians, and an oncology nurse. An example of the general statement is ''This presentation includes exploratory information of uncertain clinical utility and should be interpreted cautiously when used to make treatment decisions.''

Outcome (dependent) variables will focus on the assessment of the data display as a whole as well as attention to the disclosure, if present. Specifically, we will examine recognition of the clinical endpoint in the data display, comprehension of the data display, perceptions of the strength of the data, and the perceived credibility of the promotional piece. We will also look at attention to the specific disclosure and the general statement, prescriber decisions, and prescriber preferences. Preferences will be determined by a secondary task at the end of the questionnaire that shows each participant all disclosure options and asks them to choose their preferred version.

Oncologists and PCPs will be recruited to participate via the internet. We plan to conduct one pretest with 90 participants and one study with 2,115 participants, both of which are expected to take approximately 20 minutes. Voluntary participants will view professionally developed promotional pieces that mimic currently available promotion and answer questions.

In the **Federal Register** of Monday, June 19, 2017 (82 FR 27845), FDA published a 60-day notice requesting public comment on the proposed collection of information (see above). Comments received along with our responses to the comments are provided below. Comments that are not PRA-relevant or do not relate to the proposed study are not included. For brevity, some public comments are paraphrased and therefore may not reflect the exact language used by the commenter. We assure commenters that the entirety of their comments was considered even if not fully captured by our paraphrasing. The following acronyms are used here: FRN = Federal Register Notice; DTC = direct-to-consumer; HCP = healthcare professional; PCP = primary care physicians; FDA = Food and Drug Administration; OPDP = FDA's Office of Prescription Drug Promotion.

The first public comment responder (*regulations.gov* tracking number 1k1–8xz7–mwcd) included eight individual comments, to which we have responded.

Comment 1: ''It is unclear why FDA has chosen to conduct a study focused on oncology therapeutics and those medical specialists who prescribe such products.'' [*verbatim*] All prescription drug products are treated the same according to regulations; therapeutic intent and prescriber type do not invoke alternate regulatory approaches.

Response: As we described in the 60-day **Federal Register** notice, promotional activities for oncology drugs are frequent and pervasive. Promotional labeling and advertising for cancer drugs deserve specific attention. Oncology drugs represented 26 percent of the 649 compounds under clinical-trial investigation from 2006 to 2011 (Ref. 3). The past decade has seen a dramatic rise in the number of oncology drugs brought to market. In the past 18 months, over 22 percent of new drug approvals at FDA were new cancer drugs. In that time period, FDA approved 16 cancer drugs as new molecular entities or new therapeutic biologics out of a total of 72 (this does not include approvals of benign hematology products or biological license application approvals of blood reagents, or assays and anti-globulin products used in testing kits) (Refs. 4 and 5). Although overall survival remains the gold standard for demonstrating clinical benefit of a cancer drug, several additional endpoints including progression free survival, disease-free or recurrence-free survival, or response rate (including hematologic response endpoints) are accepted for either regular or accelerated approval depending on the magnitude of effect, safety profile, and disease context (Ref. 6). In addition to the endpoints upon which FDA approval may be based, pharmaceutical companies typically assess many other endpoints to further explore the effects of their products. Some trials are designed to allow for formal statistical analyses of these additional endpoints; however, in many cases these endpoints are strictly exploratory and support only the reporting of descriptive results. For clinicians who are not specifically trained in clinical trial design, interpreting these endpoints can be challenging. Pharmaceutical companies invest heavily in the development and distribution of promotional materials to educate oncologists about favorable clinical trial results.

As another public comment responder (*regulations.gov* tracking number 1k1–8y3p–o6qb) notes, ''We agree with the FDA's assessment that dedicated research is necessary regarding oncology drug promotion, particularly given that a significant proportion of the drug development pipeline is comprised of oncology products . . .''

Comment 2: FDA should use a more targeted approach, including a monadic design with 100 oncologists split into two experimental conditions.

Response: To clarify the study design, we are testing two variations of disclosure (specific disclosure: Technical, non-technical), two variations of general statement (general statement: Present or absent), plus a control (control: No specific disclosure). Participants will be healthcare professionals who are members of one of two medical populations and will be randomly assigned to one condition. Because we are examining the effects of multiple variables and their interactions, the necessary sample sizes will be larger than those suggested in this comment based on power analyses. We have, however, changed the study design based on multiple comments and will now examine only oncologists and primary care physicians.

Comment 3: The length of the survey looks long—at 17 pages, it appears that it will take approximately 30–40 minutes to complete.

Response: We have tested the survey in-house with individuals unfamiliar with the research project, and it appears that this survey will take approximately 15 minutes to complete.

Comment 4: Instead of using recall as a measure, respondents should be allowed to have access to the materials while answering questions to better approximate their actual experiences.

Response: It is an open question as to whether having the materials in front of them better approximates actual HCP experiences. In past discussions with HCPs, some have reported that they do refer back to materials that sales representatives leave, and others report that they do not receive leave-behind materials or do not refer to them again. In any case, we have a mixture of recall and comprehension questions in our questionnaire. For the recall questions, respondents will not be able to access the materials. They will, however, be able to review the materials while answering the comprehension questions.

Comment 5: Why is FDA examining non-oncologists at all? Why are you screening out oncology for specialists in question SPECIALTY2?

Response: HCPs of all types are exposed to prescription drug promotion. Depending on location (*e.g.,* rural areas) and type of clinical setting, some non-oncologists may have a need to consider oncologic prescription drugs to treat their patients. We agree that oncologists are the most relevant population to study in this research. However, we also want to know whether specific education and experience influence the processing of claims, data, and disclosures. Upon further review, we agree that nurse practitioners and physician assistants without oncology experience are not a necessary group to investigate to answer our particular research questions. We intend to use PCPs as a control group to understand whether specific advanced training

influences the understanding of preliminary and/or descriptive oncology data. Some PCPs may have experience with oncology prescriptions, particularly in rural areas. We will not eliminate PCPs without oncology experience, but we will measure oncology prescribing experience and use this variable as a covariate in our studies.

Comment 6: FDA should screen for the prescribing of oncologic products.

Response: Although we do not intend to screen out physicians without oncology prescribing experience, we will measure this variable and use this information to determine whether it plays a role in the responses of PCPs.

Comment 7: From this point (ENDPOINT) responses may be based on the ability of respondents to recall information vs. the absence/presence of disclosures. If FDA continues with this design, the Agency should be prepared to control for this in the study design.

Response: Because this is an experimental design with random assignment to condition, any fatigue with questions that may affect the recall of information should fall out evenly across conditions. Therefore, any differences would be the result of our manipulations, in this case, the presence and form of disclosures. We have given thought to the ordering of the questions so that the most important questions are asked in the beginning of the survey rather than toward the end.

Comment 8: The answer to this question (CAUTIOUS) may be influenced more by personal and subjective opinion vs. the content of the disclosure.

Response: Because of the experimental design with random assignment to condition, personal and subjective opinions should be evenly and randomly spread across experimental conditions. However, upon further review, we have determined that this question has limited utility and we will delete it.

The second public comment responder (*regulations.gov* tracking number 1k1–8y3p–o6qb) included one individual comment. They reported that they support the study specifically and OPDP's overall research efforts generally, and they agree that oncology deserves special attention. We thank this commenter for taking the time to provide this comment to us.

The third public comment responder (*regulations.gov* tracking number 1k1–8y5u–5vp0) included eight individual comments, to which we have responded.

Comments 1 and 2: The commenter supports FDA social science research and this specific project, as well as the Disclosures study (Docket No. FDA–2017–N–0558). ''FDA's collective research indicates a considered, objective updating of the FDA's advertising regulations, including the use of disclosures to prevent misleading claims in advertisements for oncology products, is timely . . . . Enabling disclaimers would be one way to enable innovators to advertise new oncology therapeutics for their approved uses in ways which would be non-misleading.''

Response: Thank you for your support.

Comment 3: The commenter suggests making sure that primary care physicians and advanced practitioners have experience in the oncology field—otherwise, it seems useless to include less knowledgeable respondents whose answers are more speculative. Overall, they question whether advanced practitioners are appropriate for this study at all.

Response: We have removed advanced practitioners from the design. We will measure the oncology prescribing experience of the PCPs in our sample, but we will not eliminate those who do not have specific oncology training. One of our research questions is whether specific training and experience in oncology influences the understanding of preliminary oncology data. To do that, we need to include a group of practitioners who may not have specific training and experience in oncology, but who are licensed practitioners permitted by law to prescribe oncology drugs, and who, in some cases, may do so.

Comment 4: If the only data being presented for BENEFICIAL, EVIDENCE1 and EVIDENCE2 are the endpoints for the disclosure without presenting overall survival or more clinically validated data, we suggest removing these questions.

Response: The pieces include other clinically validated data as would be typical in an existing piece for an oncology indication.

Comment 5: Remove CONFUSING2 because it asks physicians to speculate.

Response: As this item is a perception measure, as opposed to an accuracy measure, it is reasonable to consider some level of speculation. Moreover, in cognitive testing, HCPs responded without difficulty.

Comment 6: For SCRIPT4, add an ''I don't know'' option instead of instructing respondents to ''make your best guess.''

Response: This item was cognitively tested and participants expressed no difficulty answering it.

Comment 7: Those who respond ''not at all familiar'' to FAMILIAR should skip BTKNOW1, BTKNOW2, and ACCEL.

Response: We agree with this comment. Those who respond ''not at all familiar'' to FAMILIAR will skip the three items mentioned above.

Comment 8: BTDV1 and BTDV2 present incomplete data and therefore it is unclear how this will be a useful question. The commenter suggests either adding an ''I need more information'' option or removing the question.

Response: These items present incomplete data but we have provided enough data that HCPs should be able to make a choice. HCPs in cognitive testing exhibited no difficulty with the question. There is no existing data on perceptions of FDA's ''breakthrough'' designation and this item will provide at least rudimentary information. Please note that each respondent will see only one of the items. These items are carefully crafted to avoid order effects and alphabetical effects.

The fourth public commenter (*regulations.gov* tracking number 1k1–8y5u–koc0) included 15 individual comments, to which we have responded.

Comment 1 (summarized): The commenter is concerned with the Agency's recent approaches to studies in this area. FDA has proposed to undertake projects in a variety of disparate topics without articulating a clear, overarching research agenda or adequate rationales on how the proposed research related to the goal of further protecting public health. Within the last year, the Agency has increased such efforts at an exponential pace. At times, FDA proposes new studies seemingly without fully appreciating its own previous research published on the Office of Prescription Drug Promotion (OPDP) website. Proposed studies are often unnecessary in light of existing data. The commenter suggests that the Agency publish a comprehensive list of its prescription drug advertising and promotion studies from the past five years and articulate a clear vision for its research priorities for the near future. Going forward, FDA should use such priorities to explain the necessity and utility of its proposed research and should provide a reasonable rationale for the proposed research.

Response: OPDP's mission is to protect the public health by helping to ensure that prescription drug information is truthful, balanced, and accurately communicated, so that patients and healthcare providers can make informed decisions about

treatment options. OPDP's research program supports this mission by providing scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that we believe are most central to our mission, focusing in particular on three main topic areas: Advertising features, including content and format; target populations; and research quality. Through the evaluation of advertising features we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits; focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience; and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. Because we recognize the strength of data and the confidence in the robust nature of the findings is improved through the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our homepage, which can be found at: *https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090276.htm.* The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office. The website maintains information on studies we have conducted, dating back to a survey of DTC attitudes and behaviors conducted in 1999.

Comment 2: FDA should provide more detail about the study to stakeholders. ''It is not clear from this description whether the study will yield useful information to evaluate whether disclosures provide appropriate contextual information in certain communications, whether such disclosures can be made more effective, and where the disclosures are necessary to ensure communications are truthful and non-misleading.''

Response: We have described the purpose of the study, the design, the population of interest, and have provided the questionnaire to numerous individuals upon request. These materials have proven sufficient for others to comment publicly, and for academic experts to peer-review the study successfully. Our full stimuli are under development during the PRA process. We do not make draft stimuli public during this time because of concerns that this may contaminate our participant pool and compromise the research.

Comment 3: The Agency should wait until it has completed its broader study on disclosures more generally. This study is duplicative of other studies.

Response: As we discussed in the 60-day **Federal Register** notice, oncological products deserve specific attention as they account for nearly a quarter of new drug approvals and can involve the assessment of complicated endpoints. Moreover, they have specific disclosures that are unique to their products and deserve particular study. The other disclosures study (Docket No. FDA–2017–N–0558) will provide important information about a variety of disclosures in different medical conditions. One research study cannot answer all questions or study all aspects of an issue. These two studies will be complementary but not redundant. Please also refer to our response to comment 1 from the first commenter above.

Comment 4: Given that FDA grants approval based on certain preliminary and descriptive data, and that various limitations as to the underlying data must already be communicated to prescribers, there appears to be limited utility in researching disclosures regarding such data.

Response: We disagree that FDA grants approval on preliminary or descriptive data. The evidentiary standard is substantial evidence. While we recognize that no single development program can answer all questions about a particular drug in all populations, it is not accurate to describe the evidence supporting approval as descriptive or preliminary. What is potentially unique about oncology products is that many are approved under accelerated approval, in which the substantial evidence of benefit is on a surrogate endpoint that is reasonably likely to predict a clinical outcome. There remains some residual uncertainty regarding whether the effect on a surrogate endpoint will directly correlate with a clinical benefit; however, there is a requirement that confirmatory evidence of clinical benefit be obtained after approval. This residual uncertainty about the relationship of the surrogate endpoint to the clinical benefit is communicated to prescribers through the FDA-required labeling (*e.g.,* inclusion of a limitation of use in the Indications and Usage section of the FDA-required labeling). In addition, reliance on a surrogate endpoint under accelerated approval is only done for serious diseases when the evidence indicates that the product provides a meaningful therapeutic benefit to patients over existing treatments (21 CFR 314.500).

However, this study does not focus on endpoints that formed the basis for approval. This study focuses on promotional displays of preliminary and/or descriptive data. It has not been established whether and how current disclosure-type additions to promotion are adequately communicating the limitations around this type of data, and that is the purpose of the current study. Given the importance of these limitations, it is crucial to make sure that promotional materials directed at to prescribers convey limitations appropriately. Past research has shown that simply including a statement somewhere in a promotional piece does not grant it automatic usefulness (Refs. 7 to 10).

Comment 5: FDA notes that, ''[a]lthough overall survival remains the gold standard for demonstrating clinical benefit of a drug, several additional endpoints are accepted as surrogates . . . [including] disease-free survival, objective response rate, complete response rate, progression-free survival, and time to progression.'' The Agency further states that ''[f]or clinicians who are not specifically trained in clinical trial design, interpreting these endpoints may be challenging.'' FDA does not cite any sources for this claim, and there is no basis for thinking that clinicians do not have a thorough understanding of the data limitations described in presentations of preliminary or descriptive scientific and clinical data. This is especially true of oncologists.

Response: This statement was not intended to be a claim, but rather a statement of concern. Studies report that physicians lack sufficient critical knowledge and skills to evaluate evidence based medicine (EBM) and may be influenced by the way study results are presented (Refs. 11 to 13). FDA recently conducted a systematic review of research related to prescribers' training and critical appraisal skills related to clinical trials (Ref. 14). The study found that extant physician knowledge and skills regarding certain statistical concepts and trial designs were in the middle of the possible outcome score range, at levels below those considered mastery, even after

interventions designed to increase knowledge and skills. Evidence suggested that clinical credentials affect understanding and use of clinical data. Physicians with formal training in biostatistics, epidemiology, clinical research, or EBM demonstrated higher levels of knowledge and appraisal skills than those with usual medical education and training.

Comment 6: The specific disclosures outlined by FDA include ''clinical or statistical information related to the trial design, the statistical analysis plan of the trial, or any other material statistical or clinical information necessary for evaluation or interpretation of the data.'' The breadth of the proposed specific disclosures appears burdensome, unnecessary, and overwhelming for the purposes of the proposed survey.

Response: These concepts were provided as examples of the types of information that may be necessary for the accurate evaluation or interpretation of the data. This statement was not meant to imply that all of these concepts would be included in disclosures used in this study.

Comment 7: PCPs and non-oncology mid-level practitioners will provide much less utility in their survey responses regarding such disclosures.

Response: We have changed the design. See previous comments and responses.

Comment 8: The Agency proposes to conduct its survey via electronic media. FDA should consider testing non-electronic media, including printed sales aids, as these forms are often reviewed by the proposed study subjects.

Response: To clarify, the stimuli presented will consist of mock print materials in .pdf format, administered via the internet. Conducting the study in person would require a greater expenditure of resources without appreciable benefits.

Comment 9: The Agency should consider using a consistent sliding scale format for all survey responses. Just within pages 7–9 of the survey, FDA proposes numerous different schemes for survey responses: (1) ''Not at all beneficial—Extremely beneficial;'' (2) ''Completely agree—Completely disagree;'' (3) ''No evidence—Strong (or conclusive) evidence;'' (4) ''Not at all complex—Extremely complex;'' (5) ''Not at all confusing—Extremely confusing;'' and (6) additional responses in which subjects are asked to agree with certain statements. The variety in response options is confusing in format and could potentially introduce error. To the extent possible, FDA should make the response format consistent throughout the survey. Further, the Agency should ensure the sliding scale format consistently provides an odd number of responses to permit a ''neutral'' response. Certain questions (*e.g.,* the IMPROVE question on page 7) provide six choices, not permitting a neutral response.

Response: Although one scale throughout would be easier for respondents, it will not necessarily provide better data. When a series of adjacent questions have the same response options, respondents may use a response mechanism known as anchoring and adjusting when reporting (Ref. 15). Respondents use their response to the initial survey question on a topic as the ''cognitive anchor,'' and then adjust up or down based on subsequent questions (Ref. 16). Anchoring and adjusting is more likely to occur for questions when respondents have some level of uncertainty in their answer (Ref. 17), which would be expected in this study. Epley and Gilovich (Ref. 17) found that when respondents use an anchoring and adjusting strategy, they often adjust insufficiently. Respondents start with the response they used for the first item and then search for the next value that is ''close enough.'' This can result in responses to adjacent items being more similar than responses to the same items if they used an item-specific scale (*Not at all beneficial* to *Extremely beneficial; Not at all complex* to *Extremely complex*). Using the same scale across all survey questions would artificially increase the correlations between all questions making it more difficult to identify differences based on the stimuli or respondent characteristics. Furthermore, use of item-specific scales compared with agree-disagree scales reduces primacy effects (tendency of respondents to select options at the beginning of the list) (Ref. 18), and increases reliability and validity (Ref. 19). Careful consideration was made to use agree-disagree scales only when item-specific scales would not be appropriate (*e.g.,* presenting patient vignettes) or unnecessarily complex (*e.g.,* asking about ''complex terminology, statistical terms, or jargon,'' inquiring about ''strong'' evidence).

In terms of neutral points, given the focus of the questions, we believe that offering a neutral response option is not necessary to measure opinions and attitudes accurately. Consequently, our objective is to force a selection and have participants make at least a weak commitment in either a positive or negative direction. Of concern is that offering a neutral midpoint could potentially encourage ''satisficing''—cuing participants to choose a neutral response because it is offered (Ref. 20). Additionally, providing a midpoint leads to the loss of information regarding the direction in which people lean (Ref. 21). Research has found that neither format (either with or without a neutral point) is necessarily better or produces more valid or reliable results (Ref. 22). Instead, it should be left to the researcher to determine the goals of the study. During cognitive testing, a majority of participants were satisfied with the response options and all participants felt comfortable choosing a response in the absence of a midpoint.

Use of a midpoint is an issue we have examined in previous studies and we determined that we achieve valid and reliable responses without a midpoint. To increase consistency with measures used in previous studies, and in support of the arguments presented above, we are opting to exclude a midpoint. Finally, if a participant does not feel that they can choose a response because of a lack of a neutral option, they will be able to skip the question.

Comment 10: In the BENEFICIAL question on page 7 of the survey, it is unclear what relevance the subject's perception of clinical benefit of a drug has in studying FDA's proposed research purpose.

Response: For prescription drug products, advertisers must ensure that both the benefits and limitations are appropriately conveyed. If limitations are not appropriately conveyed, viewers may have an inflated view of the benefits of the product, relative to its risks. This question investigates this issue.

Comment 11: In a study setting, subjects may be prone to read and pay attention to more or all of the information presented. Subjects also are more aware of the importance of their responses. The Agency should address what efforts it will take to avoid response bias by study subjects.

Response: We initially had this concern many years ago when OPDP began conducting research. However, since that time, we have seen no evidence of this bias. In fact, we often deal with the opposite problem—ensuring that respondents spend a minimum amount of time looking at mock materials. Moreover, cognitive testing participants have told us that they would not spend extra time on materials if they were answering questions without an interviewer in the room. Individuals, especially HCPs, are busy, and we believe our experiments do not overestimate the amount of time participants spend on actual materials.

Comment 12: Although the draft survey did not contain Informed Consent text, the Agency should ensure that this text does not state or imply that the survey is being conducted on behalf of the U.S. Food and Drug Administration. Such a statement could potentially influence subjects' responses to study questions. Instead, this information might be provided at the conclusion of the study.

Response: We will ensure that all materials reference the U.S. Department of Health and Human Services rather than FDA.

Comment 13: The CAUTIOUS question on page 8 should be rephrased or omitted. Subjects may be biased to respond that they interpret all data with caution, regardless of the underlying scientific evidence presented in study stimuli.

Response: We agree with this comment and will delete this item.

Comment 14: The DECISIONS question on page 8 should be omitted. How survey participants ''feel about the data presented'' will be highly dependent on their external experience in making prescribing decisions. This question thus may lead to highly variable results.

Response: Because this is an experimental design with random assignment to conditions, external experiences in making prescribing decisions should be randomly scattered across experimental conditions. Thus, we will be able to infer causation to our manipulations of disclosures if we find any differences across experimental conditions. We believe the presence and form of the disclosure may influence this dependent variable and believe it will reveal important information about how HCPs process the data.

Comment 15: The PREFERENCE and PREFERWHY questions on page 16 should be moved to the beginning of the survey or omitted altogether. Subjects' responses regarding their preference in sales aid disclosure statements will be heavily influenced by earlier portions of the survey.

Response: We have given careful thought to the ordering of the questions in the questionnaire. Because preference is of secondary interest to us, we have included it after our primary outcome variables, so that it does not influence them. We recognize that prior questions may influence these measures and will interpret them with that caveat in mind.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [2]	Total hours
Pretest Study Screener Completes	150	1	150	0.03 (2 minutes)	5
Main Study Screener Completes	3,525	1	3,525	0.03 (2 minutes)	106
Pretest Study	90	1	90	0.33 (20 minutes)	30
Main Study	2,115	1	2,115	0.33 (20 minutes)	698
Total					839

[1] No capital costs or operating and maintenance costs are associated with collection of this information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.

II. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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4. Centerwatch, ''FDA Approved Drugs for Oncology,'' *https://www.centerwatch.com/drug-information/fda-approved-drugs/therapeutic-area/12/oncology* (accessed on October 5, 2018).

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* 15. Tversky, A. and D. Kahneman,'' Judgment Under Uncertainty: Heuristics and Biases,'' *Science,* 185(4157):1124–1131, 1974.
* 16. Gehlbach, H. and S. Barge, ''Anchoring and Adjusting in Questionnaire Responses,'' *Basic and Applied Social Psychology,* 34(5):417–433, 2012.
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* 18. Höhne, J.K. and D. Krebs, ''Scale Direction Effects in Agree/Disagree and Item-Specific Questions: A Comparison of Question Formats,'' *International Journal of Social Research Methodology,* 21(1):91–103, 2017.
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Dated: November 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24785 Filed 11–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4206]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Small Business Qualification and Certification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Form FDA 3602 and Form FDA 3602A, which will allow domestic and foreign applicants to certify that they qualify as a small business and pay certain medical device user fees at reduced rates.

DATES: Submit either electronic or written comments on the collection of information by January 14, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 14, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 14, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2018–N–4206 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Small Business Qualification and Certification.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

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

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the

docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: 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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Device User Fee Small Business Qualification and Certification

OMB Control Number 0910–0508—Extension

Medical device user fees were first established in 2002 by the Medical Device User Fee and Modernization Act (MDUFMA) (Pub. L. 107–250). User fees were renewed in 2007, with the Medical Device User Fee Amendments to the FDA Amendments Act (MDUFA II), in 2012 with the Medical Device User Fee Amendments to the FDA Safety and Innovation Act (MDUFA III), and in 2017 with the Medical Device User Fee Amendments to the FDA Reauthorization Act (MDUFA IV). MDUFA IV will be in place from October 1, 2017, until September 30, 2022.

A business that is qualified and certified as a ''small business'' is eligible for a substantial reduction in most of these user fees. The guidance document entitled ''Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments'' describes the criteria FDA will use to decide whether an entity is eligible for a reduction in user fees and the process by which a business may request certification as a small business.

An applicant can qualify for a small business fee discount under MDUFMA if they reported gross receipts or sales of no more than $100 million on their Federal income tax return for the most recent tax year. If they have any affiliates, partners, or parent firms, the applicant must add the gross receipts or sales of the affiliates, partners, or parent firms to the applicant's, and the total must be no more than $100 million. If the applicant's gross receipts or sales are no more than $30 million, including all of their affiliates, partners, and parent firms, they will also qualify for a waiver of the fee for their first (ever) premarket application (product development protocol, biologics licensing application, or premarket report). An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the small business criteria (Form FDA 3602, ''MDUFA Small Business Certification Request for a Business Headquartered in the United States''). The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a small business within the meaning of MDUFMA.

MDUFA II provided an alternative way for a foreign business to qualify as a small business eligible to pay a significantly lower fee when a medical device user fee must be paid (Form FDA 3602A, ''MDUFA Foreign Small Business Certification Request for a Business Headquartered Outside the United States''). Before passage of MDUFA II, the only way a business could qualify as a small business was to submit a Federal (U.S.) income tax return showing its gross receipts or sales that did not exceed a statutory threshold, currently, $100 million. If a business could not provide a Federal income tax return, it did not qualify as a small business and had to pay the standard (full) fee. Because many foreign businesses have not, and cannot, file a Federal (U.S.) income tax return, this requirement effectively prevented those businesses from qualifying for the small business fee rates. Thus, foreign governments, including the European Union, objected. In lieu of a Federal income tax return, the MDUFA II allowed a foreign business to qualify as a small business by submitting a certification from its national taxing authority, the foreign equivalent of our Internal Revenue Service. This certification, referred to as a ''National Taxing Authority Certification,'' must: (1) Be in English; (2) be from the national taxing authority of the country in which the business is headquartered; (3) provide the business' gross receipts or sales for the most recent year, in both the local currency and in U.S. dollars, and the exchange rate used in converting local currency to U.S. dollars; (4) provide the dates during which the reported receipts or sales were collected; and (5) bear the official seal of the national taxing authority.

Forms FDA 3602 and FDA 3602A are available in the guidance document entitled ''Medical Device User Fee Small Business Qualification and Certification Guidance for Industry, Food and Drug Administration Staff and Foreign Governments'' on the internet at: *https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm456779.pdf.*

The estimated burden is based on the number of applications received in the last 3 years and includes time required to collect the required information. Based on our experience with Form FDA 3602, FDA believes it will take each respondent 1 hour to complete the form. Based on our experience with Form FDA 3602A, FDA also believes that it will take each respondent 1 hour to complete.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
FDA 3602—MDUFA Small Business Certification Request For a Business Headquartered in the United States	5,000	1	5,000	1	5,000
FDA 3602A—MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States	2,000	1	2,000	1	2,000
Total					7,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 2,000 hours and a corresponding increase of 2,000 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: November 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24790 Filed 11–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4461]

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products; Study Design Recommendations for Residue Studies in Honey for Establishing Maximum Residue Levels and Withdrawal Periods; 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 (GFI) #243 entitled ''Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing MRLs and Withdrawal Periods'' (VICH GL56). This guidance has been developed for veterinary use by the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This VICH guidance document is intended to provide study design recommendations that will facilitate the universal acceptance of the generated residue depletion data to fulfill the national/regional requirements in order to establish appropriate Maximum Residue Limits (MRLs) or other safe limits in honey following the treatment of honeybees with veterinary drug products, or to justify withdrawal periods in honey for registration or approval purposes, as applicable, when an MRL already exists.

DATES: The announcement of the guidance is published in the **Federal Register** on November 14, 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–4461 for ''Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing MRLs and Withdrawal Periods'' (VICH GL56). Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and

contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

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

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. 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: Julia Oriani, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0788, *julia.oriani@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of final GFI #243 entitled ''Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing MRLs and Withdrawal Periods'' (VICH GL56). In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify, and then reduce, differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use for several years to develop, with input from both regulatory and industry representatives, harmonized technical requirements for the registration or approval of pharmaceutical products for human use among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission and European Medicines Agency; International Federation for Animal Health—Europe; FDA; the U.S. Department of Agriculture; the U.S. Animal Health Institute; the Japanese Ministry of Agriculture, Forestry, and Fisheries; and the Japanese Veterinary Products Association. Six observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, one representative from the industry in Canada, one representative from the government of South Africa, and one representative from the industry in South Africa. The World Organisation for Animal Health, the Associate Member, has one delegate. The VICH Secretariat, which coordinates the preparation of documentation, is provided by HealthforAnimals.

In the **Federal Register** of January 5, 2017 (82 FR 1342), FDA published the notice of availability for a draft guidance entitled ''Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing MRLs and Withdrawal Periods'' (VICH GL56), giving interested persons until March 6, 2017, to comment on the draft guidance. FDA received two comments on the draft guidance, and those comments, as well as those received by other VICH member regulatory agencies, were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance dated January 2017. The final guidance is a product of the Metabolism and Residue Kinetics Expert Working Group of the VICH.

This VICH guidance document is intended to provide study design recommendations that will facilitate the universal acceptance of the generated residue depletion data to fulfill the national/regional requirements in order to establish appropriate MRLs or other safe limits in honey following the treatment of honeybees with veterinary drug products, or to justify withdrawal periods in honey for registration or approval purposes, as applicable, when an MRL already exists.

II. Significance of Guidance

This guidance, developed under the VICH process, is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). For example, the document has been designated ''guidance'' rather than ''guideline.'' In addition, guidance documents must not include mandatory language such as ''shall,'' ''must,'' ''require,'' or ''requirement,'' unless FDA is using these words to describe a statutory or regulatory requirement.

The guidance represents the current thinking of FDA on ''Studies to Evaluate the Metabolism and Residue Kinetics of Veterinary Drugs in Food-Producing Species: Study Design Recommendations for Residue Studies in Honey for Establishing MRLs and Withdrawal Periods'' (VICH GL56). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

IV. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *https://www.regulations.gov.*

Dated: November 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24762 Filed 11–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0268]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by December 14, 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 0910–0728. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

OMB Control Number 0910–0728—Extension

The definition of ''food'' under the Federal Food, Drug, and Cosmetic Act (FD&C Act) (see 21 U.S.C. 321(f)), includes ''articles used for food or drink'' and thus includes alcoholic beverages. As such, alcoholic beverages are subject to the FD&C Act's adulteration and misbranding provisions and implementing regulations related to food. For example, manufacturers of alcoholic beverages are responsible for adhering to the registration of food facilities requirements in 21 CFR part 1 and to the good manufacturing practice regulations in 21 CFR part 110. There are also certain requirements for nutrition labeling on menus, menu boards, and other written materials for alcohol beverages served in restaurants or similar retail food establishments in 21 CFR part 101. However, as reflected in a 1987 Memorandum of Understanding between FDA and the Alcohol and Tobacco Tax and Trade Bureau (TTB), TTB is responsible for the dissemination and enforcement of regulations with respect to the labeling of distilled spirits, certain wines, and malt beverages issued in the Federal Alcohol Administration Act (FAA Act). In TTB Ruling 2008–3, dated July 7, 2008, TTB clarified that certain beers, which are not made from both malted barley and hops but are instead made from substitutes for malted barley (such as sorghum, rice, or wheat) or are made without hops, do not meet the definition of a ''malt beverage'' under the FAA Act. Accordingly, TTB stated in its ruling that such products (other than saké, which is classified as a wine under the FAA Act), are not subject to the labeling, advertising, or other provisions of TTB regulations issued under the FAA Act.

In cases where an alcoholic beverage is not covered by the labeling provisions of the FAA Act, the product is subject to ingredient and other labeling requirements under the FD&C Act and the implementing regulations that we administer. In addition, as provided for under the Fair Packaging and Labeling Act (FPLA), alcoholic beverages that are not covered by the labeling provisions of the FAA Act are subject to the provisions of the FPLA, which we administer.

Therefore, the beers described in TTB's ruling as not being a ''malt beverage'' are subject to the labeling requirements under the FD&C Act and FPLA, and our implementing regulations. In general, we require that food products under our jurisdiction be truthfully and informatively labeled in accordance with the FD&C Act, the FPLA, and FDA's regulations. Furthermore, some TTB labeling requirements, such as the Government Health Warning Statement under the Alcoholic Beverage Labeling Act and certain marking requirements under the Internal Revenue Code, continue to apply to these products.

Persons with access to the internet may obtain the guidance entitled, ''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration,'' located at *https://www.fda.gov/FoodGuidances.* This guidance is intended to assist manufacturers on how to label bottled or otherwise packaged beers that are subject to our labeling laws and regulations.

Our food labeling regulations under parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) were issued under the authority of sections 4, 5, and 6 of the FPLA (15 U.S.C. 1453, 1454, and 1455) and under sections 201, 301, 402, 403, 409, 411, 701, and 721 of the FD&C Act (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the FD&C Act, which provides that a food product shall be deemed to be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products produced or sold in the United States are in compliance with the labeling provisions of the FD&C Act and the FPLA.

The primary user of the information to be disclosed on the label or labeling of food products is the consumer that purchases the food product. Consumers will use the information to assist them in making choices concerning their purchase of a food product, including choices related to substances that the consumer must avoid to prevent adverse reactions. This information also enables the consumer to determine the role of the food product in a healthful diet. Additionally, FDA intends to use the information to determine whether a manufacturer or other supplier of food products is meeting its statutory and regulatory obligations. Failure of a manufacturer or other supplier of food products to label its products in compliance with section 403 of the FD&C Act and parts 101, 102, 104, and 105 of FDA's food labeling regulations may result in a product being misbranded under the FD&C Act, subjecting the firm and product to regulatory action.

Description of Respondents: The respondents to this collection of

information are manufacturers of beers that are subject to our labeling laws and regulations.

In the **Federal Register** of June 29, 2018 (83 FR 30738), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two comments were received. One comment was unrelated to the Paperwork Reduction Act and is not addressed. The second comment was in favor of the practical utility and necessity of labeling the ingredients of beer for transparency to the consumer. We are appreciative of these comments. At this time, we do not plan on adjusting our current estimate.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
§§ 101.3 and 101.22; principal display and display panel.	12	2	24	0.5 (30 minutes)	12
§ 101.4; designation of ingredients	12	2	24	1	24
§ 101.5; name of manufacturer; packer; distributor	12	2	24	0.25 (15 minutes)	6
§ 101.9; nutrition labeling	12	2	24	4	96
§ 101.7 (formerly 101.105); quantity of contents	12	2	24	0.5 (30 minutes)	12
Section 403(w)(1) of the FD&C Act	12	2	24	1	24
Review of Guidance Document: ''Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration''.	12	1	12	1	12
Total					186

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Our estimate of the number of respondents is based on the number of regulatory submissions to TTB for beers that do not meet the definition of a ''malt beverage'' under the FAA Act. Based on its records of submissions received from manufacturers of such products, TTB estimates the annual number of respondents to be 12 and the annual number of disclosures to be 24. Thus, we adopt TTB's estimate of 12 annual respondents, and an annual number of disclosures per respondent of 2 in table 1.

Our estimates of the average burden per disclosure for each collection provision are based on our experience with food labeling under the Agency's jurisdiction. The estimated average burden per disclosure for §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 in table 1 are equal to, and based upon, the estimated average burden per disclosure approved by OMB in OMB control number 0910–0381. We further estimate that the labeling burden of section 403(w)(1) of the FD&C Act, which specifies requirements for the declaration of food allergens, will be 1 hour based upon the similarity of the requirements to that of § 101.4. Finally, FDA estimates that a respondent will spend 1 hour reading the guidance.

Thus, we estimate that 12 respondents will each label 2 products annually, for a total of 24 labels. We estimate that the manufacturers will spend 7.25 hours (0.5 hours + 1 hour + 0.25 hour + 4 hours + 0.5 hour + 1 hour = 7.25 hours) on each label to comply with our labeling regulations and the requirements of section 403(w)(1) of the FD&C Act, for a total of 174 hours (24 labels × 7.25 hours = 174 hours). In addition, 12 respondents will each spend 1 hour reading the guidance document, for a total of 12 hours. Thus, we estimate the total hour burden of the proposed collection of information to be 186 hours (174 hours + 12 hours = 186 hours).

The guidance also refers to previously approved collections of information found in our regulations. The collections of information in §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.105 have been approved under OMB control number 0910–0381. Allergen labeling of these beers under section 403(w)(1) of the FD&C Act, which was added by the Food Allergen Labeling and Consumer Protection Act of 2004, has been approved under OMB control number 0910–0792.

Dated: November 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24786 Filed 11–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3931]

Nonmetastatic, Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Nonmetastatic, Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials.'' This draft guidance provides recommendations to sponsors regarding the use of metastasis-free survival (MFS) as an endpoint in clinical trials for nonmetastatic, castration-resistant prostate cancer (nmCRPC) development programs for drug or biological products regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

DATES: Submit either electronic or written comments on the draft guidance by January 14, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

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

Written/Paper Submissions

Submit written/paper submissions as follows:

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

Instructions: All submissions received must include the Docket No. FDA–2018–D–3931 for ''Nonmetastatic, Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

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

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

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

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Julia Beaver, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2100, Silver Spring, MD 20993–0002, 240–402–0489; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonmetastatic, Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials.'' This draft guidance provides recommendations to sponsors regarding the use of MFS as an endpoint in clinical trials for nmCRPC development programs for drug or biological products regulated by CDER and CBER.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Nonmetastatic, Castration-Resistant Prostate Cancer: Considerations for Metastasis-Free Survival Endpoint in Clinical Trials.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in 21 CFR part 312 has been approved under OMB control number 0910–0014. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0755.

III. Electronic Access

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

Dated: November 7, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–24763 Filed 11–13–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OMHA–1802–N]

Medicare Program; Administrative Law Judge Hearing Program for Medicare Claim and Entitlement Appeals; Quarterly Listing of Program Issuances—July Through September 2018

AGENCY: Office of Medicare Hearings and Appeals (OMHA), HHS.

ACTION: Notice.

SUMMARY: This quarterly notice lists the OMHA Case Processing Manual (OCPM) instructions that were published from July through September 2018. This manual standardizes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations, and OMHA directives, and gives OMHA staff direction for processing appeals at the OMHA level of adjudication.

FOR FURTHER INFORMATION CONTACT: Jason Green, by telephone at (571) 777–2723, or by email at *jason.green@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Medicare Hearings and Appeals (OMHA), a staff division within the Office of the Secretary within the U.S. Department of Health and Human Services (HHS), administers the nationwide Administrative Law Judge hearing program for Medicare claim; organization, coverage, and at-risk determination; and entitlement appeals under sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D–4(h) of the Social Security Act (the Act). OMHA ensures that Medicare beneficiaries and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as Medicare Advantage organizations (MAOs), Medicaid State agencies, and applicable plans, have a fair and impartial forum to address disagreements with Medicare coverage and payment determinations made by Medicare contractors, MAOs, or Part D plan sponsors (PDPSs), and determinations related to Medicare eligibility and entitlement, Part B late enrollment penalty, and income-related monthly adjustment amounts (IRMAA) made by the Social Security Administration (SSA).

The Medicare claim, organization determination, coverage determination, and at-risk determination appeals processes consist of four levels of administrative review, and a fifth level of review with the Federal district courts after administrative remedies under HHS regulations have been exhausted. The first two levels of review are administered by the Centers for Medicare & Medicaid Services (CMS) and conducted by Medicare contractors for claim appeals, by MAOs and an independent review entity for Part C organization determination appeals, or by PDPSs and an independent review entity for Part D coverage determination and at-risk determination appeals. The third level of review is administered by OMHA and conducted by Administrative Law Judges and attorney adjudicators. The fourth level of review is administered by the HHS Departmental Appeals Board (DAB) and conducted by the Medicare Appeals Council (Council). In addition, OMHA and the DAB administer the second and third levels of appeal, respectively, for Medicare eligibility, entitlement, Part B late enrollment penalty, and IRMAA reconsiderations made by SSA; a fourth level of review with the Federal district courts is available after administrative remedies within SSA and HHS have been exhausted.

Sections 1869, 1155, 1876(c)(5)(B), 1852(g)(5), and 1860D–4(h) of the Act are implemented through the regulations at 42 CFR part 405 subparts I and J; part 417, subpart Q; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B. As noted above, OMHA administers the nationwide Administrative Law Judge hearing program in accordance with these statutes and applicable regulations. To help ensure nationwide consistency in that effort, OMHA established a manual, the OCPM. Through the OCPM, the OMHA Chief Administrative Law Judge establishes the day-to-day procedures for carrying out adjudicative functions, in accordance with applicable statutes, regulations, and OMHA directives. The OCPM provides direction for processing appeals at the OMHA level of adjudication for Medicare Part A and B claims; Part C organization determinations; Part D coverage determinations and at-risk determinations; and SSA eligibility and entitlement, Part B late enrollment penalty, and IRMAA determinations.

Section 1871(c) of the Act requires that the Secretary publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every three months in the **Federal Register**.

II. Format for the Quarterly Issuance Notices

This quarterly notice provides the specific updates to the OCPM that have occurred in the three-month period of July through September 2018. A hyperlink to the available chapters on the OMHA website is provided below. The OMHA website contains the most current, up-to-date chapters and revisions to chapters, and will be available earlier than we publish our quarterly notice. We believe the OMHA website provides more timely access to the current OCPM chapters for those involved in the Medicare claim; organization, coverage, and at-risk determination; and entitlement appeals processes. We also believe the website offers the public a more convenient tool for real time access to current OCPM provisions. In addition, OMHA has a listserv to which the public can subscribe to receive notification of certain updates to the OMHA website, including when new or revised OCPM chapters are posted. If accessing the OMHA website proves to be difficult, the contact person listed above can provide the information.

III. How To Use the Notice

This notice lists the OCPM chapters and subjects published during the quarter covered by the notice so the reader may determine whether any are of particular interest. We expect this notice to be used in concert with future published notices. The OCPM can be accessed at *https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html.*

IV. OCPM Releases for July Through September 2018

The OCPM is used by OMHA adjudicators and staff to administer the OMHA program. It offers day-to-day operating instructions, policies, and procedures based on statutes and regulations, and OMHA directives.

The following is a list and description of OCPM provisions that were revised in the three-month period of July through September 2018. This information is available on our website at *https://www.hhs.gov/about/agencies/omha/the-appeals-process/case-processing-manual/index.html.*

OCPM Chapter 5: Representatives

Chapter 5, Representatives. This chapter describes the role of representatives in the appeals process, including the documentation required

to establish a valid representation, representative rights and responsibilities, communications with representatives and represented parties, and changes of representative due to delegation, revocation, or termination of an appointment. This chapter also discusses the fee approval process for representatives and the circumstances under which an eligible individual or entity may be entitled to reasonable attorney fees and other expenses under the Equal Access to Justice Act.

OCPM Chapter 6: CMS, CMS Contractor, and Plan Roles

Chapter 6, CMS, CMS Contractor, and Plan Roles. This chapter describes when and how CMS, a CMS contractor, or a plan (for example, a Medicare Advantage organization or Part D plan sponsor) may join the proceedings on a request for hearing as a party or as a non-party participant. This chapter also describes the requirements for a valid election or request to participate in the proceedings, and the circumstances under which an election may be deemed invalid or a request may be denied. This chapter also discusses when evidence, position papers, and written testimony may be submitted by CMS, a CMS contractor, or a plan.

OCPM Chapter 7: Adjudication Time Frames, Case Prioritization, and Escalations

Chapter 7, Adjudication Time Frames, Case Prioritization, and Escalations. This chapter describes the time frames for an adjudicator to issue a decision, dismissal, or remand in an appeal. This chapter also addresses when an adjudication time frame may be delayed or extended, and how it can be waived by the appellant. This chapter discusses OMHA's case prioritization policy, which determines the general order in which appeals are processed. Lastly, this chapter describes the types of appeal that may be escalated to the Medicare Appeals Council when an adjudicator is unable to issue a decision, dismissal, or remand within an applicable adjudication time frame, and the requirements for a valid request for escalation.

OCPM Chapter 14: Scheduling and Noticing for Prehearing Conferences and Hearings

Chapter 14, Scheduling and Noticing for Prehearing Conferences and Hearings. This chapter describes the process for scheduling and providing notice of prehearing conferences and hearings, the actions that must be completed before a hearing is scheduled, and the circumstances when a hearing is required. This chapter also identifies the parties, potential parties, and participants to whom notices must be sent, and how to address responses to these notices and any objections or requests that may be made by the notice recipients. Finally, this chapter discusses the circumstances in which a hearing may be rescheduled or canceled, and when a supplemental hearing may be necessary.

Dated: November 6, 2018.

Jason M. Green,

Chief Advisor, Office of Medicare Hearings and Appeals.

[FR Doc. 2018–24722 Filed 11–13–18; 8:45 am]

BILLING CODE 4150–46–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0110]

Agency Information Collection Activities: Visa Waiver Program Carrier Agreement

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted (no later than December 14, 2018) to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number (202) 325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (Volume 83 FR Page 35674) on July 27, 2018, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Visa Waiver Program Carrier Agreement.

OMB Number: 1651–0110.

Form Number: CBP Form I–775.

Current Actions: This submission is being made to extend the expiration date with a decrease in burden hours due to updated agency estimates on respondents. There is no change to information collected or to CBP Form I–775.

Type of Review: Extension (without change).

Abstract: Section 223 of the Immigration and Nationality Act (INA) (8 U.S.C. 1223(a)) provides for the necessity of a transportation contract. The statute provides that the Attorney General may enter into contracts with transportation lines for the inspection and administration of aliens coming into the United States from a foreign territory or from adjacent islands. No such transportation line shall be allowed to land any such alien in the United States until and unless it has entered into any such contracts which may be required by the Attorney General. Pursuant to the Homeland Security Act of 2002, this authority was transferred to the Secretary of Homeland Security.

The Visa Waiver Program Carrier Agreement (CBP Form I–775) is used by carriers to request acceptance by CBP into the Visa Waiver Program (VWP). This form is an agreement whereby carriers agree to the terms of the VWP as delineated in Section 217(e) of the INA (8 U.S.C. 1187(e)). Once participation is granted, CBP Form I–775 serves to hold carriers liable for the transportation costs, to ensure the completion of required forms, and to share passenger data. Regulations are promulgated at 8 CFR part 217.6, Carrier Agreements. A copy of CBP Form I–775 is accessible at: *http://www.cbp.gov/newsroom/publications/forms?title=775.*

Affected Public: Businesses.

Estimated Number of Respondents: 98.

Estimated Number of Total Annual Responses: 98.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 49.

Dated: November 8, 2018.

Seth D. Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2018–24756 Filed 11–13–18; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0103]

Agency Information Collection Activities: Passenger List/Crew List

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted (no later than December 14, 2018 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs,

Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to *dhsdeskofficer@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, telephone number (202) 325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (Volume 83 FR Page 34856) on July 23, 2018, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of this Information Collection:

Title: Passenger List/Crew List.

OMB Number: 1651–0103.

Form Number: Form I–418.

Current Actions: CBP proposes to extend the expiration date of this information collection with an increase to the estimated burden hours. There is no change to the information collected.

Type of Review: Extension (without change).

Abstract: CBP Form I–418 is prescribed by CBP, for use by masters, owners, or agents of vessels in complying with Sections 231 and 251 of the Immigration and Nationality Act (INA). This form is filled out upon arrival of any person by commercial vessel at any port within the United States from any place outside the United States. The master or commanding officer of the vessel is responsible for providing CBP officers at the port of arrival with lists or manifests of the persons on board such conveyances. CBP is in the process of amending its regulations to allow for the electronic submission of the data elements required on CBP Form I–418. This form is provided for in 8 CFR 251.1 and 251.3. A copy of CBP Form I–418 can be found at *https://www.cbp.gov/newsroom/publications/forms?title=i-418&=Apply.*

Affected Public: Businesses.

Estimated Number of Respondents: 77,935.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Hours: 77,935.

Dated: November 8, 2018.

Seth Renkema,

Branch Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection.

[FR Doc. 2018–24757 Filed 11–13–18; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Test to Collect Facial Images From Occupants in Moving Vehicles at the Anzalduas Port of Entry (Anzalduas Biometric Test)

AGENCY: U.S. Customs and Border Protection; Department of Homeland Security.

ACTION: General notice.

SUMMARY: This notice announces that U.S. Customs and Border Protection (CBP) is conducting a voluntary test to collect biometrics, namely facial images, from travelers who choose to participate and who are entering or departing the United States via moving motor vehicles at the Anzalduas, Texas, land border port of entry (Anzalduas Biometric Test). CBP is conducting this test to determine the effectiveness of certain technology. Specifically, the test will: Evaluate the technology's effectiveness to capture a quality facial image for occupants within a vehicle while that vehicle is moving; evaluate biometric matching accuracy of images captured; and, evaluate transaction time for matching images captured. CBP will not use facial images collected during this test to identify threats or determine admissibility. All analysis of the facial images collected during this test will be conducted off-line at a later time, and no information collected during this test will be retained in association with an individual's official border-crossing records. This notice describes the purpose of the test as well as how the facial images collected will be used. It also describes the test procedures, the persons covered, the duration of the test, how CBP will analyze the results, and privacy considerations.

DATES: This voluntary test began August 30, 2018, and will run for approximately one year.

FOR FURTHER INFORMATION CONTACT: Colleen Manaher, Executive Director, Planning, Program Analysis and Evaluation, U.S. Customs and Border Protection at (202) 344–3003 or *colleen.manaher@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Department of Homeland Security (DHS) has broad authority to control alien travel and to inspect aliens under various provisions of the Immigration and Nationality Act of 1952, as amended (INA).[1]

In addition, numerous federal statutes require DHS to create an integrated, automated biometric entry and exit system that records the arrival and departure of aliens, compares the biometric data of aliens to verify their identity, and authenticates travel documents presented by such aliens through the comparison of biometrics.[2]

The federal statutes requiring DHS to create a biometric entry and exit system to record the arrival and departure of aliens include, but are not limited to:

- Section 110 of the Illegal Immigration Reform and Immigrant Responsibility Act of 1996, Public Law 104–208, 110 Stat. 3009–546;
- Section 2(a) of the Immigration and Naturalization Service Data Management Improvement Act of 2000 (DMIA), Public Law 106–215, 114 Stat. 337;
- Section 205 of the Visa Waiver Permanent Program Act of 2000, Public Law 106–396, 114 Stat. 1637, 1641;
- Section 414 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), Public Law 107–56, 115 Stat. 272, 353;
- Section 302 of the Enhanced Border Security and Visa Entry Reform Act of 2002 (Border Security Act), Public Law 107–173, 116 Stat. 543, 552;
- Section 7208 of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA), Public Law 108–458, 118 Stat. 3638, 3817;
- Section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007, Public Law 110–52, 121 Stat. 266;
- Section 802 of the Trade Facilitation and Trade Enforcement Act of 2015, Public Law 114–125, 130 Stat. 122, 199 (6 U.S.C. 211(c)(10)).

Additionally, on March 6, 2017, the President signed Executive Order 13780, Protecting the Nation from Foreign Terrorist Entry into the United States (published in the **Federal Register** on March 9, 2017; 82 FR 13209). Section 8 of this Order requires the Secretary of Homeland Security to expedite the completion and implementation of a biometric entry-exit tracking system for ''in-scope travelers'' [3] to the United States.

Pursuant to various authorities under Titles 8 and 19 of the U.S. Code, and other authorities CBP enforces on behalf of third party agencies at the border, CBP routinely collects biographic data from travelers entering and departing the United States. *See, e.g.,* 8 U.S.C. 1181, 1185, 1221; and 19 U.S.C. 1433. Additionally, DHS regulations authorize DHS to collect biometric data from certain aliens seeking admission to the United States and to collect biometrics from aliens upon departure from the United States under pilot programs at land ports and up to 15 air and seaports. *See* Sections 215.8 and 235.1(f)(1)(ii) of Title 8 of the Code of Federal Regulations (CFR) (8 CFR 215.8 and 235.1(f)(1)(ii).[4]

Since 2004, DHS, through CBP, has been collecting biometric data from aliens arriving in the United States. However, there is no comprehensive system in place to collect biometrics from aliens departing the country. Collecting biometrics at both arrival and departure will enable CBP and DHS to know with better accuracy whether aliens are departing the country when they are required to depart, reduce visa or travel document fraud, and improve CBP's ability to identify criminals and known or suspected terrorists before they depart the United States.

CBP has been testing various options to collect biometrics at departure in the land and air environments. For example, from February to May 2016, CBP conducted a pilot program to test facial and iris scanning technology for pedestrian travelers departing through the Otay Mesa, California, land border port of entry.[5] CBP is also conducting

[1] DHS may require aliens to provide biometrics and other relevant identifying information upon entry to, or departure from, the United States. Specifically, DHS may control alien entry and departure and inspect aliens under sections 215(a) and 235 of the INA (8 U.S.C. 1185, 1225). Aliens may be required to provide fingerprints, photographs, or other biometrics upon arrival in, or departure from, the United States, and select classes of aliens may be required to provide information at any time. *See, e.g.,* INA 214, 215(a), 235, 262(a), 263(a), 264(c), (8 U.S.C. 1184, 1185(a), 1225, 1302(a), 1303(a), 1304(c)); 8 U.S.C. 1365b.

[2] As used in this notice, ''biometrics'' means a physical characteristic or other physical attribute unique to a person that can be collected, stored, and used to verify the identity of a person who chooses to participate in the test by using the testing lanes, as defined in the ''Test Procedures'' section below. To verify a person's identity, a similar physical characteristic or attribute is collected and compared against the previously collected identifier.

[3] Although the term ''in-scope travelers'' is not defined in the Executive Order, DHS interprets this to mean those travelers who are currently required to provide biometric information upon entry to the United States.

[4] Certain categories of aliens are exempt from the collection of biometrics upon entering or departing the United States. *See* 8 CFR 235.1(f)(1)(ii), (iv); 8 CFR 215.8(a)(1)–(2).

[5] *See* 80 FR 70241 (Nov. 31, 2015).

pilots at some airports to evaluate the effectiveness of biometric facial recognition matching of a real-time photograph of an individual to a photograph gallery stored in a database.

CBP is now conducting a test that involves the collection of facial images from occupants in moving vehicles as they enter and exit the United States at the Anzalduas land border port of entry (Anzalduas Biometric Test). This notice describes the purpose of the test as well as how the facial images collected will be used. It also describes the test procedures, the persons covered, the duration of the test, how CBP will analyze the results, and privacy considerations.

Anzalduas Biometric Test

Overview and Purpose

The Anzalduas Biometric Test is a voluntary test to collect biometrics, namely facial images, from travelers who choose to participate and who are entering or departing the United States via moving motor vehicles at the Anzalduas, Texas, land border port of entry. This test will help CBP determine the effectiveness of certain technology used to capture a quality facial image for occupants within a vehicle while that vehicle is moving, evaluate biometric matching accuracy of images captured, and evaluate transaction time to conduct a match of images captured to determine whether a real-time match could be provided to the CBP Officer. This test is one of CBP's key efforts in developing the capability to fulfill DHS's mandate to collect biometric information from arriving and departing aliens. The test procedures will operate in conjunction with CBP's normal entry-exit processes but facial images collected during this test will not be used to identify threats or to determine admissibility.

Normal Entry/Exit Procedures Remain In Place

During this test, the normal entry/exit procedures will apply. This means that all persons seeking admission at the Anzalduas land border port of entry must show a valid passport or other acceptable travel document when entering the United States. Some aliens may also be required to provide fingerprint biometric data for CBP to verify their identity upon entry.[6] All persons exiting the United States at the Anzalduas land border port of entry may be subject to additional screening. Some aliens may also be required to provide fingerprint biometric data for CBP to verify their identity upon exit.

The facial images collected during this test will not be analyzed by CBP officers at the time the traveler enters or exits. Rather, the facial matching technology will perform matching analysis, which will be reviewed and analyzed by CBP analysists on the back end for accuracy, as described below. Therefore, the entry and exit procedures for both travelers and CBP officers at the Anzalduas port of entry will not change as a result of this test.

Test Procedures

For this test, cameras have been installed at both entry and exit lanes which will attempt to capture facial images of all occupants in vehicles traveling in designated arrival and departure lanes (''testing lanes'') as the vehicles move through the lane. The cameras are located prior to the inspection booths where travelers present their travel documentation to CBP officers. This process is completely passive for the vehicle occupants and does not require the travelers to engage in any additional action outside of the normal CBP processing on entry or exit. All travelers are subject to inspection upon entry to and exit from the United States, but U.S. citizens and certain categories of aliens are not specifically required to provide biometrics pursuant to 8 CFR 235.1(f)(1)(ii) and 215.8. For purposes of this pilot, CBP has provided an optional lane, both inbound and outbound, where no facial images will be captured for biometric matching purposes (''non-testing lane''). Due to the difficulty of sorting vehicle occupants by citizenship or category while they are in a moving vehicle, the non-testing lane is available for use by any vehicle, regardless of the occupants' citizenship or status. CBP has posted signs sufficiently in advance of lane divisions to allow drivers to select their desired lane. Other than signs indicating non-testing lanes or a flash of light in the testing lanes when a photo is taken, the travelers should not notice any differences in the wait times or experience of crossing at the Anzalduas port of entry.

Use of Facial Images Collected During the Test

CBP will create a photograph gallery of border crossers, which will include the photographs captured by the cameras at both entry and exit operations during this test. This gallery will also include photos and biographical information from travelers' document(s)[7] that were previously captured by CBP or another government agency and which are associated with travelers whose facial images were captured during this test. CBP will not store or use facial images captured from out-of-scope aliens or U.S. citizens for the purposes of this test. If an out-of-scope alien or U.S. citizen chooses to travel through the testing lanes and his or her facial image is captured, the image will be deleted as soon as it is identified as an out-of-scope alien or U.S. citizen by the analysts comparing the matching results of the technology as described below.

The facial recognition technology will compare live images captured during the vehicle crossings with the photos and biographic information on file and will attempt to match the captured images with identified facial images in the photograph gallery. All facial images captured during this test, and previously collected traveler photos and associated document data will be stored in a secure, standalone database and analyzed off-line to test the biometric matching capabilities of the technology. No biometric data will be distributed from the standalone database, except for analysis and reporting purposes on the results of the test.[8]

In order to determine the accuracy of the biometric matching system, CBP analysts will compare the matching results produced by the facial recognition technology with stored traveler data (*e.g.,* RFID card scans, traveler biographical information collected by an officer from travel documents, and license plate data). By reviewing traveler data that are matched to test images by the system, CBP analysts can confirm that the traveler associated with a given individual record with which the technology matched a given facial image did in fact cross the Anzalduas port of entry on a particular day. For example, if the technology matches a captured facial image to the photograph on a certain individual's travel document, an analyst could review the border crossing biographical records from that day to confirm that the individual identified by the technology did cross that day. Alternatively, if the analyst finds no record of that individual crossing on the

[6] Certain aliens, including individuals traveling on A or G visas and others as specified in 8 CFR 215.8 and 235.1, are exempt from this requirement.

[7] Traveler documents include but are not limited to: passports, visas, and trusted traveler radio-frequency identification (RFID) cards such as Border Crossing Cards, Enhanced Driver's Licenses, passport cards, and tribal cards. See 8 CFR 235.1 for complete travel document requirements.

[8] As noted above, facial images collected from exempt aliens or U.S. citizens will be deleted as soon as they are identified as an exempt alien or U.S. citizen.

particular day, CBP may need to do further analysis on the match provided by the technology to determine if there is a ''false match'' or some other issue. The biographical information provides an additional level of verification to determine the accuracy of the facial matching technology.

Persons Covered

Participation in the test is voluntary. All individuals entering or exiting the United States at the Anzalduas port of entry in a vehicle may participate by entering and/or exiting through the testing lanes. Individuals who choose not to participate may use the non-testing lanes. No person or group of people will be required to use the testing lanes and there will be no penalty for using the non-testing lanes.

Duration of Test

This voluntary test began August 30, 2018, and will run for approximately one year.

Analysis of Results

CBP will generally retain facial images collected during this test until December 2020 for the sole purpose of testing facial recognition technology against a photograph gallery that most closely simulates CBP's operational land environment.[9] All analysis will be performed on the back end using the standalone database created for this test. CBP will use the results of this test to assess the operational feasibility of collecting biometric information from occupants in moving vehicles entering and exiting at all U.S. land border ports of entry. CBP will evaluate the test based on a number of criteria, including:

- The ability of the technology to capture high-quality facial images in vehicles traveling at various speeds, and in various lighting and weather conditions;
- the ability of the technology to correctly match the facial images captured to the correct individuals' facial image(s) on file; and,
- the transaction time to match the facial images captured to the photograph gallery to determine whether a real-time match could be provided to the CBP Officer performing traveler screening at the entry or exit lanes of the port.

[9] As noted above, facial images collected from exempt aliens or U.S. citizens will be deleted as soon as they are identified as an exempt alien or U.S. citizen. Further information about the retention of facial images will be provided in CBP's Privacy Impact Assessment (PIA) for Traveler Verification Services (TVS). It will be available at *http://www.dhs.gov/privacy-documents-us-customs-and-border-protection.*

Privacy

CBP will ensure that all Privacy Act requirements and applicable DHS privacy policies are adhered to during the implementation of this test. Additionally, as noted previously, CBP will be issuing a PIA for TVS, which will outline how CBP will ensure compliance with Privacy Act protections and DHS privacy policies, including DHS's Fair Information Practice Principles (FIPPs). The FIPPs account for the nature and purpose of the information being collected in relation to DHS's mission to preserve, protect and secure the United States. The PIA will address issues such as the security, integrity, and sharing of data, use limitation and transparency. The PIA will be made publicly available at: *http://www.dhs.gov/privacy-documents-us-customs-and-border-protection.*

CBP has also issued an update to the DHS/CBP–007 Border Crossing Information (BCI) System of Records, which fully encompasses all the data that is being collected at the Anzalduas land border port of entry for the purposes of this test. The system of records notice (SORN) was published in the **Federal Register** on December 13, 2016 (81 FR 89957).

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3507(d)) requires that CBP consider the impact of paperwork and other information collection burdens imposed on the public. This information collection is covered by OMB control number 1651–0138. This information collection has been updated to include information being collected pursuant to this notice.

Dated: November 7, 2018.

Kevin K. McAleenan,

Commissioner.

[FR Doc. 2018–24850 Filed 11–13–18; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4404–DR; Docket ID FEMA–2018–0001]

Commonwealth of the Northern Mariana Islands; Amendment No. 1 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of the Northern Mariana Islands (FEMA–4404–EM), dated October 26, 2018, and related determinations.

DATES: This amendment was issued October 31, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this disaster is closed effective October 26, 2018.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–24776 Filed 11–13–18; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3408–EM; Docket ID FEMA–2018–0001]

Commonwealth of the Northern Mariana Islands; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the Commonwealth of the Northern Mariana Islands (FEMA–3408–EM), dated October 23, 2018, and related determinations.

DATES: This amendment was issued October 31, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency

Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective October 26, 2018.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–24778 Filed 11–13–18; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3406–EM; Docket ID FEMA–2018–0001]

Georgia; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the State of Georgia (FEMA–3406–EM), dated October 10, 2018, and related determinations.

DATES: This amendment was issued November 2, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective October 23, 2018.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–24736 Filed 11–13–18; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4400–DR; Docket ID FEMA–2018–0001]

Georgia; Amendment No. 4 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Georgia (FEMA–4400–DR), dated October 14, 2018, and related determinations.

DATES: This amendment was issued November 2, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the incident period for this emergency is closed effective October 23, 2018.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–24738 Filed 11–13–18; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4405–DR; Docket ID FEMA–2018–0001]

Montana; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This is a notice of the Presidential declaration of a major disaster for the State of Montana (FEMA–4405–DR), dated October 31, 2018, and related determinations.

DATES: The declaration was issued October 31, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated October 31, 2018, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''), as follows:

I have determined that the damage in certain areas of the State of Montana resulting from flooding during the period of May 1 to June 10, 2018, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the ''Stafford Act''). Therefore, I declare that such a major disaster exists in the State of Montana.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75

percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, James R. Stephenson, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of Montana have been designated as adversely affected by this major disaster:

Carbon, Custer, Golden Valley, Lewis and Clark, Missoula, Musselshell, Park, Powell, and Treasure Counties for Public Assistance.

All areas within the State of Montana are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–24784 Filed 11–13–18; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4404–DR; Docket ID FEMA–2018–0001]

Commonwealth of the Northern Mariana Islands; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the Commonwealth of the Northern Mariana Islands (FEMA–4404–DR), dated October 26, 2018, and related determinations.

DATES: This amendment was issued October 31, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the Commonwealth of the Northern Mariana Islands is hereby amended to include debris removal and permanent work among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 26, 2018.

The municipality of Rota for debris removal [Category A] (already designated for Individual Assistance and assistance for emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program).

The municipalities of Saipan and Tinian for debris removal [Category A] and permanent work [Categories C–G] (already designated for Individual Assistance and assistance for emergency protective measures [Category B], including direct federal assistance, under the Public Assistance program).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–24777 Filed 11–13–18; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4400–DR; Docket ID FEMA–2018–0001]

Georgia; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Georgia (FEMA–4400–DR), dated October 14, 2018, and related determinations.

DATES: This amendment was issued November 1, 2018.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW, Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Georgia is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of October 14, 2018.

Baker, Calhoun, Crisp, Decatur, Dougherty, Early, Grady, Laurens, Lee, Miller, Mitchell, Seminole, Sumter, Terrell, Thomas, Turner, and Worth Counties for Public Assistance [Categories C–G] (already designated for Individual Assistance and assistance for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

Bleckley, Burke, Colquitt, Dodge, Dooly, Emanuel, Houston, Jefferson, Jenkins, Johnson, Macon, Pulaski, Treutlen, and Wilcox Counties for Public Assistance [Categories C–G](already designated for debris removal and emergency protective measures [Categories A and B], including direct federal assistance, under the Public Assistance program).

Clay, Randolph, and Tift Counties for Public Assistance (already designated for Individual Assistance).

Appling, Atkinson, Bacon, Ben Hill, Berrien, Brooks, Bulloch, Candler, Chattahoochee, Coffee, Cook, Crawford, Echols, Evans, Glascock, Irwin, Jeff Davis, Jones, Marion, Peach, Putnam, Quitman, Schley, Screven, Stewart, Toombs, Twiggs, Washington, Webster, Wheeler, and Wilkinson Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034,

Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

Brock Long,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2018–24737 Filed 11–13–18; 8:45 am]

BILLING CODE 9111–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCO922000–L13100000–FI0000–19X]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease COC75893, Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of reinstatement.

SUMMARY: As provided for under the Mineral Leasing Act of 1920, as amended, the Bureau of Land Management (BLM) received a petition for reinstatement of competitive oil and gas lease COC75893 from Griffin Properties Inc. for land in Moffat County, Colorado. The lessee filed the petition on time, along with all rentals due since the lease terminated under the law. No leases affecting these lands were issued before the petition was filed. The BLM proposes to reinstate this lease.

FOR FURTHER INFORMATION CONTACT: Jonathan Fairbairn, Branch Chief, Fluid Minerals, BLM Colorado State Office, 2850 Youngfield Street, Lakewood, CO 80215, phone: (303) 239–3753, email: *jfairbairn@blm.gov.* 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. The FRS is available 24 hours a day, 7 days a week, to leave a message or questions with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The lessee agrees to the new lease terms for rentals and royalties of $10 per acre, or fraction thereof, per year, and 16 ⅔ percent, respectively. The lessee paid the required $500 administrative fee for lease reinstatement and the $159 cost of publishing this notice. The lessee met the requirements for reinstatement of the lease per Sec. 31(d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188). The BLM proposes to reinstate the lease effective April 1, 2016, under amended lease terms and the increased rental and royalty rates described above.

(Authority: 30 U.S.C. 188(e)(4) and 43 CFR 3108.2–3).

Gregory P. Shoop,

Acting BLM Colorado State Director.

[FR Doc. 2018–24862 Filed 11–13–18; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0026732; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Riverside Metropolitan Museum, Riverside, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Riverside Metropolitan Museum has completed an inventory of human remains, 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 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 should submit a written request to the Riverside Metropolitan Museum. If no additional requestors come forward, transfer of control of the human remains 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 should submit a written request with information in support of the request to the Riverside Metropolitan Museum at the address in this notice by December 14, 2018.

ADDRESSES: Robyn G. Peterson, Ph.D., Museum Director, Riverside Metropolitan Museum, 3580 Mission Inn Avenue, Riverside, CA 92501, telephone 951–826–5792, email *rpeterson@riversideca.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 under the control of the Riverside Metropolitan Museum, Riverside, CA. The human remains were removed from an unknown location, AK.

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. 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 Riverside Metropolitan Museum professional staff in consultation with representatives of Inupiat Community of the Arctic Slope.

History and Description of the Remains

At an unknown date, human remains representing, at minimum, one individual were removed from an unknown location in Alaska and entered the possession of a Captain Hammond. Captain Hammond is known to have sailed between San Francisco, CA, and Alaska in the late 19th and early 20th centuries. During this period, he acquired a collection of Inupiat objects. Upon Captain Hammond's death, the human remains and other Inupiat ethnographic materials were acquired by a collector, who donated them in 1982 to the Riverside Metropolitan Museum. No known individuals were identified. No associated funerary objects are present.

Historical records suggest Captain Hammond worked for Alaskan salmon fishing companies and his travels along the coast provided him with opportunities to interact with Alaskan coastal Inupiat peoples. This geographic evidence, and the association of these human remains within the Hammond Collection of Inupiat materials, suggests that these human remains are Inupiat. According to oral history, archaeological evidence, and ethnographic records, the Inupiat Community of the Arctic Slope are directly descended from the earlier Inupiat peoples who lived in this region.

Determinations Made by the Riverside Metropolitan Museum

Officials of the Riverside Metropolitan Museum have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice

represent the physical remains of one individual of Native American ancestry.

• Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Inupiat Community of the Arctic Slope.

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 should submit a written request with information in support of the request to Robyn G. Peterson, Ph. D., Museum Director, Riverside Metropolitan Museum, 3580 Mission Inn Avenue, Riverside, CA 92501, telephone 951–826–5792, email *rpeterson@riversideca.gov,* by December 14, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Inupiat Community of the Arctic Slope may proceed.

The Riverside Metropolitan Museum is responsible for notifying the Inupiat Community for the Arctic Slope that this notice has been published.

Dated: October 9, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–24764 Filed 11–13–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0026718; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Kansas State Historical Society, Topeka, KS

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Kansas State Historical Society 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 Kansas State Historical Society. 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 Kansas State Historical Society at the address in this notice by December 14, 2018.

ADDRESSES: Dr. Robert J. Hoard, Kansas State Historical Society, 6425 SW 6th Avenue, Topeka, KS 66615–1099, telephone (785) 272–8681 Ext. 269, email *Robert.hoard@ks.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 Kansas State Historical Society, Topeka, KS. The human remains and associated funerary objects were removed from Doniphan County, KS.

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 Kansas State Historical Society professional staff in consultation with representatives of the Kaw Nation, Oklahoma.

History and Description of the Remains

In 1963, human remains representing, at minimum, three individuals were removed from the Fanning site, 14DP1 (UBS 2015–04), in Doniphan, Kansas. The human remains are part of a larger collection donated to the Wyandotte County Historical Society and Museum by a local collector. In May 2015, the Kansas State Historical Society agreed to take these materials for the purpose of carrying out the requirements of the Native American Graves Protection and Repatriation Act (NAGPRA). Staff identified and took possession of human remains: One left tibia, one right tibia, one left femur, one right femur, one immature right radius, one left fibula diaphysis, one unidentified long bone fragment, one primary lower incisor, one secondary upper right canine, one secondary dentition tooth with significant wear, with each of these three teeth probably representing a different individual; one right side of a mandible with teeth, one right fourth metatarsal, left and right tali and naviculars, one each; one right calcaneus, one each second and third cuneiforms (19 elements/teeth). The 7 associated funerary objects identified from the 14DP1 collection are one diaphysis of an animal humerus, possibly belonging to a badger; five middle phalanges belonging to an unidentified species; and one proximal epiphyseal plate of a phalanx belonging to an unidentified species.

The site is affiliated with the Oneota archeological manifestation (A.D. 1000 to 1600), which is believed to be ancestral to the Kaw, the Otoe, or the Iowa. Several archeological sites in Kansas and Nebraska have been identified as Oneota (Ritterbush 2006:151). The Fanning site is tied both to the Oneota tradition and the historic Kansa (Buffalohead 2004:334–335; Marshall 2006:219, 230–231; 2008:87–92; O'Shea and Ludwickson 1992:16–17; Ritterbush 2006:151–152; Ritterbush and Logan 2009; Unrau 1971:19, Wedel 1959: 29, 51).

Determinations Made by the Kansas State Historical Society

Officials of the Kansas State Historical Society 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(3)(A), the seven 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 the Kaw 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 Dr. Robert J. Hoard, Kansas State Historical Society, 6425 SW 6th Avenue, Topeka, KS 66615–1099, telephone (785) 272–8681 Ext. 269, email *Robert.hoard@ks.gov,* by December 14, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Kaw Nation, Oklahoma may proceed.

The Kansas State Historical Society is responsible for notifying the Kaw Nation, Oklahoma that this notice has been published.

Dated: October 9, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–24767 Filed 11–13–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA- NPS0026865; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Army Corps of Engineers, Albuquerque District, Trinidad Lake, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The U.S. Army Corps of Engineers, Albuquerque District, has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the U.S. Army Corps of Engineers, Albuquerque District. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the U.S. Army Corps of Engineers, Albuquerque District, at the address in this notice by December 14, 2018.

ADDRESSES: U.S. Army Corps of Engineers, Albuquerque District, ATTN: George MacDonell, 4101 Jefferson Plaza NE, Albuquerque, NM 87109, telephone (505) 342–3281, email *George.H.Macdonell@usace.army.mil.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the U.S. Army Corps of Engineers, Albuquerque District. The human remains and associated funerary objects were removed from fee-titled property at Trinidad Lake, Las Animas County, CO.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Albuquerque District professional staff in consultation with representatives of the Apache Tribe of Oklahoma; Arapaho Tribe of the Wind River Reservation, Wyoming; Cheyenne and Arapaho Tribes, Oklahoma (previously listed as the Cheyenne-Arapaho Tribes of Oklahoma); Comanche Nation, Oklahoma; Fort Sill Apache Tribe of Oklahoma; Hopi Tribe of Arizona; Jicarilla Apache Nation, New Mexico; Kewa Pueblo, New Mexico (previously listed as the Pueblo of Santo Domingo); Kiowa Indian Tribe of Oklahoma; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; Navajo Nation, Arizona, New Mexico & Utah; Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana; Ohkay Owingeh, New Mexico (previously listed as the Pueblo of San Juan); Pawnee Nation of Oklahoma; 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 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 Santa Clara, New Mexico; Pueblo of Taos, New Mexico; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; Southern Ute Tribe of the Southern Ute Reservation, Colorado; Ute Mountain Ute Tribe (previously listed as the Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah); White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma; Ysleta del Sur Pueblo (previously listed as the Ysleta Del Sur Pueblo of Texas); and Zuni Tribe of the Zuni Reservation, New Mexico, hereafter referred to as ''The Consulting Tribes.''

History and Description of the Remains

Between 1963 and 1976, human remains representing, at minimum, nine individuals were removed from the Leone Bluff site, 5LA1211, in Las Animas County, CO. Excavations at the site were undertaken in advance of the construction of Trinidad Dam and Reservoir by Trinidad State Junior College archeologists Galen Baker (1963, 1965), Edwin Guilinger (1967), Stephen Ireland (1969–1972), and Gerald Bair (1975, 1976). All human remains and associated funerary objects have been stored at the Louden-Henritze Archeology Museum in Trinidad, CO, since their excavation. Individuals from the Leone Bluff site include an adult female, adult male, two infants of undetermined sex, four adolescents of undetermined sex, and an adult of undetermined sex. No known individuals were identified. The 19 associated funerary objects are: two groundstone implements, one lithic core, one lithic flake, two incised bone beads, three lots of fire-cracked rock fragments, one lot of burned jacal, one lot of bone and seed beads, one lot of snail beads, three lots of unidentified animal bone, two small lots of charcoal, one lot of micro lithic debitage, and one lot of organic material from flotation samples.

In 1963, human remains representing, at minimum, two individuals were removed from archeological site 5LA1413 in Las Animas County, CO. Excavations at the site were undertaken in advance of the construction of Trinidad Dam and Reservoir by Trinidad State Junior College archeologist Galen Baker. All human remains have been stored at the Louden-Henritze Archeology Museum in Trinidad, CO, since their excavation. The two individuals include a young adult female and an infant of

undetermined sex. No known individuals were identified. No associated funerary objects are present.

In 1952 and 1953, human remains representing, at minimum, one individual were removed from archeological site 5LA1415 in Las Animas County, CO. Excavations at the site were undertaken in advance of the construction of Trinidad Dam and Reservoir by archeologist Haldon Chase. All human remains have been stored at the Louden-Henritze Archeology Museum in Trinidad, CO, since their excavation. The individual is an adult of undetermined sex. No known individuals were identified. No associated funerary objects are present.

Between 1954 and 1977, human remains representing, at minimum, 21 individuals were removed from the Sopris archeological site, 5LA1416, in Las Animas County, CO. Archeological investigations, including excavation, were undertaken at the site in advance of the construction of Trinidad Dam and Reservoir starting in 1954 and 1957 by Herb Dick, and followed by Trinidad State Junior College archeologists Galen Baker (1964, 1965), Stephen Ireland (1970, 1971, 1972, 1974), and Gerald Bair (1975, 1976, 1977). All human remains and associated funerary objects have been stored at the Louden-Henritze Archeology Museum in Trinidad, CO, since their excavation. The 21 individuals include three infants of undetermined sex, two children of undetermined sex, two adolescents of undetermined sex, three adolescent females, one young adult of undetermined sex, one young adult male, one adult female, six adult males, and two adults of undetermined sex. No known individuals were identified. The 2,349 associated funerary objects are: 26 pieces of lithic debitage, three projectile points, one lithic biface tool, 16 faunal remains, 603 bone beads, five incised bone beads, 1,475 snail shell beads, 10 seed beads, three bone wrenches, one bone awl, 36 pottery sherds, two corn cobs, one antler tine fragment, one piece of graphite, four snail shells, 43 lots of basket and matting impressions in soil, seven lots of bulks soil samples form burials, 33 lots of unsorted flotation samples taken from burials, two lots of snail shells, one lot of shell beads, two lots of shell fragments, seven lots of snail shell beads, 17 lots of bone beads, five lots of seed beads, eight lots of seeds, 11 lots of lithic debitage, three lots of charcoal, four lots of mixed fire-cracked rock and charcoal, three lots of corn cobs, and 16 lots of faunal remains.

In 1963, human remains representing, at minimum, three individuals were removed from archeological site 5LA1418 in Las Animas County, CO. Excavations at the site were undertaken in advance of the construction of Trinidad Dam and Reservoir by Trinidad State Junior College archeologist Galen Baker. All human remains have been stored at the Louden-Henritze Archeology Museum in Trinidad, CO, since their excavation. The three individuals include an infant of undetermined sex, an adolescent of undetermined sex, and an adult male. No known individuals were identified. No associated funerary objects are present.

In 1964 and 1968, human remains representing, at minimum, five individuals were removed from the Messina Bluff site, 5LA1424, in Las Animas County, CO. Excavations at the site were undertaken in advance of the construction of Trinidad Dam and Reservoir by Trinidad State Junior College archeologists Galen Baker (1964) and Edwin Guilinger (1968). All human remains and associated funerary objects have been stored at the Louden-Henritze Archeology Museum in Trinidad, CO, since their excavation. Individuals from the Messina Bluff Site include two infants of undetermined sex, two adolescents of undetermined sex, and an adult of undetermined sex. No known individuals were identified. The seven associated funerary objects are one groundstone mano, one lithic flake, one lithic biface, one lithic core, and three faunal bones.

Between 1950 and 1972, human remains representing, at minimum, one individual were removed from archeological site 5LA1426 in Las Animas County, CO. Excavation and site collection at the site were undertaken in advance of the construction of Trinidad Dam and Reservoir by Trinidad State Junior College archeologists. All human remains have been stored at the Louden-Henritze Archeology Museum in Trinidad, CO, since their excavation. The single individual is an adolescent of undetermined sex. No known individuals were identified. No associated funerary objects are present.

In 1967, human remains representing, at minimum, one individual were removed from archeological site 5LA1450 in Las Animas County, CO. Excavation at the site was undertaken in advance of the construction of Trinidad Dam and Reservoir by Trinidad State Junior College archeologist Edwin Guilinger. All human remains have been stored at the Louden-Henritze Archeology Museum in Trinidad, CO, since their excavation. The single individual is an adolescent of undetermined sex. No known individuals were identified. No associated funerary objects are present.

In 1970, human remains representing, at minimum, two individuals were removed from archeological site 5LA1478 in Las Animas County, CO. Excavation at the site was undertaken by Trinidad State Junior College archeologist Stephen Ireland due to the discovery of human burials during gravel quarry operations. All human remains and associated funerary objects have been stored at the Louden-Henritze Archeology Museum in Trinidad, CO, since their excavation. The individuals include a middle-aged, adult female and an adolescent female. No known individuals were identified. The 188 associated funerary objects are: One shell pendant, 166 bone beads, 13 animal bone fragments, three lithic flakes, one groundstone mano, one polishing stone, one burned corn cob, one seed/nut hull, and one lot of animal bone fragments.

In 1963, human remains representing, at minimum, one individual were removed from archeological site 5LA1523 in Las Animas County, CO. Excavations at the site were undertaken in advance of the construction of Trinidad Dam and Reservoir by Trinidad State Junior College archeologist Galen Baker. All human remains have been stored at the Louden-Henritze Archeology Museum in Trinidad, CO, since their excavation. The single individual is a young adult female. No known individuals were identified. No associated funerary objects are present.

Between 1950 and 1974, human remains representing, at minimum, one individual were removed from the Blasi Place archeological site in Las Animas County, CO. Excavation at the site was undertaken by archeologist Herb Dick due to the inadvertent discovery of a human burial. All human remains have been stored at the Louden-Henritze Archeology Museum in Trinidad, CO since their excavation. The individual is an adolescent of undetermined sex. No known individuals were identified. No associated funerary objects are present.

Determinations Made by the U.S. Army Corps of Engineers, Albuquerque District

Officials of the U.S. Army Corps of Engineers, Albuquerque District have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American based on morphological characteristics of the skeletal remains, archeological context, and diagnostic artifacts associated with the human remains.

• Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 48 individuals of Native American ancestry.

• Pursuant to 25 U.S.C. 3001(3)(A), the 2,563 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.

• Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian Tribe.

• According to final judgments of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains and associated funerary objects were removed is the aboriginal land of the Jicarilla Apache Nation, New Mexico.

• Treaties in 1851 and 1865 indicate that the land from which the Native American human remains and associated funerary objects were removed is the aboriginal land of the Arapaho Tribe of the Wind River Reservation, Wyoming; Cheyenne and Arapaho Tribes, Oklahoma (previously listed as the Cheyenne-Arapaho Tribes of Oklahoma); Comanche Nation, Oklahoma; and the Kiowa Indian Tribe of Oklahoma.

• Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains and associated funerary objects may be to the Arapaho Tribe of the Wind River Reservation, Wyoming; Cheyenne and Arapaho Tribes, Oklahoma (previously listed as the Cheyenne-Arapaho Tribes of Oklahoma); Comanche Nation, Oklahoma; Jicarilla Apache Nation, New Mexico; and the Kiowa Indian Tribe of Oklahoma.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to U.S. Army Corps of Engineers, Albuquerque District, ATTN: George MacDonell, 4101 Jefferson Plaza NE, Albuquerque, NM 87109, telephone (505) 342–3281, email *George.H.Macdonell@usace.army.mil,* by December 14, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Arapaho Tribe of the Wind River Reservation, Wyoming; Cheyenne and Arapaho Tribes, Oklahoma (previously listed as the Cheyenne-Arapaho Tribes of Oklahoma); Comanche Nation, Oklahoma; Jicarilla Apache Nation, New Mexico; and the Kiowa Indian Tribe of Oklahoma may proceed.

The U.S. Army Corps of Engineers, Albuquerque District is responsible for notifying The Consulted Tribes that this notice has been published.

Dated: October 22, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–24765 Filed 11–13–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0026863; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Minnesota Historical Society, St. Paul, MN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Minnesota Historical Society, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, has determined that the cultural item listed in this notice meets the definition of unassociated funerary object. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request to the Minnesota Historical Society. If no additional claimants come forward, transfer of control of the cultural items to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim these cultural items should submit a written request with information in support of the claim to the Minnesota Historical Society at the address in this notice by December 14, 2018.

ADDRESSES: Ben Gessner, Minnesota Historical Society, 345 W. Kellogg Blvd., St. Paul, MN 55102, telephone (651) 259–3281, email *benjamin.gessner@mnhs.org.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate a cultural item under the control of the Minnesota Historical Society, St. Paul, MN, that meets the definition of unassociated funerary object under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American cultural items. The National Park Service is not responsible for the determinations in this notice.

History and Description of the Cultural Item(s)

In or around 1869, one cultural item was removed from a burial mound during construction of a street in Red Wing, MN. The associated human remains were not exhumed. The item was donated to the Minnesota Historical Society in September, 1944, by Ms. Grace E. Polk. The one unassociated funerary object is a Jefferson Peace and Friendship Medal (MNHS #8407).

A preponderance of evidence surrounding the removal of MNHS #8407—the Red Wing provenience, the association in a burial mound with skeletal remains, and the size of the medal—supports the conclusion that this medal was presented to Mdewakanton Dakota Chief Tatankamani (Walking Buffalo, also known as hereditary chief Red Wing) (d. 1829) by the United States Government in the first decade of the 19th century. Tatankamani's village was located on the eastern shores of Lake Pepin, near modern day Red Wing, MN, which bears his name. Tatankamani's descendants were removed from the area during the Treaty period, and later were forcibly removed from the state of Minnesota following the U.S.-Dakota War of 1862. Many of them were relocated to the Santee Reservation in Nebraska, although contemporary descendants can be found in many of the Dakota communities and reservations. A summary was submitted for review and consultation to representatives of Tatankamani lineal descendants, and the Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota; Flandreau Santee Sioux Tribe of South Dakota; Lower Sioux Indian Community in the State of Minnesota; Oglala Sioux Tribe (previously listed as the Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota); Prairie Island Indian Community in the State of Minnesota; Santee Sioux Nation, Nebraska; Shakopee Mdewakanton Sioux Community of Minnesota;

Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota; and the Upper Sioux Community, Minnesota (hereafter known as ''The Affiliated Tribes'').

Determinations Made by the Minnesota Historical Society

Officials of the Minnesota Historical Society have determined that:

- Pursuant to 25 U.S.C. 3001(3)(B), the one cultural item described above is reasonably believed to have been placed with or near the individual human remains of Tatankamani at the time of his death or later as part of the death rite or ceremony, and is believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual, *i.e.* the burial site of Tatankamani.
- Pursuant to 43 CFR 10.14(b), Josie Redwing and Melody Redwing are direct lineal descendants of Tatankamani, based on genealogical evidence on file with the Minnesota Historical Society.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to claim this cultural item should submit a written request with information in support of the claim to Ben Gessner, Minnesota Historical Society, 345 W. Kellogg Blvd., St. Paul, MN 55102, telephone (651) 259–3281, email *benjamin.gessner@mnhs.org,* by December 14, 2018. After that date, if no additional claimants have come forward, pursuant to 25 U.S.C. 3005(a), transfer of control of the unassociated funerary object to the lineal descendants of Tatankamani represented by Josie Redwing and Melody Redwing may proceed.

The Minnesota Historical Society is responsible for notifying Josie Redwing, Melody Redwing, and The Affiliated Tribes that this notice has been published.

Dated: October 22, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–24768 Filed 11–13–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0026864; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of the Interior, Bureau of Land Management, Idaho State Office, Boise, ID

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management, Idaho State Office (BLM) 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 Bureau of Land Management, Idaho State Office. If no additional requestors come forward, transfer of control of the human remains 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 Bureau of Land Management, Idaho State Office at the address in this notice by December 14, 2018.

ADDRESSES: F. Kirk Halford, BLM Idaho State NAGPRA Coordinator, Idaho Bureau of Land Management, 1387 South Vinnell Way, Boise, ID 83709, telephone (208) 373–4043, email *fhalford@blm.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 U.S. Department of the Interior, Bureau of Land Management, Idaho State Office, Boise, ID and housed at the Idaho Museum of Natural History, Earl H. Swanson Archaeological Repository, Idaho State University, Pocatello, ID (IMNH). The human remains and associated funerary objects were removed from Hanging Valley Cave (10JE5), Jerome County, ID, on land administered by the BLM.

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. 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 BLM and IMNH professional staff in consultation with representatives of the Shoshone-Bannock Tribes of the Fort Hall Reservation and the Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada.

History and Description of the Remains

At an unknown date, human remains representing, at minimum, one individual were removed from a crevice in Hanging Valley Cave (10JE5) in Jerome County, ID, by Gene Titmus of Twin Falls, ID. In 1962, Mr. Titmus turned over the human remains to IMNH. Forensics analysis of the two parietal cranial bones conducted by IMNH concluded the human remains were from one middle aged individual based on ''obliteration of the sagittal sutures.'' Burning on the human remains suggests they were cremated. No known individuals were identified. The seven associated funerary objects are six Rose Spring/Eastgate corner notched projectile points and one basal fragment.

Based on projectile point typology and chronologies for southern Idaho, the site can be dated to the Late Period, with a date range from A.D. 300 to 1850. As evidenced by the geographic location (Jerome County, ID), chronology of the site, archeological, ethnographic, oral history and historic evidence, the human remains and associated funerary objects are determined to be culturally affiliated to the Uto Aztecan speaking Bannock, Northern Shoshone and Northern Paiute tribes who inhabited the region during the period of use and today. The burial site is within the territory of the Northwestern Band of Shoshone Nation, the Shoshone-Bannock Tribes of the Fort Hall Reservation, Idaho, and the Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada. In consultation with the tribes, and as supported in

ethnographies, the seven projectile points determined to be associated funerary objects are the types of objects interred with burials.

Determinations Made by the Bureau of Land Management, Idaho State Office

Officials of the Bureau of Land Management, Idaho State Office have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the seven 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 Northwestern Band of Shoshone Nation (previously listed as Northwestern Band of Shoshoni Nation and the Northwestern Band of Shoshoni Nation (Washakie)); Shoshone-Bannock Tribes of the Fort Hall Reservation; and the Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada.

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 F. Kirk Halford, BLM Idaho State NAGPRA Coordinator, Idaho Bureau of Land Management, 1387 South Vinnell Way, Boise, ID 83709, telephone (208) 373–4043, email *fhalford@blm.gov,* by December 14, 2018. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to the Northwestern Band of Shoshone Nation (previously listed as Northwestern Band of Shoshoni Nation and the Northwestern Band of Shoshoni Nation (Washakie)); Shoshone-Bannock Tribes of the Fort Hall Reservation; and the Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada may proceed.

The Bureau of Land Management, Idaho State Office is responsible for notifying the Northwestern Band of Shoshone Nation (previously listed as Northwestern Band of Shoshoni Nation and the Northwestern Band of Shoshoni Nation (Washakie)); Shoshone-Bannock Tribes of the Fort Hall Reservation; and the Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada that this notice has been published.

Dated: October 22, 2018.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2018–24766 Filed 11–13–18; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

[Docket No. ONRR–2011–0018; DS63644000 DR2000000.CH7000 189D0102R2]

Notice of Audit Delegation Renewal for the States of Montana, New Mexico, and Oklahoma

AGENCY: Office of the Secretary, Office of Natural Resources Revenue, Interior.

ACTION: Notice.

SUMMARY: The Office of Natural Resources Revenue (ONRR) renewed current delegations of audit and investigation authority for the States of Montana, New Mexico, and Oklahoma. This notice gives members of the public an opportunity to review and comment on the States' delegations.

DATES: Submit written comments on or before December 14, 2018.

ADDRESSES: You may submit comments on this notice by any of the following methods:

- Electronically go to *http://www.regulations.gov.* In the entry titled ''Enter Keyword or ID,'' enter ''ONRR–2011–0018,'' and then click search. Follow the instructions to submit public comments. ONRR will post all comments.
- Email comments to Armand Southall, Regulatory Specialist, at *Armand.Southall@onrr.gov.* Please reference the Docket No. ONRR–2011–0018 in your comments.
- Hand-carry comments or use an overnight courier service. Our courier address is Building 85, Entrance N–1, Denver Federal Center, West 6th Ave. and Kipling St., Denver, Colorado 80225. Please reference the Docket No. ONRR–2011–0018 in your comments.

FOR FURTHER INFORMATION CONTACT: Mr. Patrick Milano, Indian and State Audit, ONRR; telephone (303) 231–3434; or by email to *Patrick.Milano@onrr.gov.*

SUPPLEMENTARY INFORMATION: The following officials are the State contacts for their respective proposals:

State	Department	Contact information
Montana	Montana Department of Revenue, Business, & Income Taxes.	Van Charlton, 125 North Roberts, Helena, MT 59601–4558.
New Mexico	Taxation and Revenue Department, Oil and Gas Bureau	Gilbert Martinez, 1200 South St. Francis Drive, Santa Fe, NM 87502–4034.
Oklahoma	Oklahoma State Auditor & Inspector's Office	Mark Hudson, Director, Minerals Management Division, 3020 North Stiles Avenue, Oklahoma City, OK 73105.

In accordance with 30 CFR 1227.101(b)(1), the States requested that ONRR delegate the royalty management functions of conducting audits and investigations. The States requested delegation of these functions for producing Federal oil and gas leases within the State boundaries, as applicable. This is also for other producing solid mineral or geothermal Federal leases within the States. The States did not request delegation of royalty and production reporting functions. The States included their respective budget and work plans in their respective agreement applications. In addition, the States requested ONRR to renew their delegations within the time required by 30 CFR 1227.110(b).

ONRR determined not to hold a formal hearing under 30 CFR 1227.105. Therefore, in accordance with 30 CFR 1227.107, ONRR delegated the royalty management functions of conducting audits and investigations to the States of Montana, New Mexico, and Oklahoma. The States of Montana and Oklahoma requested 100-percent funding of the delegated functions for a 3-year period beginning October 1, 2017, with the opportunity to extend for an additional 3-year period. The State of New Mexico also requested 100-percent funding of the delegated functions for a 3-year period beginning July 1, 2018, with the opportunity to extend for an additional

3-year period. The States' new audit delegation agreements with ONRR are shown in the table below:

State	Agreement No.	Term
Montana	D17AC00024	10/01/2017–9/30/2020 10/01/2020–9/30/2023
New Mexico	D18AC0004	7/01/2018–6/30/2021 7/01/2021–6/30/2024
Oklahoma	D17AC00021	10/01/2017–9/30/2020 10/01/2020–9/30/2023

Authority: 30 U.S.C. 1701 *et seq.,* Federal Oil and Gas Royalty Management Act.

James D. Steward,

Deputy Director for Office of Natural Resources Revenue.

[FR Doc. 2018–24745 Filed 11–13–18; 8:45 am]

BILLING CODE 4335–30–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Consortium for Strategic and Spectrum Mission Advanced Resilient Trusted Systems

Notice is hereby given that, on October 16, 2018, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), the Consortium for Strategic and Spectrum Mission Advanced Resilient Trusted Systems (''Consortium for Strategic'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) The identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties to the venture are: Consortium Management Group, Inc., on behalf of the Consortium for Strategic and Spectrum Mission Advanced Resilient Trusted Systems, Washington, DC; Fathom 4, LLC, Charleston, SC; Logistic Services International, Inc., Jacksonville, FL; Quantum Signal, LLC, Saline, MI; SIA Solutions, LLC, Houston, TX; and Tiburon Associates, Inc., Grand Rapids, MI.

The general area of Consortium for Strategic's planned activity is to enter into an Other Transaction Agreement (''OT Agreement'') with the U.S. Government (''Government'') (a) for the funding of certain research and development of prototype projects to enhance the capabilities of the Government in the fields of electromagnetic spectrum, trusted microelectronic and strategic missions hardware environments (''Strategic and Spectrum Mission''); (b) to participate in the establishment of sound technical and programmatic performance goals based on the needs and requirements of the Government's Technology Objectives; (c) to provide a unified voice to effectively articulate the global and strategically important role Strategic and Spectrum Mission plays in furthering national security objectives; and (d) to maximize the utilization of the Government's and Members' capabilities to effectively develop critical technologies which can be transitioned and commercialized.

Suzanne Morris,

Chief, Premerger and Division Statistics Unit, Antitrust Division.

[FR Doc. 2018–24809 Filed 11–13–18; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0135]

Proposed Extension of Information Collection; Health Standards for Diesel Particulate Matter Exposure

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor, 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 collections of information in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection for Health Standards for Diesel Particulate Matter Exposure.

DATES: All comments must be received on or before January 14, 2019.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below.

- *Federal E-Rulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments for docket number MSHA–2018–0036.
- *Regular Mail:* Send comments to USDOL–MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452.
- *Hand Delivery:* USDOL-Mine Safety and Health Administration, 201 12th Street South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

FOR FURTHER INFORMATION CONTACT: Sheila McConnell, Director, Office of Standards, Regulations, and Variances, MSHA, at *MSHA.information.collections@dol.gov* (email); (202) 693–9440 (voice); or (202) 693–9441 (facsimile).

SUPPLEMENTARY INFORMATION:

I. Background

Diesel particulate matter (DPM) is a carcinogen that consists of tiny particles present in diesel engine exhaust that can readily penetrate into the deepest recesses of the lungs. Despite ventilation, the confined underground mine work environment may contribute to significant concentrations of particles produced by equipment used in the mine. Underground miners are exposed to higher concentrations of DPM than any other occupational group. As a result, they face a significantly greater risk than other workers of developing such diseases as lung cancer, heart failure, serious allergic responses, and other cardiopulmonary problems.

The DPM regulation established a permissible exposure limit to total carbon, which is a surrogate for measuring a miner's exposure to DPM. These regulations include a number of other requirements for the protection of miners' health. The DPM regulations contain information collection requirements for underground metal nonmetal mine operators under sections 57.5060, 57.5065, 57.5066, 57.5070, 57.5071, and 57.5075(a) and (b)(3).

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information

collection related to Health Standards for Diesel Particulate Matter Exposure. MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to 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.

The information collection request will be available on *http://www.regulations.gov.* MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on *www.regulations.gov* and *www.reginfo.gov.*

The public may also examine publicly available documents at USDOL-Mine Safety and Health Administration, 201 12th South, Suite 4E401, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th floor via the East elevator.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

III. Current Actions

This request for collection of information contains provisions for Health Standards for Diesel Particulate Matter Exposure. MSHA has updated the data with respect to the number of respondents, responses, burden hours, and burden costs supporting this information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0135.

Affected Public: Business or other for-profit.

Number of Respondents: 195.

Frequency: On occasion.

Number of Responses: 54,175.

Annual Burden Hours: 9,661 hours.

Annual Respondent or Recordkeeper Cost: $431,508

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Roslyn B. Fontaine,

Certifying Officer.

[FR Doc. 2018–24788 Filed 11–13–18; 8:45 am]

BILLING CODE 4510–43–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meeting of Humanities Panel

AGENCY: National Endowment for the Humanities, National Foundation on the Arts and the Humanities.

ACTION: Notice of meeting.

SUMMARY: The National Endowment for the Humanities will hold ten meetings of the Humanities Panel, a federal advisory committee, during December 2018. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National Foundation on the Arts and Humanities Act of 1965.

DATES: See **SUPPLEMENTARY INFORMATION** for meeting dates. The meetings will open at 8:30 a.m. and will adjourn by 5:00 p.m. on the dates specified below.

ADDRESSES: The meetings will be held at Constitution Center at 400 7th Street SW, Washington, DC 20506, unless otherwise indicated.

FOR FURTHER INFORMATION CONTACT: Elizabeth Voyatzis, Committee Management Officer, 400 7th Street SW, Room 4060, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given of the following meetings:

1. Date: December 3, 2018
   This meeting will discuss applications for Humanities Connections Planning Grants, submitted to the Division of Education Programs.
2. Date: December 3, 2018
   This meeting will discuss applications for Humanities Connections Planning Grants, submitted to the Division of Education Programs.
3. Date: December 4, 2018
   This meeting will discuss applications for Humanities Connections Planning Grants, submitted to the Division of Education Programs.
4. Date: December 5, 2018
   This meeting will discuss applications for Humanities Connections Planning Grants, submitted to the Division of Education Programs.
5. Date: December 6, 2018
   This meeting will discuss applications for Humanities Connections Planning Grants, submitted to the Division of Education Programs.
6. Date: December 6, 2018
   This meeting will discuss applications for the Fellowship Programs at Independent Research Institutions grant program, submitted to the Division of Research Programs.
7. Date: December 10, 2018
   This meeting will discuss applications for the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.
8. Date: December 11, 2018
   This meeting will discuss applications for the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.
9. Date: December 12, 2018
   This meeting will discuss applications for the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.
10. Date: December 13, 2018
    This meeting will discuss applications for the Dialogues on the Experience of War grant program, submitted to the Division of Education Programs.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C., as amended. I have made this determination pursuant to the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated April 15, 2016.

Dated: November 7, 2018.

Elizabeth Voyatzis,

Committee Management Officer, National Endowment for the Humanities.

[FR Doc. 2018–24748 Filed 11–13–18; 8:45 am]

BILLING CODE 7536–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meeting; National Science Board

The National Science Board's Committee on Honorary Awards, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of a teleconference for the transaction of National Science Board business, as follows:

TIME AND DATE: November 20, 2018 from 1:00 p.m. to 2:00 p.m. EST.

PLACE: This meeting will be held by teleconference at the National Science Foundation, 2415 Eisenhower Ave., Alexandria, VA 22314.

STATUS: Closed.

MATTERS TO BE CONSIDERED: (1) Subcommittee Chair's opening remarks; (2) Review and discuss candidates for the 2018 National Science Board Honorary Awards—the Vannevar Bush Award and the NSB Public Service Award; and subcommittee Chair's closing remarks.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is: Kim Silverman, 2415 Eisenhower Ave., Alexandria, VA 22314, *ksilverm@nsf.gov,* (703) 292–7000. Meeting information and updates may be found at *http://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.* Please refer to the National Science Board website *www.nsf.gov/nsb* for general information.

Chris Blair,

Executive Assistant to the NSB Office.

[FR Doc. 2018–24923 Filed 11–9–18; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of November 12, 19, 26, December 3, 10, 17, 2018.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

MATTERS TO BE CONSIDERED:

Week of November 12, 2018

There are no meetings scheduled for the week of November 12, 2018.

Week of November 19, 2018—Tentative

There are no meetings scheduled for the week of November 19, 2018.

Week of November 26, 2018—Tentative

Thursday, November 29, 2018

9:45 a.m. Affirmation Session (Public Meeting) (Tentative)

Motion to Quash Office of Investigations Subpoena Filed by Reed College (Tentative)

Thursday, November 29, 2018

10:00 a.m. Briefing on Security Issues (Closed Ex. 1)

Week of December 3, 2018—Tentative

Monday, December 3, 2018

10:00 a.m. Briefing on Equal Employment Opportunity, Affirmative Employment, and Small Business (Public)

(Contact: Larniece McKoy Moore: 301–415–1942)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Thursday, December 6, 2018

10:00 a.m.

Meeting with Advisory Committee on Reactor Safeguards (Public)

(Contact: Mark Banks: 301–415–3718)

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of December 10, 2018—Tentative

There are no meetings scheduled for the week of December 10, 2018.

Week of December 17, 2018—Tentative

There are no meetings scheduled for the week of December 17, 2018.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.* The schedule for Commission meetings is subject to change on short notice.

The NRC Commission Meeting Schedule can be found on the internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Kimberly Meyer-Chambers, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or you may email *Patricia.Jimenez@nrc.gov* or *Wendy.Moore@nrc.gov.*

Dated at Rockville, Maryland, this 9th day of November, 2018.

For the Nuclear Regulatory Commission.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2018–24948 Filed 11–9–18; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–391; NRC–2018–0263]

Watts Bar Nuclear Plant, Unit 2

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment request; opportunity to provide comments, request a hearing and to petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Facility Operating License (FOL) No. NPF–96 for the Watts Bar Nuclear Plant (WBN), Unit 2. The proposed amendment would revise the completion date for License Condition (LC) 2.C.(5) for WBN Unit 2, regarding the completion of action to resolve the issues identified in NRC Bulletin 2012–01, ''Design Vulnerability in Electric Power System,'' from December 31, 2018, to December 31, 2019, to align with the remainder of the Tennessee Valley Authority fleet and with the nuclear industry.

DATES: Submit comments by December 14, 2018. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date. A request for a hearing or petition for leave to intervene must be filed by January 14, 2019.

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

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0263. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical

questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* May Ma, Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

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

FOR FURTHER INFORMATION CONTACT: Natreon Jordan, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–7410; email: *Natreon.Jordan@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0263 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0263.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

• *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2018–0263 in your comment submission.

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

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

II. Introduction

The NRC is considering issuance of an amendment to Facility Operating License No. NPF–96 for WBN Unit 2, located in Rhea County, Tennessee.

The proposed license amendment request would amend the WBN Unit 2, FOL No. NPF–96 for the Tennessee Valley Authority WBN Unit 2. The proposed change revises the completion date for FOL License Condition (LC) 2.C.(5) regarding the reporting of actions taken to resolve issues identified in NRC Bulletin 2012–01, ''Design Vulnerability in Electrical Power System'' (ADAMS Accession No. ML12074A115). The proposed change revises the completion date in LC 2.C.(5) from December 31, 2018 to December 31, 2019, to align with the industry's completion date in the Nuclear Energy Institute letter to the NRC, ''Industry Initiative on Open Phase Condition, Revision 2,'' dated September 20, 2018 (ADAMS Accession No. ML18268A114).

Before issuance of the proposed license amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and NRC's regulations.

The NRC has made a proposed determination that the license amendment request involves no significant hazards consideration. Under the NRC's regulations in section 50.92 of title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed changes to revise the completion date for OL Condition 2.C.(5) for WBN Unit 2 regarding the reporting of actions taken to resolve issues identified in NRC Bulletin 2012–01 from December 31, 2018, to December 31, 2019, do not affect the structures, systems, or components (SSCs) of the plant, affect plant operations, or any design function or any analysis that verifies the capability of an SSC to perform a design function. No change is being made to any of the previously evaluated accidents in the WBN dual-unit Updated Final Safety Analysis Report (UFSAR).

The proposed changes do not 1) require physical changes to plant SSCs; 2) prevent the safety function of any safety-related system, structure, or component during a design basis event; 3) alter, degrade, or prevent action described or assumed in any accident described in the WBN UFSAR from being performed because the safety-related SSCs are not modified; 4) alter any assumptions previously made in evaluating radiological consequences; or 5) affect the integrity of any fission product barrier.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The proposed changes do not introduce any new accident causal mechanisms, because no physical changes are being made to the plant, nor do they affect any plant systems that are potential accident initiators.

Therefore, the proposed change does not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The margin of safety associated with the acceptance criteria of any accident is unchanged. The proposed changes will have no effect on the availability, operability, or performance of safety-related systems and components. The proposed change will not adversely affect the operation of plant equipment or the function of equipment assumed in the accident analysis.

The proposed amendment does not involve changes to any safety analyses assumptions, safety limits, or limiting safety system settings. The changes do not adversely affect plant-operating margins or the reliability of equipment credited in the safety analyses.

Therefore, the proposed change does not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the license amendment request involves no significant hazards consideration.

The NRC is seeking public comments on this proposed determination that the license amendment request involves no significant hazards consideration. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-day notice period if the Commission concludes the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. If the Commission takes action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. If the Commission makes a final no significant hazards consideration determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any persons (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult a current copy of 10 CFR 2.309. The NRC's regulations are accessible electronically from the NRC Library on the NRC's website at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* Alternatively, a copy of the regulations is available at the NRC's Public Document Room, located at One White Flint North, Room O1–F21, 11555 Rockville Pike (first floor), Rockville, Maryland 20852. If a petition is filed, the Commission or a presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

As required by 10 CFR 2.309(d) the petition should specifically explain the reasons why intervention should be permitted with particular reference to the following general requirements for standing: (1) The name, address, and telephone number of the petitioner; (2) the nature of the petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the petitioner's interest. In accordance with 10 CFR 2.309(f), the petition must also set forth the specific contentions which the petitioner seeks to have litigated in the proceeding. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner must provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to the specific sources and documents on which the petitioner intends to rely to support its position on the issue. The petition must include sufficient information to show that a genuine dispute exists with the applicant or licensee on a material issue of law or fact. Contentions must be limited to matters within the scope of the proceeding. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to satisfy the requirements at 10 CFR 2.309(f) with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene. Parties have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that party's admitted contentions, including the opportunity to present evidence, consistent with the NRC's regulations, policies, and procedures.

Petitions must be filed no later than 60 days from the date of publication of this notice. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii). The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document.

If a hearing is requested, and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, Federally-recognized Indian Tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission no later than 60 days from the date of publication of this notice. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions set forth in this section, except that under 10 CFR 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian Tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. Alternatively, a State, local governmental body, Federally-recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

If a hearing is granted, any person who is not a party to the proceeding and is not affiliated with or represented by a party may, at the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of his or her position on the issues but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Details regarding the opportunity to make a limited appearance will be provided by the presiding officer if such sessions are scheduled.

IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing and petition for leave to intervene (petition), any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities that request to participate under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC website at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public website at *http://www.nrc.gov/site-help/electronic-sub-ref-mat.html.* A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory documents in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *https://adams.nrc.gov/ehd,* unless excluded pursuant to an order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click cancel when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or personal phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to this action, see the application for license amendment dated October 31, 2018 (ADAMS Accession No. ML18305A365).

Attorney for licensee: General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, 6A West Tower, Knoxville, TN 37902.

NRC Branch Chief: Undine Shoop.

Dated at Rockville, Maryland, on November 8, 2018.

For the Nuclear Regulatory Commission.

Farideh E. Saba,

Senior Project Manager, Plant Licensing Branch II–2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2018–24814 Filed 11–13–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Meeting of the Advisory Committee on Reactor Safeguards (ACRS); Subcommittee on Regulatory Policies and Practices

The ACRS Subcommittee on Regulatory Policies and Practices will

hold a meeting on November 14, 2018, at Three White Flint North, 11601 Landsdown Street, Conference Rooms 1C3–1C5, North Bethesda, MD 20852.

This meeting will be open to public attendance. The agenda for the subject meeting shall be as follows:

Wednesday, November 14, 2018–8:30 a.m. Until 5:00 p.m.

The Subcommittee will review the following sections of the safety evaluation associated with Tennessee Valley Authority's (TVA) Clinch River Early Site Permit (ESP) application: Meteorology (2.3); Hydrologic Engineering (2.4); Radioactive Waste Management (11); and Quality Assurance (17) and will hear presentations by and hold discussions with the NRC staff, and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Quynh Nguyen (Telephone 301–415–5844 or Email *Quynh.Nguyen@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. The public bridgeline number for the meeting is 866–822–3032, passcode 8272423. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 4, 2017 (82 FR 46312).

Detailed meeting agendas and meeting transcripts are available on the NRC website at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the website cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the Three White Flint North Building, 11601 Landsdown Street, North Bethesda, MD 20852. After registering with Security, please proceed to conference Room 1C3–1C5, located directly behind the security desk on the first floor. You may contact Mr. Theron Brown (Telephone 301–415–6702) for assistance or to be escorted to the meeting room.

Dated: November 6, 2018.

Michael Snodderly,

Acting Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2018–24749 Filed 11–13–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–458; NRC–2017–0141]

Entergy Operations, Inc., River Bend Station, Unit 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Final supplemental environmental impact statement; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a final plant-specific Supplement 58 to the Generic Environmental Impact Statement (GEIS) for License Renewal of Nuclear Plants, NUREG–1437, regarding the renewal of operating license NPF–47 for an additional 20 years of operation for River Bend Station, Unit 1 (RBS). The RBS is located in West Feliciana Parish, Louisiana.

DATES: The final supplemental environmental impact statement referenced in this document is available on November 14, 2018.

ADDRESSES: Please refer to Docket ID NRC–2017–0141 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- Federal Rulemaking website: Go to *http://www.regulations.gov* and search for Docket ID NRC–2017–0141. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The final supplemental environmental impact statement is available in ADAMS under Accession No. ML18310A072.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *Library:* The final supplemental environmental impact statement is available for public inspection at the West Feliciana Parish Library, 5114 Burnett Road, St. Francisville, Louisiana 70775.

FOR FURTHER INFORMATION CONTACT: David Drucker, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6223; email: *David.Drucker@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with § 51.118 of title 10 of the *Code of Federal Regulations,* the NRC is issuing the final Supplement 58 to the GEIS regarding the renewal of Entergy Operations, Inc. operating license NPF–47 for an additional 20 years of operation for RBS. The draft Supplement 58 to the GEIS was noticed by the NRC in the **Federal Register** on June 6, 2018 (83 FR 26310), and noticed by the Environmental Protection Agency on June 8, 2018 (83 FR 26665). The public comment period on the draft Supplement 58 to the GEIS ended on July 23, 2018, and the comments received are addressed in the final Supplement 58 to the GEIS.

II. Discussion

As discussed in Chapter 5 of the final Supplement 58 to the GEIS, the NRC determined that the adverse environmental impacts of license renewal for RBS are not so great that preserving the option of license renewal for energy-planning decisionmakers would be unreasonable.

This recommendation is based on: (1) The analysis and findings in the GEIS;

(2) information provided in the environmental report and other documents submitted by Entergy Operations, Inc.; (3) consultation with Federal, State, local, and Tribal agencies; (4) the NRC staff's independent environmental review; and (5) the NRC staff's consideration of public comments received during the scoping process and on the draft Supplement 58 to the GEIS.

Dated at Rockville, Maryland, on November 8, 2018.

For the Nuclear Regulatory Commission.

Eric R. Oesterle,

Chief, License Renewal Projects Branch, Division of Materials and License Renewal, Office of Nuclear Reactor Regulation.

[FR Doc. 2018–24813 Filed 11–13–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–295, 50–304, and 72–1037; NRC–2018–0243]

Zion*Solutions,* LLC; Zion Nuclear Power Station, Units 1 and 2; Independent Spent Fuel Storage Installation

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to a November 2, 2017, request submitted by Zion*Solutions,* for its general license to operate an independent spent fuel storage installation (ISFSI) at the Zion Nuclear Power Station (ZNPS). The exemption would allow Zion*Solutions* to deviate from the requirements in Certificate of Compliance (CoC) No. 1031, Amendment No. 6, Appendix A, Technical Specifications and Design Features for the Modular Advanced Generation Nuclear All-purpose STORage (MAGNASTOR®) System, Section 5.7, ''Training Program.''

DATES: This exemption is being issued on November 14, 2018.

ADDRESSES: Please refer to Docket ID NRC–2018–0243 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0243. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Yen-Ju Chen, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555; telephone: 301–415–1018; email: *Yen-Ju.Chen@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On February 13, 1998, Commonwealth Edison Company, the ZNPS licensee at that time, submitted a letter (ADAMS Accession No. ML15232A492) to the NRC certifying the permanent cessation of operations at ZNPS, Units 1 and 2. On March 9, 1998, Commonwealth Edison Company submitted a letter (ADAMS Accession No. ML15232A487) to the NRC certifying the permanent removal of fuel from the reactor vessels at ZNPS. On May 4, 2009, the NRC issued the Order (ADAMS Accession No. ML090930037) to transfer the ownership of the permanently shut down ZNPS facility and responsibility for its decommissioning to Zion*Solutions.* This transfer was effectuated on September 1, 2010 (ADAMS Accession No. ML102290437).

Zion*Solutions* was established solely for the purpose of acquiring and decommissioning the ZNPS facility for release for unrestricted use, while transferring the spent nuclear fuel and greater-than-Class C radioactive waste to the ZNPS ISFSI. Zion*Solutions* holds Facility Operating License Nos. DPR–39 and DPR–48, which authorize possession of spent fuel from the operation of ZNPS, Units 1 and 2, in Zion, Illinois, pursuant to part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Domestic Licensing of Production and Utilization Facilities.'' The licenses provide, among other things, that the facility must comply with all applicable NRC requirements.

Consistent with subpart K of 10 CFR part 72, ''General License for Storage of Spent Fuel at Power Reactor Sites,'' a general license is issued for the storage of spent fuel in an ISFSI at power reactor sites to persons authorized to possess or operate nuclear power reactors under 10 CFR part 50. Zion*Solutions* is currently authorized to store spent fuel at the ZNPS ISFSI under the 10 CFR part 72 general license provisions.

The conditions of the 10 CFR part 72 general license, specifically 10 CFR 72.212(a)(2), 72.212(b)(3), 72.212(b)(5)(i), and 72.212(b)(11), require a general licensee to store spent fuel in an approved spent fuel storage cask listed in 10 CFR 72.214, and to comply with the conditions specified in the cask's CoC. Zion*Solutions* previously registered to load and store spent fuel in MAGNASTOR® storage casks, as approved by the NRC under CoC No. 1031, Amendment No. 3 (ADAMS Accession No. ML14028A257) at the ZNPS ISFSI. In 2015, the NRC granted Zion*Solutions'* exemption request for CoC No. 1031, Amendment No. 3. This exemption relieved Zion*Solutions,* under CoC No. 1031, Amendment No. 3, from the requirement to develop training modules under the general licensee's systematic approach to training (SAT) that include comprehensive instructions for the operation and maintenance of the ISFSI Structures, Systems and Components (SSCs), that as defined in 10 CFR 72.3, are not important to safety (80 FR 53347). On April 17, 2017, Zion*Solutions* re-registered to load and store spent fuel in MAGNASTOR® storage casks, approved by the NRC under CoC No. 1031, Amendment No. 6 (ADAMS Accession No. ML17116A314). As a result, the 2015 exemption no longer applies and so, Zion*Solutions* has submitted this exemption request for using MAGNASTOR® storage casks under Amendment No. 6.

II. Request/Action

By letter dated November 2, 2017 (ADAMS Accession No. ML17311A148), Zion*Solutions* submitted a request for exemptions from certain requirements of 10 CFR 72.212(a)(2), 72.212(b)(5), 72.212(b)(11), and 72.214. Specifically, Zion*Solutions* has requested an exemption from the requirements of CoC No. 1031, Amendment No. 6, Appendix A, Technical Specifications

and Design Features for the MAGNASTOR® System, Section 5.7, ''Training Program.'' Upon review, NRC staff has added 10 CFR 72.212(b)(3) to the exemption for the proposed action pursuant to its authority under 10 CFR 72.7. The requirements in 10 CFR 72.212(b)(3) provide that the general licensee must ensure that each cask used by the general licensee conforms to the terms, conditions, and specifications of a CoC or an amended CoC listed in 10 CFR 72.214.

Section 5.7 in Appendix A requires the following: ''A training program for the MAGNASTOR® system shall be developed under the general licensee's systematic approach to training (SAT). Training modules shall include comprehensive instructions for the operation and maintenance of the MAGNASTOR® system and the independent spent fuel storage installation (ISFSI) as applicable to the status of ISFSI operations.'' Zion*Solutions* has stated that its training program for the MAGNASTOR® system was developed using the SAT methods. The training modules included comprehensive instructions for the operation and maintenance of the MAGNASTOR® system. The exemption request applies only to developing a training program under SAT for operation and maintenance of ISFSI SSCs, that as defined in 10 CFR 72.3, are not important to safety. If granted, Zion*Solutions* will provide training/instructions for such SSCs in accordance with manufacturer's instructions and Zion*Solutions* approved procedures, instead of developing such training and instructions using the SAT methods.

III. Discussion

Pursuant to 10 CFR 72.7, the Commission may, upon application by any interested person or upon its own initiative, grant such exemptions from the requirements of the regulations of 10 CFR part 72 as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Authorized by Law

The provisions in 10 CFR part 72 from which Zion*Solutions* is requesting an exemption require the licensee to comply with the terms, conditions, and specifications of the CoC for the approved cask model it uses. The requested exemption would also allow Zion*Solutions* to provide training/instructions in accordance with the manufacturer's instructions and Zion*Solutions* approved procedures instead of using the SAT methods for ISFSI SSCs not important to safety. Consistent with 10 CFR 72.7, the Commission may grant exemptions from the requirements of 10 CFR part 72. Additionally, as explained below, the proposed exemption will not endanger life or property or the common defense and security, and is otherwise in the public interest. Issuance of this exemption is consistent with the Atomic Energy Act of 1954, as amended, and not otherwise inconsistent with NRC's regulations or other applicable laws. Therefore, the exemption is authorized by law.

Will Not Endanger Life or Property or the Common Defense and Security

If the requested exemption is granted, Zion*Solutions* would provide training/instructions in accordance with manufacturer's instructions and Zion*Solutions* approved procedures, instead of using the SAT methods, for ISFSI SSCs not important to safety. There are no changes to design or operations of the ISFSI, and no changes to safety- or security-related components. Therefore, issuance of the exemption will not endanger life or property or the common defense and security.

Additionally, in 2015, the NRC granted a similar exemption to Zion*Solutions* that only applied to using MAGNASTOR® storage casks under Amendment No. 3. In April 2017, Zion*Solutions* re-registered to load and store spent fuel in MAGNASTOR® storage casks under Amendment No. 6 and so, the 2015 exemption no longer applies. As a result, Zion*Solutions* submitted this exemption request for using MAGNASTOR® storage casks under Amendment No. 6.

Otherwise in the Public Interest

Approval of this exemption request will only allow Zion*Solutions* to provide training that is not developed under a SAT program for ISFSI SSCs not important to safety. The costs associated with these activities are paid from the decommissioning trust fund for ZNPS. Decommissioning trust funds are funds set aside during plant operation. These funds do not belong to the utility and are retained in the public interest solely to pay for eventual decommissioning of the plant. ZNPS is currently in a decommissioning process. As such, there is a finite amount of funds, which exists to complete decommissioning activities. With regard to the subject request, exemption from implementation of this training process relieves the need to expend decommissioning trust fund resources on these additional training requirements.

NRC staff finds that the exemption is otherwise in the public interest because the resources saved from developing training activities under the SAT program can be utilized for other decommissioning activities. For example, it could reduce the time needed to complete decommissioning activities and reduce the risk of radiological effects to workers and the public and ameliorate any unexpected event.

Environmental Considerations

In reviewing this exemption request, the NRC staff also considered whether there would be any significant environmental impacts associated with the exemption. Granting this exemption from 10 CFR 72.212(a)(2), 72.212(b)(3), 72.212(b)(5)(i), 72.212(b)(11), and 72.214 only allows the licensee to develop a training program not under the SAT program for operation and maintenance of ISFSI SSCs not important to safety as defined in 10 CFR 72.3. The NRC staff has determined that this proposed action meets the categorical exclusion criteria in 10 CFR 51.22(c)(25). Specifically, the criteria under 10 CFR 51.22(c)(25)(i)–(v) are also satisfied. In its review, the NRC staff determined that approving *ZionSolutions'* request is in accordance with10 CFR 51.22(c)(25) because the exemption request: (i) Does not involve a significant hazards considerations because the requested exemption does not involve changes to the design or operation of the safety systems for the MAGNASTOR® system or ISFSI, and it would not reduce a margin of safety, nor create a new or different kind of accident from any accident previously evaluated, nor significantly increase the probability or consequences of an accident previously evaluated; (ii) would not produce a significant change in either the types or the amounts of any effluents that may be released offsite because the requested exemption neither changes the effluents nor produces additional avenues of effluent release; (iii) would not result in a significant increase in either occupational radiation exposure or public radiation exposure because the requested exemption neither introduces new radiological hazards nor increases existing radiological hazards; (iv) would not result in a significant construction impact because there is no construction activity associated with the requested exemption; and (v) would not increase either the potential for or consequences from radiological accidents because the requested exemption does not involve

any changes to the design, safety limits, or safety analysis assumptions associated with the cask system and would not create any new accident precursors. The exemption also relates solely to training requirements. Therefore this exemption is categorically excluded from further analysis under 10 CFR 51.22(c)(25)(vi)(E).

Pursuant to 10 CFR 51.22(c), no environmental impact statement or environmental assessment needs to be prepared in connection with the approval of this exemption request.

IV. Conclusions

Based on the above considerations, the NRC staff has determined, pursuant to 10 CFR 72.7, that this exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. Therefore, the Commission hereby grants Zion*Solutions* an exemption from 10 CFR 72.212(a)(2), 72.212(b)(3), 72.212(b)(5)(i), 72.212(b)(11), and 72.214, which state that the licensee shall comply with the terms, conditions, and specifications of the CoC, only with regard to the requirements of CoC No. 1031, Amendment No. 6, Appendix A, Technical Specifications and Design Features for the MAGNASTOR® System, Section 5.7, ''Training Program.'' The exemption only exempts Zion*Solutions* from the requirement to develop training modules under the SAT program that include comprehensive instructions for the operation and maintenance of the ISFSI SSCs that are not important to safety. The SAT training requirements are still applicable to all important to safety components, as required by the CoC.

The exemption is effective upon issuance.

Dated at Rockville, Maryland, on November 7, 2018

For the Nuclear Regulatory Commission.

John McKirgan,

Chief, Spent Fuel Licensing Branch, Division of Spent Fuel Management, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2018–24726 Filed 11–13–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Meeting of the Advisory Committee on Reactor Safeguards (ACRS); Subcommittee on Plant License Renewal

The ACRS Subcommittee on Plant License Renewal will hold a meeting on November 15, 2018 at U.S. Nuclear Regulatory Commission, Three White Flint North, 11601 Landsdown Street, Conference Rooms 1C3–1C5, North Bethesda, MD 20852.

The meeting will be open to public attendance. The agenda for the subject meeting shall be as follows:

Thursday November 15, 2018–8:30 a.m. until 12:00 p.m.

The Subcommittee will review the Seabrook License Renewal Amendment. The Subcommittee will hear presentations by and hold discussions with NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Kent Howard (Telephone 301–415–2989 or Email: *Kent.Howard@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Seventy-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. The public bridgeline number for the meeting is 866–822–3032, passcode 8272423. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 4, 2017 (82 FR 46312).

Detailed meeting agendas and meeting transcripts are available on the NRC website at *http://www.nrc.gov/reading-rm/doc-collections/#acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the website cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the Three White Flint North Building, 11601 Landsdown Street, North Bethesda, MD 20852. After registering with Security, please proceed to Conference Room 1C3–1C5, located directly behind the security desk on the first floor. You may contact Mr. Theron Brown (Telephone 301–415–6702) for assistance or to be escorted to the meeting room.

Dated: November 6, 2018.

Michael Snodderly,

Acting Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2018–24751 Filed 11–13–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Meeting of the Advisory Committee on Reactor Safeguards (ACRS); Subcommittee on Thermal-Hydraulic Phenomena

The ACRS Subcommittee on Thermal-Hydraulic Phenomena will hold a meeting on November 16, 2018, at the U.S. Nuclear Regulatory Commission, Three White Flint North, 11601 Landsdown Street, Conference Rooms 1C3–1C5, North Bethesda, MD 20852.

The meeting will be open to public attendance with the exception of portions that will be closed to protect information that is proprietary pursuant to 5 U.S.C. 552b(c)(4). The agenda for the subject meeting shall be as follows:

Friday, November 16, 2018–8:30 a.m. until 5:00 p.m.

The Subcommittee will conduct a meeting to learn about user needs for computer codes as applied to safety analyses in advanced non-light water reactors (non-LWRs) and accident-tolerant fuels in LWRs. The Subcommittee will hear presentations by and hold discussions with NRC staff, industry representatives, and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Weidong Wang (Telephone 301–415–6279 or Email: *Weidong.Wang@nrc.gov*) one day prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each

presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. The public bridgeline number for the meeting is 866–822–3032, passcode 8272423. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 4, 2017 (82 FR 46312).

Detailed meeting agendas and meeting transcripts are available on the NRC website at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the website cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the Three White Flint North Building, 11601 Landsdown Street, North Bethesda, MD 20852. After registering with Security, please proceed to Conference Room 1C3–1C5, located directly behind the security desk on the first floor. You may contact Mr. Theron Brown (Telephone 301–415–6702) for assistance or to be escorted to the meeting room.

Dated: November 6, 2018.

Michael Snodderly,

Acting Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2018–24750 Filed 11–13–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0094]

Information Collection: NRC Form 171, ''Duplication Request''

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, NRC Form 171, ''Duplication Request.''

DATES: Submit comments by December 14, 2018. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit comments directly to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150–0066), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street NW, Washington, DC 20503; email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: David Cullison, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0094 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal rulemaking website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0094. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2018–0094 on this website.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML18151B019. The supporting statement is available in ADAMS under Accession No. ML18298A300.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *http://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

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

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, NRC Form 171, ''Duplication Request.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on August 14, 2018, 85 FRN 40341.

1. *The title of the information collection:* Duplication Request.

2. *OMB approval number:* 3150–0066.

3. *Type of submission:* Renewal.

4. *The form number if applicable:* NRC Form 171.

5. *How often the collection is required or requested:* As needed (determined by the public ordering documents.)

6. *Who will be required or asked to respond:* Individuals, companies, or organizations requesting document duplication..

7. *The estimated number of annual responses:* 74.

8. *The estimated number of annual respondents:* 74.

9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 6.

10. *Abstract:* NRC Form 171 is used by the Public Document Room (PDR) staff members who collect information from the public requesting reproduction of publicly available documents in NRC Headquarters' PDR. The information collected on the form is necessary for the reproduction contractor to process and fulfill reproduction service orders from members of the public. Copies of the form are used by the reproduction contractor to accompany the orders. One copy of the form is kept by the contractor for their records, one copy is sent to the public requesting the documents, and the third copy (with no credit card data) is kept by the PDR staff for 90 calendar days, and then securely discarded.

Dated at Rockville, Maryland, this 8th day of November 2018.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2018–24771 Filed 11–13–18; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2018–0106]

Information Collection: Form 790, Classification Record

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, ''NRC Form 790, Classification Record.''

DATES: Submit comments by January 14, 2019. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

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

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0106. Address questions about Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–2 F43, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

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

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0106 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2018–0106. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2018–0106 on this website.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession ML18204A250. The supporting statement is available in ADAMS under Accession No. ML18173A197.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

Please include Docket ID NRC–2018–0106 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

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

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

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* NRC Form 790, ''Classification Record''.

2. *OMB approval number:* 3150–0052.

3. *Type of submission:* Extension.

4. *The form number, if applicable:* NRC Form 790.

5. *How often the collection is required or requested:* On occasion. NRC Form 790 is required each time an authorized classifier makes a classification determination to classify, declassify, or downgrade a document.

6. *Who will be required or asked to respond:* NRC licensees, licensees' contractors, and certificate holders who classify and declassify NRC information.

7. *The estimated number of annual responses:* 500.

8. *The estimated number of annual respondents:* 2.

9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 54 hours.

10. *Abstract:* Completion of the NRC Form 790 is a mandatory requirement for NRC licensees, licensees' contractors, and certificate holders who classify and declassify NRC information in accordance with Executive Order 13526, ''Classified National Security Information,'' the Atomic Energy Act, and implementing directives. The NRC uses the information on the form to report statistics related to its security classification program on an annual basis to the Information Security Oversight Office.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the estimate of the burden of the information collection accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated at Rockville, Maryland, this 8th day of November, 2018.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2018–24772 Filed 11–13–18; 8:45 am]

BILLING CODE 7590–01–P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collection for OMB Review; Comment Request; Qualified Domestic Relations Orders Submitted to PBGC

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of request for extension of OMB approval.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) is requesting that the Office of Management and Budget extend approval (with modifications), under the Paperwork Reduction Act of 1995, of the information collection related to PBGC's booklet, Qualified Domestic Relations Orders & PBGC. This notice informs the public of PBGC's request and solicits public comment on the collection.

DATES: Comments must be submitted by December 14, 2018.

ADDRESSES: Comments should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Pension Benefit Guaranty Corporation, via electronic mail at *OIRA_submission@omb.eop.gov* or by fax to (202) 395–6974.

A copy of the request will be posted on PBGC's website at *https://www.pbgc.gov/prac/laws-and-regulations/information-collections-under-omb-review.* It may also be obtained without charge by writing to the Disclosure Division of the Office of the General Counsel of PBGC, 1200 K Street NW, Washington, DC 20005–4026; faxing a request to 202–326–4042; or, calling 202–326–4040 during normal business hours (TTY users may call the Federal Relay Service toll-free at 800–877–8339 and ask to be connected to 202–326–4040). The Disclosure Division will email, fax, or mail the information to you, as you request.

FOR FURTHER INFORMATION CONTACT: Karen Levin (*levin.karen@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026, 202–326–4400, extension 3559. (TTY users may call the Federal Relay Service toll-free at 800–877–8339 and ask to be connected to 202–326–4400, extension 3559.)

SUPPLEMENTARY INFORMATION: A defined benefit pension plan that does not have enough money to pay benefits may be terminated if the employer responsible for the plan faces severe financial difficulty, such as bankruptcy, and is unable to maintain the plan. In such an event, PBGC becomes trustee of the plan and pays benefits, subject to legal limits, to plan participants and beneficiaries.

The benefits of a pension plan participant generally may not be assigned or alienated. Title I of ERISA provides an exception for domestic relations orders that relate to child support, alimony payments, or marital property rights of an alternate payee (a spouse, former spouse, child, or other dependent of a plan participant). The exception applies only if the domestic relations order meets specific legal requirements that make it a qualified domestic relations order (QDRO).

When PBGC is trustee of a plan, it reviews submitted domestic relations orders to determine whether the order is qualified before paying benefits to an alternate payee. The requirements for submitting a domestic relations order and the contents of such orders are established by statute. The models and the guidance provided by PBGC assist parties by making it easier for them to comply with ERISA's QDRO requirements in plans trusteed by PBGC; they do not create any additional requirements and result in a reduction of the statutory burden.

The existing collection of information was approved under OMB control number 1212–0054 (expires December 31, 2018). On August 31, 2018, PBGC published in the **Federal Register** (at 83 FR 44681), a notice informing the public of its intent to request an extension of this collection of information, as modified. No comments were received. PBGC is requesting that OMB extend approval of the collection with modifications for three years. The modifications requested are not material. 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.

PBGC estimates that it will receive approximately 630 domestic relations orders each year from prospective alternate payees and participants. PBGC further estimates that the total average annual burden of this collection of information will be approximately 473 hours and $945,000 based on revised estimates since publication of the notice on August 31.

Issued in Washington, DC.

Stephanie Cibinic,

Deputy Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2018–24787 Filed 11–13–18; 8:45 am]

BILLING CODE 7709–02–P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collection for OMB Review; Comment Request; Annual Reporting (Form 5500 Series)

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of request for extension of OMB approval, with modifications.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) is requesting that the Office of Management and Budget

(OMB) extend approval, with modifications, of a collection of information under the Paperwork Reduction Act of 1995, of its collection of information for Annual Reporting under OMB control number 1212–0057. This notice informs the public of PBGC's request and solicits public comment on the collection.

DATES: Comments must be submitted by December 14, 2018.

ADDRESSES: Comments should be sent to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Pension Benefit Guaranty Corporation, via electronic mail at *OIRA_submission@omb.eop.gov* or by fax to (202) 395–6974.

A copy of the request will be posted on PBGC's website at: *https://www.pbgc.gov/prac/laws-and-regulations/information-collections-under-omb-review.* It may also be obtained without charge by writing to the Disclosure Division of the Office of the General Counsel of PBGC at 1200 K Street NW, Washington, DC 20005–4026; faxing a request to 202–326–4042; or, calling 202–326–4040 during normal business hours (TTY users may call the Federal Relay Service toll-free at 800–877–8339 and ask to be connected to 202–326–4040). The Disclosure Division will email, fax, or mail the information to you, as you request.

FOR FURTHER INFORMATION CONTACT: Karen Levin (*levin.karen@pbgc.gov*), Attorney, Regulatory Affairs Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW, Washington, DC 20005–4026, 202 326–4400, extension 3559. TTY users may call the Federal Relay Service toll-free at 800–877–8339 and ask to be connected to 202–326–4400, extension 3559.

SUPPLEMENTARY INFORMATION: This information collection is needed because annual reporting to the Internal Revenue Service (IRS), the Employee Benefits Security Administration (EBSA), and the Pension Benefit Guaranty Corporation (PBGC) is required by law for most employee benefit plans. For PBGC, section 4065 of the Employee Retirement Income Security Act of 1974 (ERISA) requires annual reporting to PBGC for pension plans covered by title IV of ERISA. To accommodate these filing requirements, PBGC, IRS, and EBSA have jointly promulgated the Form 5500 Series, which includes the Form 5500 Annual Return/Report of Employee Benefit Plan and the Form 5500–SF Short Form Annual Return/Report of Small Employee Benefit Plan.

PBGC is proposing modifications to the 2019 Schedule R (Retirement Plan Information), Form 5500–SF, and Schedule SB (Single-Employer Defined Benefit Plan Actuarial Information), and their related instructions. The Schedules are part of the Form 5500 Series. These proposed modifications affect some, but not all, single-employer defined benefit plans covered by title IV of ERISA. PBGC also is proposing minor modifications to the Form 5500 Series to improve the accuracy of reported information. The modifications are described in greater detail in the supporting statement submitted to OMB with this information collection, along with PBGC's rationale for each modification.

PBGC is proposing to modify Schedule R to obtain information from single-employer plans related to unpaid minimum required contributions. Single-employer plans are required to report the amount of unpaid minimum required contributions on Schedule SB and, in most cases, report additional information about the unpaid (''missed'') contributions to PBGC on the applicable PBGC form (*i.e.,* Form 10 or Form 200). In some cases, this PBGC reporting requirement is waived (*e.g.,* if the contribution is made within 30 days of the due date). PBGC has found a significant number of plans that are required to file these PBGC form(s) do not. As part of its enforcement effort, PBGC regularly contacts plans that report unpaid contributions on Schedule SB if the applicable PBGC form is not received. With limited exception, PBGC cannot distinguish between plans that were required to report missed contributions and those that qualified for a regulatory waiver, and as a result, PBGC ends up contacting many plans for which reporting was waived. PBGC is proposing to modify Schedule R by requiring PBGC-insured single-employer plans that report unpaid minimum required contributions on Schedule SB to check a box indicating whether PBGC reporting of the missed contributions was waived or required (and if required, whether such reporting requirement has been satisfied). PBGC is proposing this addition of information to enable PBGC to limit its contact to plans that were required, but failed to, report information about unpaid contributions to PBGC.

Because many small PBGC-insured plans are not required to complete Schedule R (*i.e.,* plans that file Form 5500–SF), PBGC also is proposing to add a similar question about missed contributions to Form 5500–SF.

With regard to the Schedule SB form and instructions, PBGC is proposing to modify line 23 to eliminate three boxes representing mortality tables that are no longer applicable.

The existing collection of information was approved under OMB control number 1212–0057 (expires March 31, 2021). On August 20, 2018, PBGC published in the **Federal Register** (at 83 FR 42172), a notice informing the public of its intent to request an extension of this collection of information, as modified. PBGC received one comment in support of the collection of information. PBGC is requesting that OMB extend approval of the collection, with modifications, for three years. 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.

PBGC estimates that it will receive approximately 23,900 Form 5500 and Form 5500–SF filings per year under this collection of information. PBGC further estimates that the total annual burden of this collection of information for PBGC will be 1,200 hours and $1,531,000.

Issued in Washington, DC.

Hilary Duke,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2018–24753 Filed 11–13–18; 8:45 am]

BILLING CODE 7709–02–P

OFFICE OF PERSONNEL MANAGEMENT

Senior Executive Service—Performance Review Board

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: Notice is hereby given of the appointment of members of the OPM Performance Review Board.

FOR FURTHER INFORMATION CONTACT: Carmen Garcia, OPM Human Resources, Office of Personnel Management, 1900 E Street NW, Washington, DC 20415, (202) 606–1048.

SUPPLEMENTARY INFORMATION: Section 4314(c) (1) through (5) of Title 5, U.S.C., requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more SES performance review boards. The board reviews and evaluates the initial appraisal of a senior executive's performance by the supervisor, and considers

recommendations to the appointing authority regarding the performance of the senior executive.

The following have been designated as members of the Performance Review Board of the U.S. Office of Personnel Management:

Michael Rigas, Deputy Director, Chair
Kathleen McGettigan, Chief Management Officer
Andrea Bright, Chief Human Capital Officer
Mark Reinhold, Associate Director for Employee Services
Dennis Coleman, Chief Financial Officer
Charles Phalen, National Background Investigations Bureau Director
Kenneth Zawodny, Associate Director for Retirement Services
Alan Spielman, Healthcare and Insurance Director

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2018–24724 Filed 11–13–18; 8:45 am]

BILLING CODE 6325–45–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2019–11 and CP2019–10]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 15, 2018.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3007.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3010, and 39 CFR part 3020, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2019–11 and CP2019–10; *Filing Title:* USPS Request to Add Priority Mail Contract 472 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 6, 2018; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3020.30 *et seq.,* and 39 CFR 3015.5; *Public Representative:* Curtis E. Kidd; *Comments Due:* November 15, 2018.

This Notice will be published in the **Federal Register**.

Stacy L. Ruble,

Secretary.

[FR Doc. 2018–24725 Filed 11–13–18; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84546; File No. SR–BX–2018–051]

Self-Regulatory Organizations; Nasdaq BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Derivative Securities Traded Under Unlisted Trading Privileges

November 7, 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 October 26, 2018, Nasdaq BX, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's Rule 4421 related to derivative securities traded under unlisted trading privileges (''UTP'') to: (i) Remove the requirement in Rule 4421(a)(1) for the Exchange to file with the Commission a Form 19b–4(e) for each ''new derivative securities product'' as defined in Rule 19b–4(e) under the Act[3] (''Derivative Security'') traded under UTP; (ii) add a word that was inadvertently omitted in the previous version of Rule 4421(a)(2); and (iii) renumber the remaining provisions of Rule 4421(a) to maintain an organized rule structure. The Exchange has designated this rule change as ''non-controversial'' under Section 19(b)(3)(A) of the Act[4] and provided the Commission with the notice required by Rule 19b–4(f)(6) thereunder.[5]

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqbx.cchwallstreet.com/,* at the principal office of the Exchange, and

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(e).

[4] 15 U.S.C. 78s(b)(3)(A).

[5] 17 CFR 240.19b–4(f)(6).

at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend Rule 4421 related to derivative securities traded under UTP by: (i) Removing the requirement in Rule 4421(a)(1) for the Exchange to file with the Commission a Form 19b–4(e) for each Derivative Security; (ii) adding a word that was inadvertently omitted in the previous version of Rule 4421(a)(2); and (iii) renumbering the remaining rules of Rule 4421(a) to maintain an organized rule structure, as described below.

Rule 4421(a)(1) sets forth the requirement for the Exchange to file with the Commission a Form 19b–4(e) with respect to each Derivative Security that is traded under UTP. However, the Exchange believes that it should not be necessary to file a Form 19b–4(e) with the Commission if it begins trading a Derivative Security on a UTP basis because Rule 19b–4(e)(1) under the Act refers to the ''listing and trading'' of a ''new derivative securities product.'' The Exchange believes that the requirements of that Rule refer to when an exchange lists and trades a Derivative Security, and not when an exchange seeks only to trade such product on a UTP basis pursuant to Rule 12f–2 under the Act.[6] Therefore, the Exchange proposes to delete the requirement in current Rule 4421(a)(1) for the Exchange to file a Form 19b–4(e) with the Commission with respect to each Derivative Security it begins trading on a UTP basis.

Rule 4421(a)(2) sets forth the requirement for the Exchange to distribute an information circular prior to the commencement of trading a Derivative Security on a UTP basis. The Exchange proposes to add a ''the'' that was inadvertently omitted in the previous version of clause (c) of Rule 4421(a)(2) to enhance the readability of the Rule. This change is not substantive.

Lastly, as a result of the deletion of current Rule 4421(a)(1), the Exchange proposes to renumber current Rules 4421(a)(2)–(6), as Rules 4421(a)(1)–(5) respectively.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6(b)[7] of the Act, in general, and furthers the objectives of Section 6(b)(5) of the Act[8] in particular, in that it is 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 a national market system, and, in general, to protect investors and the public interest. Specifically, eliminating the requirement to file a Form 19b–4(e) for each Derivative Security is consistent with the Act because the regulatory requirement was not intended to apply in the context of Derivative Securities trading on a UTP basis. The proposal, moreover, will provide for a more efficient process for adding Derivative Securities to trading on the Exchange on a UTP basis.

In addition, the Exchange notes that the Commission recently approved a substantially identical proposed rule change filed by NYSE National, Inc. (''NYSE National'').[9] In particular, the Commission noted in the NYSE National Approval Order that it ''believes that the filing of a Form 19b–4(e) is not required when an Exchange is trading a new derivative securities product on a UTP basis only'' [10] and it also found that the NYSE National's proposed rule change was ''consistent with the requirements of Section 6(b)(5) of the Act.'' [11]

With respect to the addition of a ''the'' that was inadvertently omitted in the previous version of clause (c) of Rule 4421(a)(2), the Exchange believes that this change is consistent with the Act because it will improve the readability and clarity of the Rule. This change is not substantive.

Lastly, the Exchange believes that renumbering the current Rules 4421(a)(2)–(6) as Rules 4421(a)(1)–(5) is consistent with the Act because it will allow the Exchange to maintain a clear and organized rule structure, thus preventing investor confusion.

For these reasons, the Exchange believes the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.[12]

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, removing the requirement to file a Form 19b–4(e) will serve to enhance competition by providing for the efficient addition of Derivative Securities for trading under UTP on the Exchange. To the extent that a competitor marketplace believes that the proposed rule change places it at a competitive disadvantage, it may file with the Commission a proposed rule change to adopt the same or similar rule.

In addition, the proposal to add a ''the'' that was inadvertently omitted in the previous version of clause (c) of Rule 4421(a)(2) does not impact competition in any respect since it merely corrects a non-substantive rule text error.

Lastly, the proposal to renumber the current Rules 4421(a)(2)–(6) as Rules 4421(a)(1)–(5) does not impact competition in any respect since it merely maintains a clear and organized rule structure.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; or (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to

[6] 17 CFR 240.12f–2.

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *See* Securities Exchange Act Release No. 34–83289 (May 17, 2018), 83 FR 23968 (May 23, 2018) (Order Approving File No. SR–NYSENAT–2018–02) (the ''NYSE National Approval Order'').

[10] *See supra* note 9, at 23975, n.149.

[11] *See supra* note 9 at page 23975–6.

[12] *See supra* note 8.

Section 19(b)(3)(A) of the Act[13] and Rule 19b–4(f)(6) thereunder.[14]

The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. Waiving the 30-day delay would permit the Exchange to more efficiently add Derivative Securities to the Exchange under UTP without the unnecessary requirement to file a 19b–4(e) with the Commission. The Commission also notes that because the Exchange is adopting a rule that is substantially identical to a similar NYSE National rule, the proposed change does not present any new or novel issues. Thus, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest and hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.[15]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2018–051 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2018–051. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BX–2018–051 and should be submitted on or before December 5, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–24733 Filed 11–13–18; 8:45 am]

BILLING CODE 8011–01–P

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[15] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–84547; File No. SR–NYSEARCA–2018–77]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change To Amend Rule 7.44–E

November 7, 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 October 26, 2018, NYSE Arca, Inc. (''NYSE Arca'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 7.44–E, which sets forth the Exchange's Retail Liquidity Program. 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 Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.44–E, which sets forth the Exchange's Retail Liquidity Program (the ''Program''), to: (i) Expand the Program's availability to all securities traded on the Exchange; (ii) remove unused functionality by eliminating the Type 2—Retail Order and no longer permit Retail Price Improvement Orders (''RPI'') to be designated as a Mid-Point Liquidity (''MPL'') Order;[3] and (iii) offer additional functionality to RPI Orders by allowing them to include an optional offset.

The Exchange established the Program to attract retail order flow to the Exchange, and allow such order flow to receive potential price improvement.[4] The Program is currently

[3] Rule 7.31–E(d)(3).

[4] *See* Securities Exchange Act Release No. 71176 (December 23, 2013), 78 FR 79524 (December 30, 2013) (SR–NYSEArca–2013–107) (''RLP Approval Order'').

limited to trades occurring at prices equal to and greater than $1.00 a share. The program currently operates on a pilot basis and is set to expire on December 31, 2018.

Under Exchange Rule 7.44–E, a class of market participant called Retail Liquidity Providers (''RLPs'') [5] and non-RLP member organizations are able to provide potential price improvement to retail investor orders in the form of a non-displayed order that is priced better than the best protected bid or offer (''PBBO''), called an RPI. When there is an RPI in a particular security priced at least $0.001 better than the PBB or PBO, the Exchange disseminates an indicator, known as the Retail Liquidity Identifier (''RLI''), that such interest exists. Retail Member Organizations (''RMOs'') can submit a Retail Order to the Exchange, which interacts, to the extent possible, with available contra-side RPIs and orders with a working price between the PBBO. The segmentation in the Program allows retail order flow to receive potential price improvement as a result of their order flow being deemed more desirable by liquidity providers.[6]

Expansion of Program's Scope

The Exchange proposes to expand the Program's availability to all securities traded on the Exchange. Today, the Program is limited to NYSE Arca-listed securities and UTP Securities. Securities listed on the New York Stock Exchange LLC (''NYSE'') are specifically excluded from the Program. Rule 7.44–E(a)(4), therefore, states that a RPI Order is ''non-displayed interest in NYSE Arca-listed securities and UTP Securities, excluding NYSE-listed (Tape A) securities, that would trade at prices better than the PBB or PBO by at least $0.001 and that is identified as such.'' To expand the Program to all securities traded on the Exchange, including NYSE-listed securities, the Exchange proposes to amend Rule 7.44–E(a)(4) to provide that a RPI Order is ''non-displayed interest that would trade at prices better than the PBB or PBO by at least $0.001 and that is identified as such.'' This language is similar to that of Cboe BYX Exchange, Inc. (''BYX''), which also operates a retail price improvement program that is available to all securities trading on BYX.[7]

Elimination of Type 2—Retail Orders

The Exchange proposes to amend Rule 7.44–E(k) to remove unused functionality by eliminating the Type 2—Retail Order. As a result, the Exchange would now offer a single category of Retail Orders. To date, the Exchange has not received a Retail Order designated as Type 2 and, therefore, proposes to no longer support this functionality.

Rule 7.44–E(a)(3) defines a ''Retail Order'' as an agency order or a riskless principal order that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by an RMO, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. Under Rule 7.44–E(k), an RMO may designate how their Retail Order interacts with available contra-side interest by designating it as either a Type 1 or Type 2 Retail Order.

A Type 1—Retail Order to buy (sell) is a Limit Immediate-or-Cancel (''IOC'') Order that will trade only with available Retail Price Improvement Orders to sell (buy) and all other orders to sell (buy) with a working price below (above) the PBO (PBB) on the NYSE Arca Book and will not route. The quantity of a Type 1—Retail Order to buy (sell) that does not trade with eligible orders to sell (buy) will be immediately and automatically cancelled. A Type-1 designated Retail Order will be rejected on arrival if the PBBO is locked or crossed.

A Type 2—Retail Order may be a Limit Order designated IOC or Day or a Market Order, and functions as follows:

- A Type 2—Retail Order IOC to buy (sell) is a Limit IOC Order that will trade first with available Retail Price Improvement Orders to sell (buy) and all other orders to sell (buy) with a working price below (above) the PBO (PBB) on the NYSE Arca Book. Any remaining quantity of the Retail Order will trade with orders to sell (buy) on the NYSE Arca Book at prices equal to or above (below) the PBO (PBB) and will be traded as a Limit IOC Order and will not route.
- A Type 2—Retail Order Day to buy (sell) is a Limit Order that will trade first with available RPI Orders to sell (buy) and all other orders to sell (buy) with a working price below (above) the PBO (PBB) on the NYSE Arca Book. Any remaining quantity of the Retail Order, if marketable, will trade with orders to sell (buy) on the NYSE Arca Book or route, and if non-marketable, will be ranked in the NYSE Arca Book as a Limit Order.
- A Type 2—Retail Order Market to buy (sell) is a Market Order that will trade first with available Retail Price Improvement Orders to sell (buy) and all other orders to sell (buy) with a working price below (above) the NBO (NBB). Any remaining quantity of the Retail Order will function as a Market Order.

The Exchange proposes to no longer offer the Type 2—Retail Order and delete all references to it in Rule 7.44–E. Rule 7.44–E(k) would be amended to delete subparagraph (2) that describes the operation of the Type 2—Retail Order. The Exchange would continue to offer Type 1—Retail Orders, which would be referred to as ''Retail Orders'' in Rule 7.44–E(k) and described as:

''[a] Retail Order to buy (sell) is a Limit IOC Order that will trade only with available Retail Price Improvement Orders to sell (buy) and all other orders to sell (buy) with a working price below (above) the PBO (PBB) on the NYSE Arca Book and will not route. The quantity of a Retail Order to buy (sell) that does not trade with eligible orders to sell (buy) will be immediately and automatically cancelled. A Retail Order will be rejected on arrival if the PBBO is locked or crossed.''

The Exchange does not propose to amend the operation of Retail Orders. The proposed text is substantially similar to current Rule 7.44–E(k)(1) with minor changes to remove references to ''Type 1''.

The Exchange also proposes to make related changes to Rule 7.44–E(l). First, the last sentence in the first paragraph (l) would be amended to no longer state that any remaining unfilled quantity of a Retail Order posts to the NYSE Arca Book. Only Type 2—Retail Orders designated as Day were able to be posted the NYSE Arca Book and would no longer be offered by the Exchange. Retail Orders would be Limit IOC orders and would either execute or be cancelled upon entry and, therefore, never post to the NYSE Arca Book. As such, the last sentence of the first paragraph Rule 7.44–E(l) would be amended to remove a reference to posting to the NYSE Arca Book and state, ''[a]ny remaining unfilled quantity of the Retail Order will cancel or execute [sic] in accordance with Rule 7.44–E(k).'' The Exchange notes that treating all Retail Orders as IOC is similar to that of BYX and the Exchange's affiliate, NYSE, both of

[5] The Program also allows for RLPs to register with the Exchange. However, any firm can enter RPI orders into the system.

[6] RLP Approval Order, 77 FR at 79528.

[7] *See* BYX Rule 11.24(a)(3). *See* Securities Exchange Act Release No. 68303 (November 27, 2012), 77 FR 71652 (December 3, 2012) (''BYX RPI Approval Order''). *See also* and NASDAQ Stock Market LLC (''NASDAQ'') Rule 4780(a)(3). *See* Securities Exchange Act Release No. 69837 (February 15, 2013), 78 FR 12397 (February 22, 2013) (''NASDAQ RPI Approval Order''). *See also* Securities Exchange Act Release No. 75252 (June 22, 2015), 80 FR 36866 (June 26, 2015) (SR–NASDAQ–2015–024) (removing NASDAQ's Retail Price Improvement Program from its rules).

which also operate retail price improvement programs that treats their similar retail orders as IOC.[8]

The Exchange also proposes to remove from Rule 7.44–E(l) an example that describes the operation of a Type 2—Retail Order and to replace all references to Type 1—Retail Orders in the remaining examples with the term Retail Order.

RPI Orders

The Exchange proposes to remove unused functionality by no longer permitting RPI Orders to be designated as MPL Orders. The Exchange also proposes to offer additional functionality to RPI Orders by allowing them to include an optional offset.

RPIs are non-displayed and only execute against Retail Orders. RPIs are generally entered at a single limit price, rather than being pegged to the PBBO. One exception is that a RPI Order could also be designated as an MPL Order, in which case the order would be pegged to the midpoint of the PBBO and re-priced as the PBBO changes.

Designation as MPL Orders. The Exchange proposes to remove unused functionality that permits RPI Orders to be designated as MPL Orders. Rule 7.44–E(a)(4)(D) currently states that ''[a]n RPI must be designated as either a Limit Non-Displayed Order or MPL Order, and an order so designated will interact with incoming Retail Orders only and will not interact with either a Type 2—Retail Order Day or Type 2—Retail Order Market that is resting on the NYSE Arca Book.'' The Exchange notes that to date all RPI Orders have been designated as Non-Displayed Limit Orders, not MPL Orders.

As proposed, RPI Orders could no longer be designated as MPL Orders. To effect this change, the Exchange proposes to revise the above-referenced sentence from Rule 7.44–E(a)(4)(D) to provide instead that ''[a]n RPI . . . will interact with incoming Retail Orders only.'' The remaining text of the current rule is no longer necessary because the reference to Non-Displayed Limit Orders is superfluous as RPI Orders by definition are non-displayed and must include a limit price.[9] Further, references to Type 2—Retail Orders are unnecessary because they would no longer be offered by the Exchange, as proposed above.

Optional Offset Functionality. The Exchange proposes to allow RPIs to include an optional offset. Rule 7.44–E(a)(4) would be amended to include new paragraph (a)(4)(C)[10] that would provide that an RPI may include an optional offset, which may be specified up to three decimals. The working price of an RPI to buy (sell) with an offset would be the lower (higher) of the PBB (PBO) plus (minus) the offset or the limit price of the RPI. An RPI with an offset would not be eligible to trade if the working price is below $1.00. If an RPI to buy (sell) with an offset would have a working price that is more than three decimals, the working price would be truncated to three decimals.

RPIs that include an offset would interact with Retail Orders as follows. Assume an RLP enters RPI sell interest with an offset of $0.001 and a limit price of $10.10 while the PBO is $10.11. The RPI could interact with an incoming buy Retail Order at $10.109. If the PBO changes to $10.12, the RPI could interact with an incoming buy Retail Order at $10.119. If, however, the PBO changes again to $10.10, the RPI could not interact with the Retail Order because the price required to deliver the minimum $0.001 price improvement ($10.099) would violate the RLP's limit price of $10.10.

If an RLP otherwise enters an offset greater than the minimum required price improvement and the offset would produce a price that would violate the RLP's limit price, the offset would be applied only to the extent that it respects the RLP's limit price. By way of illustration, assume RPI buy interest is entered with an offset of $0.005 and a limit price of $10.112 while the PBB is at $10.11. The RPI could interact with an incoming sell Retail Order at $10.112, because it would produce the required price improvement without violating the RLP's limit price, but it could not interact above the $10.112 limit price.

The Exchange proposes to make a related change to Rule 7.16–E(f)(5)(C) to specify that, like Pegged Orders and MPL Orders, RPIs with an offset would use the National Best Bid (''NBB'') instead of the PBB as the reference price when a Short Sale Price Test is triggered pursuant to Rule 201 of Regulation SHO.[11]

* * * * *

The Exchange anticipates implementing this proposed rule change in the second quarter of 2019, subject to Commission approval, and will publicly announce the exact implementation date by Trader Update.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(5) of the Act,[13] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. As explained below, the proposed rule change would further align the Program with that offered by the Exchange's affiliate, NYSE, by adopting optional offset functionality for RPIs and removing unused functionality that is not offered by the NYSE. The proposal also expands the scope of the Program to mirror that of BYX and improve the Program's overall competiveness. Each portion of the proposal is based on the rules of NYSE and/or BYX, and, therefore, does not raise any new or novel issues not already considered by the Commission. First, the proposal to expand the Program to include all securities traded on the Exchange is identical to the scope of a similar retail order price improvement program operated by BYX. Second, the proposal provide RLPs with greater pricing flexibility in the form of an optional offset for their RPIs is based on the rules of its affiliate, NYSE, and BYX, both of which permit their equivalent RPI Orders to include an offset. Lastly, the proposal to eliminate Type 2—Retail Orders and RPIs designated as MPL Orders is based on the rules of its affiliate, NYSE, or BYX, neither of which offer similar functionality as part of their respective retail price improvement programs.

Expansion of Program's Scope. The Exchange believes expanding the Program's availability to all securities traded on the Exchange would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest by enabling Retail Orders in all securities to participate in the Program

[8] *See* NYSE Rule 107C(k). *See also* BYX Rule 11.24(f).

[9] Under Rule 7.44–E(a).

[10] The Exchange proposes to renumber the remaining paragraphs under Rule 7.44–E(a)(4) accordingly.

[11] 17 CFR 242.201.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

and receive potential price improvement. The proposal should benefit retail investors by providing increased opportunities for price improvement in any security traded on the Exchange. The proposed scope of the Program would improve its competitiveness because it would be identical to BYX, which also operates a retail price improvement program that is available to all securities traded on BYX.[14]

Type 2—Retail Orders. The Exchange believes that its proposal to eliminate the Type 2—Retail Order would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system by simplifying and streamlining the operation of Retail Orders. To date, the Exchange has not received a Retail Order designated as Type 2 for participation in the Program. Therefore, no longer offering the Type 2—Retail Order should not impact market participants' trading activity and would serve to remove unused functionality from the Program and the Exchange's rules. The Proposal would also simplify the operation of the Program and allow the Exchange to no longer support functionality that is not utilized. Lastly, the proposal would result in all Retail Orders being treated as IOC, which is identical to the treatment of retail orders on the Exchange's affiliate, NYSE, and BYX, both of which execute Retail Orders upon entry or cancel.[15]

RPI Orders Designated as MPL Orders. The Exchange believes that its proposal to no longer permit RPI Orders to be designated as MPL Orders would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system by simplifying and streamlining the operation of RPIs. The Exchange notes that to date, all RPIs have been designated as Limit Orders, not MPL Orders. ETP Holders that that wish to interact with Retail Orders at the midpoint are not limited to utilizing RPI Orders designated as MPL Orders and may enter an MPL Order generally to interact with Retail Orders at the midpoint of PBBO. Therefore, elimination of this functionality from the Program would have little to no impact on an ETP Holder's trading activity. The Exchange also notes that similar functionality is not offered as part of the retail price improvement programs operated by BYX and NYSE, neither of which specifically permit their retail price improvement orders to be designated as midpoint only order types.[16]

Options Offset Functionality. The Exchange believes that providing the option for RPI Orders to include an offset would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest by enhancing the operation of the Program while creating additional price improvement opportunities for retail investors and their order flow. The proposed rule change should encourage RLPs and non-RLP member organizations to enter RPI Orders by allowing them to include an offset amount by which it is willing to improve the PBBO, subject to a the limit price of the order. Absent the ability, RLPs would only be able to enter RPIs with a single limit price. The ability to add an offset would provide RLPs with increased control over their RPIs as well as greater pricing flexibility. The anticipated increased availability of RPIs would, therefore, facilitate transactions in securities, remove impediments to, and perfect the mechanisms of a free and open market and a national market system by increasing price improvement opportunities on the Exchange for retail order flow. The proposed rule change is based on and would operate in an identical manner as the rules of its affiliate, NYSE,[17] and BYX,[18] both of which permit their equivalent RPI Orders to include an optional offset.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[19] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because it should promote competition for retail order flow among exchanges and execution venues. The proposed rule change to expand the Program to include all securities traded on the Exchange and to allow RPIs to include an optional offset should increase competition because it would enable the Exchange to better compete with similar programs on other exchanges, such as BYX, that are of similar scope and offer the same functionality.

The proposal to eliminate Type 2—Retail Orders and RPIs designated as MPL Orders are not intended to have a competitive impact. These changes simply remove functionality from the Program that has not been used at all to date.

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 *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–2018–77 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–2018–77. 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

[14] *See* BYX Rule 11.24(a)(3).

[15] *See* NYSE Rule 107C(k). *See also* BYX Rule 11.24(f).

[16] *See* BYX Rule 11.24(f). *See* NYSE Rule 107C(a)(4)(B). *See also* Securities Exchange Act Release No. 67347 (July 3, 2012), 77 FR 40673 (July 10, 2012) (Order approving SR–NYSE–2011–55).

[17] *See* NYSE Rule 107C(a)(4)(B).

[18] *See* BYX Rule 11.24(a)(3).

[19] 15 U.S.C. 78f(b)(8).

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 offices 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–2018–77 and should be submitted on or before December 5, 2018.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2018–24732 Filed 11–13–18; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 10607]

E.O. 13224 Designation of Jawad Nasrallah, aka, Mohammad Jawad Nasrallah, aka Juad Nasrallah, as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the person known as Jawad Nasrallah, also known as Mohammad Jawad Nasrallah, also known also Juad Nasrallah, committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This determination shall be published in the **Federal Register**.

Dated: August 27, 2018.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2018–24843 Filed 11–13–18; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 10605]

Review of the Designation as a Foreign Terrorist Organization of Hizballah (and Other Aliases)

Based upon a review of the Administrative Record assembled pursuant to Section 219(a)(4)(C) of the Immigration and Nationality Act, as amended (8 U.S.C. 1189(a)(4)(C)) (''INA''), and in consultation with the Attorney General and the Secretary of the Treasury, I conclude that the circumstances that were the basis for the designation of the aforementioned organization as a Foreign Terrorist Organization have not changed in such a manner as to warrant revocation of the designation and that the national security of the United States does not warrant a revocation of the designation.

Therefore, I hereby determine that the designation of the aforementioned organization as a Foreign Terrorist Organization, pursuant to Section 219 of the INA (8 U.S.C. 1189), shall be maintained.

This determination shall be published in the **Federal Register**.

Dated: July 23, 2018.

Michael R. Pompeo,

Secretary of State, Department of State.

Editorial Note: This document was received for publication by the Office of the Federal Register on November 8, 2018.

[FR Doc. 2018–24840 Filed 11–13–18; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 10608]

E.O. 13224 Designation of Al-Mujahidin Brigades, aka Khatib Al-Mujahidin, aka Holy Warriors Battalion, aka Al Mujahideen Brigades, aka Ansar al-Mujahidin Movemement as a Specially Designated Global Terrorist

Acting under the authority of and in accordance with section 1(b) of Executive Order 13224 of September 23, 2001, as amended by Executive Order 13268 of July 2, 2002, and Executive Order 13284 of January 23, 2003, I hereby determine that the person known as Al-Mujahidin Brigades, also known as Khatib Al-Mujahidin, also known as Holy Warriors Battalion, also known as Al Mujahideen Brigades, also known as Ansar al-Mujahidin Movemement, committed, or poses a significant risk of committing, acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of Executive Order 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This notice shall be published in the **Federal Register**.

Dated: September 12, 2018.

Michael R. Pompeo,

Secretary of State.

[FR Doc. 2018–24841 Filed 11–13–18; 8:45 am]

BILLING CODE 4710–AD–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36241]

Coos Bay Rail Line, Inc.—Change in Operators Exemption—Coos Bay Railroad Operating Company, LLC d/b/a Coos Bay Rail Link

Coos Bay Rail Line, Inc. (Coos Rail), has filed a verified notice of exemption under 49 CFR 1150.31 to assume operations over two interconnected railroad lines (the Line) owned by Oregon International Port of Coos Bay (the Port). The Line extends from milepost 652.114 at Danebo, Or., to

[20] 17 CFR 200.30–3(a)(12).

milepost 763.13 at Cordes, Or.; and from milepost 763.13 at Cordes to milepost 785.5 at Coquille, Or., a total distance of approximately 133 miles. The Line is currently operated by Coos Bay Railroad Operating Company, LLC d/b/a Coos Bay Rail Link (CBR). The verified notice states that the Port formed Coos Rail to operate the Line on its behalf.[1] Upon consummation of the subject transaction, Coos Rail will succeed and replace CBR as rail common carrier on the Line. Coos Rail states that CBR has advised Coos Rail that it does not object to the proposed change in operators and that it will cooperate in the transition.

The transaction is related to a concurrently filed verified notice of exemption in *Oregon International Port of Coos Bay—Continuance in Control Exemption—Coos Bay Rail Line, Inc.,* Docket No. FD 36242, in which the Port seeks to continue in control of Coos Rail upon Coos Rail's becoming a Class III rail carrier.

Coos Rail certifies that the proposed change in operators transaction and Coos Rail's anticipated operation of the Line do not involve any provision or agreement that would limit future interchange with a third-party connecting carrier. Further, Coos Rail certifies that its projected annual rail revenues as a result of the transaction will not exceed $5 million and will not result in Coos Rail's becoming a Class II or Class I rail carrier. Under 49 CFR 1150.32(b), a change in operator requires that notice be given to shippers. Coos Rail states that it provided notice of the proposed change in operators to the shippers on the Line.

The earliest this transaction may be consummated is November 28, 2018, the effective date of exemption (30 days after the verified notice was filed).[2]

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than November 21, 2018.[3]

An original and 10 copies of all pleadings, referring to Docket FD 36241, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606.

Board decisions and notices are available on our website at *www.stb.gov.*

Decided: November 8, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2018–24839 Filed 11–13–18; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36242]

Oregon International Port of Coos Bay—Continuance in Control Exemption—Coos Bay Rail Line, Inc.

Oregon International Port of Coos Bay (the Port) filed a verified notice of exemption pursuant to 49 CFR 1180.2(d)(2) to continue in control of Coos Bay Rail Line, Inc. (Coos Rail), a nonprofit corporate entity under the control of the Port, upon Coos Rail's becoming a Class III rail carrier.

The transaction is related to a concurrently filed verified notice of exemption in *Coos Bay Rail Line, Inc.—Change in Operators Exemption—Coos Bay Railroad Operating Company, LLC d/b/a Coos Bay Rail Link,* Docket No. FD 36241. In that proceeding, Coos Rail seeks an exemption under 49 CFR 1150.31 to replace Coos Bay Railroad Operating Company, LLC d/b/a Coos Bay Rail Link as the operator of two interconnected railroad lines owned by the Port, extending from milepost 652.114 at Danebo, Or., to milepost 763.13 at Cordes, Or.; and from milepost 763.13 at Cordes to milepost 785.5 at Coquille, Or., a total of approximately 133 miles (collectively, the Line).

The earliest this transaction may be consummated is November 28, 2018, the effective date of the exemption (30 days after the verified notice was filed).[1] The Port states that it intends to consummate the transaction no later than November 28, 2018.

The Port is a Class III rail carrier and will continue in control of Coos Rail upon Coos Rail's becoming a Class III rail carrier. The Line is the only rail line owned or operated by the corporate family, and therefore: It does not connect with any other railroads in the corporate family; and the continuance in control is not part of series of anticipated transactions that would connect the Line with any other railroad in the corporate family. Furthermore, the transaction does not involve a Class I rail carrier. Therefore, the transaction is exempt from the prior approval requirements of 49 U.S.C. 1180.2(d)(2).

Under 49 U.S.C. 10502(g), the Board may not use its exemption authority to relieve a rail carrier of its statutory obligation to protect the interests of its employees. Section 11326(c), however, does not provide for labor protection for transactions under sections 11324 and 11325 that involve only Class III rail carriers. Accordingly, the Board may not impose labor protective conditions here because all the carriers involved are Class III carriers.

If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Stay petitions must be filed no later than November 21, 2018.[2]

An original and 10 copies of all pleadings, referring to Docket No. FD 36242, must be filed with the Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001. In addition, one copy of each pleading must be served on Robert A. Wimbish, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 800, Chicago, IL 60606.

Board decisions and notices are available on our website at *www.stb.gov.*

Decided: November 8, 2018.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2018–24838 Filed 11–13–18; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee; Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

[1] According to the verified notice, Coos Rail is a public, nonprofit corporation formed and controlled by the Port.

[2] On October 31, 2018, Coos Rail filed a petition for partial waiver of 49 CFR 1150.32(b) to permit the exemption to become effective by no later than November 19, 2018, instead of the standard 30 days after the verified notice was filed. The waiver request will be addressed in a separate Board decision.

[3] Should the Board grant Coos Rail's waiver request and accelerate the effective date of the exemption, the due date for stay petitions may be revised accordingly.

[1] On October 31, 2018, the Port filed a petition for partial waiver of 49 CFR 1180.4(g)(1) to permit the exemption to become effective by no later than November 19, 2018, instead of the standard 30 days after the verified notice was filed. The waiver request will be addressed in a separate Board decision.

[2] Should the Board grant Coos Rail's waiver request and accelerate the effective date of the exemption, the due date for stay petitions may be revised accordingly.

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 December 13, 2018, starting at 1:00 p.m. Eastern Standard Time. Arrange oral presentations by November 26, 2018.

ADDRESSES: The meeting will take place at the Federal Aviation Administration, McCracken/Huerta Collaboration 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 December 12, 2018, at the Federal Aviation Administration, McCracken/Huerta Collaboration 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 November 26, 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 November 26 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 October 22, 2018.

Lirio Liu,

Designated Federal Officer, Aviation Rulemaking Advisory Committee.

[FR Doc. 2018–24720 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2018–0319]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillators

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemption; request for comments.

SUMMARY: FMCSA announces receipt of applications from four individuals for an exemption from the prohibition in the Federal Motor Carrier Safety Regulations (FMCSRs) against operation of a commercial motor vehicle (CMV) by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive heart failure. If granted, the exemptions would enable these individuals with implantable cardioverter defibrillators (ICDs) to operate CMVs in interstate commerce.

DATES: Comments must be received on or before December 14, 2018.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket ID FMCSA–2018–0319 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224,Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2018–0319), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. 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 that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* put the docket number, FMCSA–2018–0319, in the keyword box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box on 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.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2018–0319, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document 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., ET, Monday through Friday, except Federal holidays.

C. 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.*

II. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the FMCSRs for a five-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The four individuals listed in this notice have requested an exemption from 49 CFR 391.41(b)(4). Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

The physical qualification standard found in 49 CFR 391.41(b)(4) states that a person is physically qualified to drive a CMV if that person has no current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive cardiac failure.

In addition to the regulations, FMCSA has published advisory criteria [1] to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. [49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section *D. Cardiovascular: § 391.41(b)(4),* paragraph 4.] The advisory criteria states that ICDs are disqualifying due to risk of syncope.

III. Qualifications of Applicants

Herman L. Bolton

Mr. Bolton is a Class A CDL holder in Louisiana. A June 29, 2018 report from Mr. Bolton's cardiologist states his ICD was implanted August 25, 2017, and that Mr. Bolton reports no complaints of syncope.

Robert A. Crawley

Mr. Crawley is a commercial motor vehicle driver in Maryland. A September 13, 2018, report from his cardiologist states his ICD was implanted August 24, 2016, and that he denies any symptoms of device malfunction, arrhythmia recurrence, palpitations, syncope, or shocks.

Paul J. Hill

Mr. Hill is a commercial motor vehicle driver in South Dakota. A September 25, 2018 letter from Mr. Hill's electrophysiologist reports that his ICD was implanted November 27, 2013, and that he has been stable and has not had any shocks from his device.

Johnny L. Walls, Jr.

Mr. Walls is Class A CDL holder in Alabama. A September 7, 2018 letter from his electrophysiologist reports that his ICD was implanted August 13, 2018 and he has had no shocks since his hospital discharge on August 22, 2018.

IV. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the dates section of the notice.

[1] See *http://www.ecfr.gov/cgi-bin/text-idx?SID=e47b48a9ea42dd67d999246e23d97970&mc=true&node=pt49.5.391&rgn=div5#ap49.5.391_171.a* and *https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.*

Issued on: November 5, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018–24855 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2018–0136]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemption; request for comments.

SUMMARY: FMCSA announces receipt of applications from 30 individuals for an exemption from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. If granted, the exemptions would enable these hard of hearing and deaf individuals to operate CMVs in interstate commerce.

DATES: Comments must be received on or before December 14, 2018.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA–2018–0136 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal

holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2018–0136), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. 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 that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* put the docket number, FMCSA–2018–0136, in the keyword box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box on 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.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2018–0136, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document 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., ET, Monday through Friday, except Federal holidays.

C. 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.*

II. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the FMCSRs for a five-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The 30 individuals listed in this notice have requested an exemption from the hearing requirement in 49 CFR 391.41(b)(11). Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

The physical qualification standard for drivers regarding hearing found in 49 CFR 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, 35 FR 6458, 6463 (April 22, 1970) and 36 FR 12857 (July 3, 1971).

On February 1, 2013, FMCSA announced in a Notice of Final Disposition titled, Qualification of Drivers; Application for Exemptions; National Association of the Deaf, (78 FR 7479), its decision to grant requests from 40 individuals for exemptions from the Agency's physical qualification standard concerning hearing for interstate CMV drivers. Since the February 1, 2013 notice, the Agency has published additional notices granting requests from hard of hearing and deaf individuals for exemptions from the Agency's physical qualification standard concerning hearing for interstate CMV drivers.

III. Qualifications of Applicants

Andy R. Bernard

Mr. Bernard, age 60, holds a class A CDL in Ohio.

William Brogni

Mr. Brogni, age 55, holds an operator's license in Florida.

Robert Chavez

Mr. Chavez, age 28, holds an operator's license in Texas.

David Chellin

Mr. Chellin, age 64, holds a class A CDL in Minnesota.

Joshua P. Cogan

Mr. Cogan, age 25, holds an operator's license in Maryland.

Joseph A. Conversa

Mr. Conversa, age 49, holds an operator's license in Illinois.

Robert E. Cottrell

Mr. Cottrell, age 68, holds an operator's license in Oregon.

Joseph N. Dooley

Mr. Dooley, age 29, holds an operator's license in Missouri.

Janet Donaldson

Ms. Donaldson, age 40, holds an operator's license in California.

Heath Focken

Mr. Focken, age 30, holds an operator's license in Nebraska.

Ahmed Gabr

Mr. Gabr, age 32, holds an operator's license in North Carolina.

Stephen A. Goen

Mr. Goen, age 51, holds a class A CDL in Georgia.

Jaymes Harr

Mr. Haar, age 31, holds an operator's license in Iowa.

Michael J. Hague

Mr. Hague, age 34, holds an operator's license in Rhode Island.

Daniel R. Hanson

Mr. Hanson, age 70, holds an operator's license in Pennsylvania.

Arnold Hatton

Mr. Hatton, age 51, holds an operator's license in Delaware.

Nima Jafari

Mr. Jafari, age 29, holds an operator's license in Kansas.

Raymond L. Levine

Mr. Levine, age 20, holds an operator's license in California.

Donte Mason

Mr. Mason, age 33, holds an operator's license in Tennessee.

Xavier C. Matthews

Mr. Matthews, age 39, holds an operator's license in Florida.

Eric B. Oberhausen

Mr. Oberhausen, age 33, holds an operator's license in California.

Taryn Peterson

Ms. Peterson, age 31, holds an operator's license in Iowa.

Melvin R. Ross

Mr. Ross, age 64, holds a class A CDL in Ohio.

Greivin Salazar

Mr. Salazar, age 43, holds an operator's license in Michigan.

Jerry Shortland

Mr. Shortland, age 54, holds an operator's license in Ohio.

John Silver

Mr. Silver, age 54, holds an operator's license in New York.

Marcus Sylvester

Mr. Sylvester, age 44, holds an operator's license in Texas.

John Whitlock

Mr. Whitlock, age 49, holds an operator's license in Illinois.

Eric Woods

Mr. Woods, age 50, holds an operator's license in Maryland.

IV. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the dates section of the notice.

Issued on: November 5, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018–24861 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2018–0205]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 57 individuals from the prohibition in the Federal Motor Carrier Safety Regulations (FMCSRs) against persons with insulin-treated diabetes mellitus (ITDM) from operating a commercial motor vehicle (CMV) in interstate commerce. The exemptions enable these individuals with ITDM to operate CMVs in interstate commerce.

DATES: The exemptions were applicable on October 20, 2018. The exemptions expire on October 20, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2018–0205, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document 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., ET, Monday through Friday, except Federal holidays.

B. 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.*

II. Background

On September 19, 2018, FMCSA published a notice announcing receipt of applications from 57 individuals requesting an exemption from diabetes requirement in 49 CFR 391.41(b)(3) and requested comments from the public (83 FR 47399). The public comment period ended on October 19, 2018, and one comment was received.

FMCSA has evaluated the eligibility of these applicants and determined that granting the exemptions to these individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(3).

The physical qualification standard for drivers regarding diabetes found in 49 CFR 391.41(b)(3) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of diabetes mellitus currently requiring insulin for control.

III. Discussion of Comments

FMCSA received one comment in this proceeding. Mr. Jeremy Na noted, that people on insulin should be able to drive CMV's especially if its controlled with no problems. This would open up a bunch of driving opportunities for those who love to drive but can't because of a rule. On September 19, 2018, FMCSA published the Qualifications of Drivers; Diabetes Standard final rule, removing the blanket prohibition of insulin use and adopting a revised physical qualification standard for operators of CMV with ITDM (83 FR 47448). The effective date of this final rule is November 19, 2018.

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for up to five years from the diabetes standard in 49 CFR 391.41(b)(3) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows the applicants to operate CMVs in interstate commerce. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The Agency's decision regarding these exemption applications is based on the program eligibility criteria and an individualized assessment of

information submitted by each applicant. The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the September 19, 2018, **Federal Register** notice (83 FR 47399) and will not be repeated in this notice.

These 57 applicants have had ITDM over a range of 1 to 51 years. These applicants report no severe hypoglycemic reactions resulting in loss of consciousness or seizure, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning symptoms, in the past 12 months and no recurrent (two or more) severe hypoglycemic episodes in the past five years. In each case, an endocrinologist verified that the driver has demonstrated a willingness to properly monitor and manage his/her diabetes mellitus, received education related to diabetes management, and is on a stable insulin regimen. These drivers report no other disqualifying conditions, including diabetes related complications. Each meets the vision requirement at 49 CFR 391.41(b)(10).

Consequently, FMCSA finds that in each case exempting these applicants from the diabetes requirement in 49 CFR 391.41(b)(3) is likely to achieve a level of safety equal to that existing without the exemption.

IV. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and includes the following: (1) Each driver must submit a quarterly monitoring checklist completed by the treating endocrinologist as well as an annual checklist with a comprehensive medical evaluation; (2) each driver must report within two business days of occurrence, all episodes of severe hypoglycemia, significant complications, or inability to manage diabetes; also, any involvement in an accident or any other adverse event in a CMV or personal vehicle, whether or not it is related to an episode of hypoglycemia; (3) each driver must provide a copy of the ophthalmologist's or optometrist's report to the Medical Examiner at the time of the annual medical examination; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keeping a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

V. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VI. Conclusion

Based upon its evaluation of the 57 exemption applications, FMCSA exempts the following drivers from the diabetes requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above:

Joseph J. Arena, Jr. (PA)
Daniel C. Avants (WA)
Danny Bailey (TX)
Ryan P. Bankert (PA)
Jordan D. Braun (MN)
David W. Buckley (CT)
Travis R. Capesius (IA)
Delqaun S. Carter (AL)
Christopher J. Epplin (IL)
Eugenio Ezparza, Jr. (TX)
Brian L. Fairchild (ID)
Stephen A. Fleming (MN)
Luigi Forcellati (NJ)
Daniel J. Garcia (CA)
Derek A. Garibay (CO)
Caleb K. George (RI)
Dylan M. Graham (MI)
Donald D. Gueiss (NC)
Michael W. Hammarsten (MN)
Robert L. Howell (IL)
Mitchell M. Huston (CO)
Daniel J. Hutt (NY)
Curtis C. Jacobs (NC)
Steven M. Johnson (IN)
Dwyanne E. Johnson (CO)
Christopher L. Johnston (GA)
Gregory E. Jondle (IA)
Steven Kinkead (MO)
Alexander P. Laatz (VA)
David L. Lennie (MI)
Philip J. Linn (OH)
Raul Martinez (TX)
Lance E. May (PA)
Terry A. McCoy (GA)
Brian K. McGowan (AR)
Michael D. Mervenne (MI)
Kendrick D. Miller (NC)
William D. Murphy (WV)
Babykutty Oommen (IL)
Miguel A. Orozco (NJ)
Arthur W. Pahmeier (IN)
Dale W. Paul (CA)
Jason J. Phillips (NM)
Robert E. Piernik (FL)
Luc R. Poirier (MI)
Rick M. Provo (IN)
David W. Pywell (ID)
Nicholas A. Quairoli (FL)
Robert A. Raymond (IA)
Robert A. Rock, Jr. (RI)
Hector R. Rodriguez (WA)
Samuel J. Shriver (WV)
Bradley A. Sundby (SD)
Clayton A. Szydel (WI)
Jeremy R. Tatro (OH)
Imelda Y. Tolentino (AR)
Birt F. Wilkerson, Jr. (TX)

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

Issued on: November 5, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018–24859 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[FMCSA Docket No. FMCSA–2018–0054]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 11 individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to operate CMVs in interstate commerce.

DATES: The exemptions were applicable on October 17, 2018. The exemptions expire on October 17, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions

regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2018–0054, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document 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., ET, Monday through Friday, except Federal holidays.

B. 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.*

II. Background

On September 10, 2018, FMCSA published a notice announcing receipt of applications from 11 individuals requesting an exemption from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8) and requested comments from the public (83 FR 45724). The public comment period ended on October 10, 2018, and two comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that granting exemptions to these individuals would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(8).

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria [1] to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. [49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section *H. Epilepsy: § 391.41(b)(8),* paragraphs 3, 4, and 5.]

III. Discussion of Comments

FMCSA received two comments in this proceeding. These comments supported granting these exemptions.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption for up to five years from the epilepsy and seizure disorder prohibition in 49 CFR 391.41(b)(8) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. The exemption allows the applicants to operate CMVs in interstate commerce. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

In reaching the decision to grant these exemption requests, FMCSA considered the 2007 recommendations of the Agency's Medical Expert Panel (MEP). The January 15, 2013, **Federal Register** notice (78 FR 3069) provides the current MEP recommendations which is the criteria the Agency uses to grant seizure exemptions.

The Agency's decision regarding these exemption applications is based on an individualized assessment of each applicant's medical information, including the root cause of the respective seizure(s) and medical information about the applicant's seizure history, the length of time that has elapsed since the individual's last seizure, the stability of each individual's treatment regimen and the duration of time on or off of anti-seizure medication. In addition, the Agency reviewed the treating clinician's medical opinion related to the ability of the driver to safely operate a CMV with a history of seizure and each applicant's driving record found in the Commercial Driver's License Information System (CDLIS) for commercial driver's license (CDL) holders, and interstate and intrastate inspections recorded in the Motor Carrier Management Information System (MCMIS). For non-CDL holders, the Agency reviewed the driving records from the State Driver's Licensing Agency (SDLA). A summary of each applicant's seizure history was discussed in the September 10, 2018, **Federal Register** notice (83 FR 45724) change) and will not be repeated in this notice.

These 11 applicants have been seizure-free over a range of 31 years while taking anti-seizure medication and maintained a stable medication treatment regimen for the last two years. In each case, the applicant's treating physician verified his or her seizure history and supports the ability to drive commercially.

The Agency acknowledges the potential consequences of a driver experiencing a seizure while operating a CMV. However, the Agency believes the drivers granted this exemption have demonstrated that they are unlikely to have a seizure and their medical condition does not pose a risk to public safety.

Consequently, FMCSA finds that in each case exempting these applicants from the epilepsy and seizure disorder prohibition in 49 CFR 391.41(b)(8) is likely to achieve a level of safety equal to that existing without the exemption.

V. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and includes the following: (1) Each driver must remain seizure-free and maintain a stable treatment during the two-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified Medical Examiner, as defined by 49 CFR 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

[1] See *http://www.ecfr.gov/cgi-bin/text-idx?SID=e47b48a9ea42dd67d999246e23d97970&mc=true&node=pt49.5.391&rgn=div5#ap49.5.391_171.a* and *https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.*

VII. Conclusion

Based upon its evaluation of the 11 exemption applications, FMCSA exempts the following drivers from the epilepsy and seizure disorder prohibition, 49 CFR 391.41(b)(8), subject to the requirements cited above:

Jonthon A. Arrieta (FL)
Jose F.J. Cabrera Maciel (CA)
Pietro Capobianco (NJ)
Armando B. Castro Jr. (NV)
Joshua Cirilo (MN)
Barbara A. Cruz (IN)
Gail A. Hackathorn (IA)
Jose G. Lara-Ramirez (NV)
Bryan F. Sheehan (FL)
Christopher A. Steinke (WI)
Francis L. Stimpson (ID)

In accordance with 49 U.S.C. 31315(b)(1), each exemption will be valid for two years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

Issued on: November 5, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018–24858 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2000–7165; FMCSA–2002–11714; FMCSA–2004–17984; FMCSA–2004–18885; FMCSA–2005–21711; FMCSA–2006–24783; FMCSA–2007–27897; FMCSA–2008–0021; FMCSA–2008–0106; FMCSA–2008–0174; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2009–0206; FMCSA–2009–0303; FMCSA–2010–0082; FMCSA–2010–0114; FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0354; FMCSA–2010–0385; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2012–0104; FMCSA–2012–0160; FMCSA–2012–0215; FMCSA–2012–0216; FMCSA–2013–0169; FMCSA–2013–0170; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0005; FMCSA–2014–0006; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2016–0027; FMCSA–2016–0028; FMCSA–2016–0206]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 83 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirements in one eye.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below. Comments must be received on or before December 14, 2018.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA–2000–7165; FMCSA–2002–11714; FMCSA–2004–17984; FMCSA–2004–18885; FMCSA–2005–21711; FMCSA–2006–24783; FMCSA–2007–27897; FMCSA–2008–0021; FMCSA–2008–0106; FMCSA–2008–0174; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2009–0206; FMCSA–2009–0303; FMCSA–2010–0082; FMCSA–2010–0114; FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0354; FMCSA–2010–0385; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2012–0104; FMCSA–2012–0160; FMCSA–2012–0215; FMCSA–2012–0216; FMCSA–2013–0169; FMCSA–2013–0170; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0005; FMCSA–2014–0006; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2016–0027; FMCSA–2016–0028; FMCSA–2016–0206 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2000–7165; FMCSA–2002–11714; FMCSA–2004–17984; FMCSA–2004–18885; FMCSA–2005–21711; FMCSA–2006–24783; FMCSA–2007–27897; FMCSA–2008–0021; FMCSA–2008–0106; FMCSA–2008–0174; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2009–0206; FMCSA–2009–0303; FMCSA–2010–0082; FMCSA–2010–0114; FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0354; FMCSA–2010–0385; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2012–0104; FMCSA–2012–0160; FMCSA–2012–0215; FMCSA–2012–0216; FMCSA–2013–0169; FMCSA–2013–0170; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0005; FMCSA–2014–0006; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2016–0027; FMCSA–2016–0028; FMCSA–2016–0206), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. 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 that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* put the docket number, FMCSA–2000–7165; FMCSA–2002–11714; FMCSA–2004–17984; FMCSA–2004–18885; FMCSA–2005–21711; FMCSA–2006–24783; FMCSA–2007–27897; FMCSA–2008–0021; FMCSA–2008–0106; FMCSA–2008–0174; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2009–0206; FMCSA–2009–0303; FMCSA–2010–0082; FMCSA–2010–0114;

FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0354; FMCSA–2010–0385; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2012–0104; FMCSA–2012–0160; FMCSA–2012–0215; FMCSA–2012–0216; FMCSA–2013–0169; FMCSA–2013–0170; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0005; FMCSA–2014–0006; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2016–0027; FMCSA–2016–0028; FMCSA–2016–0206, in the keyword box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box on 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.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2000–7165; FMCSA–2002–11714; FMCSA–2004–17984; FMCSA–2004–18885; FMCSA–2005–21711; FMCSA–2006–24783; FMCSA–2007–27897; FMCSA–2008–0021; FMCSA–2008–0106; FMCSA–2008–0174; FMCSA–2008–0231; FMCSA–2008–0266; FMCSA–2009–0206; FMCSA–2009–0303; FMCSA–2010–0082; FMCSA–2010–0114; FMCSA–2010–0161; FMCSA–2010–0187; FMCSA–2010–0354; FMCSA–2010–0385; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2012–0104; FMCSA–2012–0160; FMCSA–2012–0215; FMCSA–2012–0216; FMCSA–2013–0169; FMCSA–2013–0170; FMCSA–2014–0002; FMCSA–2014–0003; FMCSA–2014–0005; FMCSA–2014–0006; FMCSA–2014–0010; FMCSA–2014–0011; FMCSA–2014–0296; FMCSA–2016–0027; FMCSA–2016–0028; FMCSA–2016–0206, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document 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., ET, Monday through Friday, except Federal holidays.

C. 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.*

II. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for five years if it finds that such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding vision found in 49 CFR 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

The 83 individuals listed in this notice have requested renewal of their exemptions from the vision standard in 49 CFR 391.41(b)(10), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable two-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than five years from its approval date and may be renewed upon application. FMCSA grants exemptions from the vision standard for a two-year period to align with the maximum duration of a driver's medical certification. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 83 applicants has satisfied the renewal conditions for obtaining an exemption from the vision standard (65 FR 33406; 65 FR 57234; 67 FR 15662; 67 FR 37907; 67 FR 57266; 69 FR 26206; 69 FR 33997; 69 FR 52741; 69 FR 53493; 69 FR 61292; 69 FR 62742; 70 FR 48797; 70 FR 61493; 71 FR 26602; 71 FR 32183; 71 FR 41310; 71 FR 53489; 71 FR 55820; 71 FR 62148; 72 FR 39879; 72 FR 52419; 73 FR 15567; 73 FR 27015; 73 FR 27018; 73 FR 35194; 73 FR 35197; 73 FR 36955; 73 FR 38498; 73 FR 46973; 73 FR 48273; 73 FR 48275; 73 FR 51689; 73 FR 54888; 73 FR 61925; 73 FR 63047; 73 FR 65009; 74 FR 41971; 74 FR 43217; 74 FR 43220; 74 FR 57551; 74 FR 57553; 74 FR 60022; 75 FR 4623; 75 FR 19674; 75 FR 25918; 75 FR 34211; 75 FR 34212; 75 FR 36778; 75 FR 36779; 75 FR 39725; 75 FR 39729; 75 FR 44050; 75 FR 44051; 75 FR 47883; 75 FR 47888; 75 FR 52063; 75 FR 57105; 75 FR 59327; 75 FR 61833; 75 FR 61883; 75 FR 63257; 75 FR 64396; 75 FR 72863; 75 FR 77942; 76 FR 2190; 76 FR 5425; 76 FR 54530; 76 FR 66123; 77 FR 543; 77 FR 15184; 77 FR 17109; 77 FR 23797; 77 FR 27845; 77 FR 27847; 77 FR 27850; 77 FR 36338; 77 FR 38381; 77 FR 38384; 77 FR 38386; 77 FR 40945; 77 FR 46153; 77 FR 51846; 77 FR 52381; 77 FR 52388; 77 FR 56261; 77 FR 56262; 77 FR 60010; 77 FR 64582; 77 FR 64583; 77 FR 64841; 77 FR 65933; 78 FR 51269; 78 FR 64274; 78 FR 67454; 78 FR 76707; 78 FR 77778; 78 FR 77782; 78 FR 78477; 79 FR 4803; 79 FR 10609; 79 FR 14571; 79 FR 22003; 79 FR 23797; 79 FR 27681; 79 FR 28588; 79 FR 35212; 79 FR 35218; 79 FR 35220; 79 FR 37843; 79 FR 38649; 79 FR 38661; 79 FR 40945; 79 FR 45868; 79 FR 46153; 79 FR 47175; 79 FR 51642; 79 FR 51643; 79 FR 56097; 79 FR 56099; 79 FR 56104; 79 FR 56117; 79 FR 58856; 79 FR 59348; 79 FR 64001; 79 FR 70928; 79 FR 72754; 80 FR 36398; 80 FR 67481; 81 FR 20435; 81 FR 26305; 81 FR 39320; 81 FR 60115; 81 FR 66720; 81 FR 66724; 81 FR 71173; 81 FR 72642; 81 FR 81230; 81 FR 90050; 81 FR 91239; 81 FR 96196). They have submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and

that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements. These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

In accordance with 49 U.S.C. 31136(e) and 31315, the following groups of drivers received renewed exemptions in the month of October and are discussed below.

As of October 1, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 21 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (73 FR 15567; 73 FR 27015; 73 FR 35197; 73 FR 48275; 74 FR 43217; 74 FR 43220; 74 FR 57551; 74 FR 57553; 74 FR 60022; 75 FR 4623; 75 FR 19674; 75 FR 34211; 75 FR 34212; 75 FR 44051; 75 FR 47888; 75 FR 72863; 76 FR 2190; 76 FR 66123; 77 FR 543; 77 FR 23797; 77 FR 27847; 77 FR 36338; 77 FR 38386; 77 FR 40945; 77 FR 46153; 78 FR 51269; 78 FR 64274; 78 FR 76707; 78 FR 77778; 78 FR 77782; 79 FR 10609; 79 FR 22003; 79 FR 23797; 79 FR 27681; 79 FR 35220; 79 FR 37843; 79 FR 38649; 79 FR 40945; 79 FR 45868; 79 FR 46153; 80 FR 36398; 80 FR 67481; 81 FR 20435; 81 FR 26305; 81 FR 39320; 81 FR 60115; 81 FR 66720; 81 FR 66724; 81 FR 72642; 81 FR 81230; 81 FR 90050; 81 FR 91239; 81 FR 96196):

Timothy D. Beaulier (MI)
Teddy S. Bioni (PA)
James F. Epperson (IN)
Sean O. Feeny (FL)
David M. Field (NH)
Spencer B. Jacobs (TX)
Gregory L. Kockelman (MN)
Michael M. Martinez (NM)
Duane A. McCord (IL)
Odilio Monterroso De Leon (TX)
Aaron L. Paustian (IA)
Markus Perkins (LA)
Kent A. Perry (WY)
Enoc Ramos III (TX)
Noel S. Robbins (PA)
Benjamin R. Sauder (PA)
Roberto E. Soto (TX)
Robert B. Steinmetz (OR)
Douglas R. Strickland (NC)
Raymond White (NC)
Brian C. Wittenburg (NC)

The drivers were included in docket numbers FMCSA–2008–0021; FMCSA–2008–0106; FMCSA–2009–0206; FMCSA–2009–0303; FMCSA–2010–0114; FMCSA–2010–0354; FMCSA–2012–0104; FMCSA–2013–0169; FMCSA–2014–0002; FMCSA–2014–0005; FMCSA–2016–0027; FMCSA–2016–0028; FMCSA–2016–0206. Their exemptions are applicable as of October 1, 2018, and will expire on October 1, 2020.

As of October 6, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 19 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (67 FR 15662; 67 FR 37907; 69 FR 26206; 70 FR 48797; 70 FR 61493; 71 FR 26602; 71 FR 32183; 71 FR 41310; 72 FR 39879; 72 FR 52419; 73 FR 27018; 73 FR 35194; 73 FR 36955; 73 FR 38498; 73 FR 48273; 74 FR 41971; 75 FR 25918; 75 FR 36778; 75 FR 36779; 75 FR 39725; 75 FR 39729; 75 FR 44050; 75 FR 44051; 75 FR 61833; 75 FR 77942; 76 FR 5425; 76 FR 54530; 77 FR 15184; 77 FR 17109; 77 FR 27845; 77 FR 27850; 77 FR 36338; 77 FR 38384; 77 FR 46153; 77 FR 56262; 78 FR 67454; 78 FR 78477; 79 FR 4803; 79 FR 14571; 79 FR 23797; 79 FR 28588; 79 FR 35212; 79 FR 35218; 79 FR 35220; 79 FR 38661; 79 FR 46153; 79 FR 47175; 79 FR 51642; 79 FR 51643; 79 FR 64001; 81 FR 71173):

Ramon Adame (IL)
John E. Breslin (NV)
Howard T. Bubel (ND)
Scott F. Chalfant (DE)
Curtis E. Firari (WI)
Kelly L. Foster (UT)
Ronald M. Green (OH)
David W. Grooms (IN)
Billy R. Holdman (IL)
Daniel Hollins (KY)
Ralph E. Holmes (MD)
Charles S. Huffman (KS)
Daniel W. Johnson (NY)
Matthew B. Lairamore (OK)
Gary McKown (WV)
Mark A. Smith (IA)
Charles E. Stokes (FL)
Samuel M. Stoltzfus (PA)
Nicholas J. Vance (OH)

The drivers were included in docket numbers FMCSA–2002–11714; FMCSA–2005–21711; FMCSA–2006–24783; FMCSA–2007–27897; FMCSA–2008–0106; FMCSA–2008–0174; FMCSA–2010–0082; FMCSA–2010–0161; FMCSA–2010–0385; FMCSA–2011–0379; FMCSA–2011–0380; FMCSA–2013–0170; FMCSA–2014–0003; FMCSA–2014–0006; FMCSA–2014–0010. Their exemptions are applicable as of October 6, 2018, and will expire on October 6, 2020.

As of October 15, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following nine individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (69 FR 33997; 69 FR 61292; 71 FR 55820; 73 FR 46973; 73 FR 54888; 73 FR 65009; 75 FR 47883; 75 FR 52063; 75 FR 57105; 75 FR 63257; 77 FR 38381; 77 FR 51846; 77 FR 52388; 77 FR 60010; 81 FR 71173):

William C. Ball (NC)
Kelly R. Konesky (AZ)
Hollis J. Martin (AL)
Kevin C. Palmer (OR)
Charles O. Rhodes (FL)
Gordon G. Roth (KS)
Ted L. Smeltzer (IN)
Stephen B. Whitt (NC)
Darrell F. Woosley (IL)

The drivers were included in docket numbers FMCSA–2004–17984; FMCSA–2008–0231; FMCSA–2010–0187; FMCSA–2012–0160. Their exemptions are applicable as of October 15, 2018, and will expire on October 15, 2020.

As of October 21, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following five individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (79 FR 56099; 79 FR 70928; 81 FR 71173):

Todd A. Carlson (MN)
Ronald Gaines (FL)
Billy R. Hampton (NC)
Raymond Holt (CA)
Juan C. Puente (TX)

The drivers were included in docket number FMCSA–2014–0011. Their exemptions are applicable as of October 21, 2018, and will expire on October 21, 2020.

As of October 22, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following five individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (73 FR 51689; 73 FR 63047; 75 FR 39725; 75 FR 47883; 75 FR 61883; 75 FR 63257; 75 FR 64396; 77 FR 64582; 79 FR 56104; 81 FR 71173):

Randall J. Benson (MN)
James D. Drabek, Jr. (IL)
Delone W. Dudley (MD)
Jeromy W. Leatherman (PA)
Sylvester Silver (VA)

The drivers were included in docket numbers FMCSA–2008–0266; FMCSA–2010–0161; FMCSA–2010–0187. Their exemptions are applicable as of October 22, 2018, and will expire on October 22, 2020.

As of October 23, 2018, and in accordance with 49 U.S.C. 31136(e) and

31315, the following six individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (77 FR 52381; 77 FR 64841; 79 FR 56097; 81 FR 71173):

Roger A. Duester (TX)
Charlene E. Geary (SD)
David N. Hinchliffe (TX)
Benny L. Sanchez (CA)
Sandeep Singh (CA)
James T. Stalker (OH)

The drivers were included in docket number FMCSA–2012–0215. Their exemptions are applicable as of October 23, 2018, and will expire on October 23, 2020.

As of October 27, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following eight individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (65 FR 33406; 65 FR 57234; 67 FR 57266; 69 FR 52741; 69 FR 53493; 69 FR 62742; 71 FR 53489; 71 FR 62148; 73 FR 61925; 75 FR 59327; 77 FR 64583; 79 FR 56117; 81 FR 71173):

David W. Brown (TN)
Monty G. Calderon (OH)
Zane G. Harvey, Jr. (VA)
Jeffrey M. Keyser (OH)
David G. Meyers (NY)
Rodney M. Pegg (PA)
Zbigniew P. Pietranik (WI)
Joseph F. Wood (MS)

The drivers were included in docket numbers FMCSA–2000–7165; FMCSA–2004–18885. Their exemptions are applicable as of October 27, 2018, and will expire on October 27, 2020.

As of October 31, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following ten individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (77 FR 56261; 77 FR 65933; 79 FR 58856; 79 FR 59348; 79 FR 72754; 81 FR 71173):

Donald L. Blakeley II (NV)
Marty R. Brewster (KS)
Henry L. Chrestensen (IA)
Sanford L. Goodwin (TX)
Thomas J. Long III (PA)
Matthew J. Mantooth (KY)
Steven W. Miller (PA)
James J. Monticello (IN)
Klifford N. Siemens (KS)
Scott E. Tussey (KY)

The drivers were included in docket numbers FMCSA–2012–0216; FMCSA–2014–0296. Their exemptions are applicable as of October 31, 2018, and will expire on October 31, 2020.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must undergo an annual physical examination (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a certified Medical Examiner, as defined by 49 CFR 390.5, who attests that the driver is otherwise physically qualified under 49 CFR 391.41; (2) each driver must provide a copy of the ophthalmologist's or optometrist's report to the Medical Examiner at the time of the annual medical examination; and (3) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file or keep a copy of his/her driver's qualification if he/her is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VI. Conclusion

Based upon its evaluation of the 83 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above. In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years unless revoked earlier by FMCSA.

Issued on: November 5, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018–24856 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2016–0002]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for 11 individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these hard of hearing and deaf individuals to continue to operate CMVs in interstate commerce.

DATES: The exemptions were applicable on September 6, 2018. The exemptions expire on September 6, 2020. Comments must be received on or before December 14, 2018.

ADDRESSES: You may submit comments identified by the Federal Docket Management System (FDMS) Docket No. FMCSA–2016–0002 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2016–0002), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. 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 that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov,* put the docket number, FMCSA–2016–0002, in the keyword box, and click ''Search.'' When the new screen appears, click on the ''Comment Now!'' button and type your comment into the text box on 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.

FMCSA will consider all comments and material received during the comment period.

B. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2016–0002, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document 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., ET, Monday through Friday, except Federal holidays.

C. 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.*

II. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for five years if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the five-year period. FMCSA grants exemptions from the FMCSRs for a two-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding hearing found in 49 CFR 391.41(b)(11) states that a person is physically qualified to driver a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5—1951.

49 CFR 391.41(b)(11) was adopted in 1970, with a revision in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid, 35 FR 6458, 6463 (April 22, 1970) and 36 FR 12857 (July 3, 1971).

The 11 individuals listed in this notice have requested renewal of their exemptions from the hearing standard in 49 CFR 391.41(b)(11), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable two-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315, FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315, each of the 11 applicants has satisfied the renewal conditions for obtaining an exemption from the hearing requirement. The 11 drivers in this notice remain in good standing with the Agency. In addition, for Commercial Driver's License (CDL) holders, the Commercial Driver's License Information System (CDLIS) and the Motor Carrier Management Information System (MCMIS) are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency (SDLA). These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each of these drivers for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

As of September 6, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 11 individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers.

Pricilla Brackenridge, (IL)
David Chappelear, (TX)
Mathias Conway, MI)
Gary Cordano, (NV)
Samuel Fennell, (OH)
Richard Hoots, (AR)
Renaldo Martinez, (TX)
Katrina Parker, (NJ)
D'Neille Smith, (OH)
Michael Smith, (CO)
Mixhael, Sweet, (GA)

The drivers were included in docket number FMCSA–2016–0002. Their exemptions are applicable as of September 6, 2018, and will expire on September 6, 2020.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) Each driver must report any crashes or accidents as defined in 49 CFR 390.5; and (2) report all citations and convictions for disqualifying offenses under 49 CFR part 383 and 49 CFR 391 to FMCSA; and (3) each driver prohibited from operating a motorcoach or bus with passengers in interstate commerce. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. In addition, the exemption does not exempt the individual from meeting the applicable CDL testing

requirements. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the 11 exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the hearing requirement in 49 CFR 391.41 (b)(11). In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for two years unless revoked earlier by FMCSA.

Issued on: November 5, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018–24852 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket Nos. FMCSA 2012–0294; FMCSA 2013–0442; FMCSA–2013–0445; FMCSA–2015–0321]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for four individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates stated in the discussions below.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA 2012–0294; FMCSA 2013–0442; FMCSA–2013–0445; FMCSA–2015–0321, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document 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., ET, Monday through Friday, except Federal holidays.

B. 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.*

II. Background

On August 15, 2018, FMCSA published a notice announcing its decision to renew exemptions for four individuals from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8) to operate a CMV in interstate commerce and requested comments from the public (83 FR 40624). The public comment period ended on September 14, 2018, and no comments were received.

As stated in the previous notice, FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would achieve a level of safety equivalent to or greater than the level that would be achieved by complying with the current regulation 49 CFR 391.41(b)(8).

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. [49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. Epilepsy: § 391.41(b)(8), paragraphs 3, 4, and 5.]

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Conclusion

Based on its evaluation of the four renewal exemption applications, FMCSA announces its decision to exempt the following drivers from the epilepsy and seizure disorders prohibition in 49 CFR 391.41(b)(8):

As of July 5, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, Brian Checkley, Jr. (NJ) has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers (83 FR 40624).

This driver was included in docket number FMCSA–2015–0321. The exemption is applicable as of July 5, 2018, and will expire on July 5, 2020.

As of July 14, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, Ronald Blount (GA) has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers (83 FR 40624).

This driver was included in docket number FMCSA–2013–0445. The exemption is applicable as of July 14, 2018, and will expire on July 14, 2020.

As of July 8, 2018, and in accordance with 49 U.S.C. 31136(e) and 31315, the following two individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers (83

FR 40624): Samuel Beverly (VA) and Michael Duprey (CT).

The drivers were included in docket numbers FMCSA 2012–0294 and FMCSA–2013–0442. Their exemptions are applicable as of July 8, 2018, and will expire on July 8, 2020.

In accordance with 49 U.S.C. 31315, each exemption will be valid for two years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

Issued on: November 5, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018–24844 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2018–0019]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of denials.

SUMMARY: FMCSA announces its decision to deny applications from 77 individuals who requested an exemption from the vision standard in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a CMV in interstate commerce.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–2018–0019, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document 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., ET, Monday through Friday, except Federal holidays.

B. 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.*

II. Background

FMCSA received applications from 77 individuals who requested an exemption from the vision standard in the FMCSRs. FMCSA has evaluated the eligibility of these applicants and concluded that granting these exemptions would not provide a level of safety that would be equivalent to or greater than, the level of safety that would be obtained by complying with the regulation 49 CFR 391.41(b)(10).

III. Basis for Exemption Determination

Under 49 U.S.C.31136 (e) and 31315, FMCSA may grant an exemption if it finds such an exemption would likely achieve a level of safety that is equivalent to, or greater then, the level that would be achieved absent such an exemption.

The Agency's decision regarding these exemption applications is based on the eligibility criteria, the terms and conditions for Federal exemptions, and an individualized assessment of each applicant's medical information provided by the applicant.

IV. Conclusion

The Agency has determined that these applicants do not satisfy the criteria eligibility or meet the terms and conditions of the Federal exemption and granting these exemptions would not provide a level of safety that would be equivalent to or greater than, the level of safety that would be obtained by complying with the regulation 49 CFR 391.41(b)(10). Therefore, the 77 applicants in this notice have been denied exemptions from the physical qualification standards in 49 CFR 391.41(b)(10).

Each applicant has, prior to this notice, received a letter of final disposition regarding his/her exemption request. Those decision letters fully outlined the basis for the denial and constitute final action by the Agency. This notice summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4) by periodically publishing names and reasons for denial.

The following three applicants did not have sufficient driving experience over the past three years under normal highway operating conditions:

Sallie R. Brenner (TX); Kenneth R. Jordan (IL); and Jackie R. Karst (MS)

The following 36 applicants had no experience operating a CMV:

Scott A. Allnutt (KY)
Linas Brock (LA)
Landon M. Brown (CA)
Shaletta C. Buford (TN)
Jackueline D. Bullock (TX)
Peter K. Chege (MN)
Christopher J. Dantoni (PA)
Catherine Davis (IL)
Davidson Dorce (FL)
Jimi L. Engler (OH)
Kevin Ezell (CA)
Darrien W. Ferrell (IL)
Terrence H. Flick (IL)
Lonnie R. Gale (MD)
Liliana Gonzalez (IL)
Raheel Hameed (IL)
Jemminson R. Homesombath (CA)
Billy M. Lamb (MI)
Brian J. Loch (MN)
Eli Mast (ND)
Israel W. McAfee (VA)
Lamar P. Moore (IL)
Amanda M. Morse (IL)
Nicolas R. Motta (NC)
Bryan C. Pratt (PA)
Harold B. Rainwater (MO)
Ashley L. Reed (AR)
Keith G. Roberts (OH)
Sinisa Sabljic (NV)
Selemani A. Said (VA)
Joseph E. Saint Jean (NY)
Allen D. Sedwick (AR)
Ronald W. Smith (TX)
Ryan J. Smith (PA)
Kip R. Stringer (OR)
Jerred L. Thomas (OK)

The following 11 applicants did not have three years of experience driving a CMV on public highways with their vision deficiencies:

Bruce Banwell (IA)
Anthony C. Bears (MO)
Donald D. Brown (NC)
Ray E. Caldwell (WA)
Robert Evans (NH)
Harold J. Hughes (FL)
David E. Nelson (ID)
Perry E. Principi (MS)
Peter J. Urlacher (WA)

John A. Valusek (ND)

Owen W. Witmer (PA)

The following eight applicants did not have three years of recent experience driving a CMV on public highways with their vision deficiencies:

Monte L. Albrecht (CO)

Gary J. Bouchard (ME)

Henry Darden (MD)

Mark P. Gilbert (MT)

Charles W. McClister (PA)

Jason J. Oaks (SD)

James L. Ross (TX)

Mark J. Simmer (MA)

The following five applicants did not have sufficient driving experience over the past three years under normal highway operating conditions (gaps in driving record):

Robert J. Campbell (ND)

Timothy V. Compton (CA)

Jordan D. Mahoney (MN)

Gale L. O'Neil (PA)

Gary Peach (IN)

The following applicant, Christopher T. Sides (ME), contributed to accident(s) in which the applicant was operating a CMV, which is a disqualifying offense.

The following applicant, Keith Hauenstein (PA), did not have an optometrist or ophthalmologist willing to make a statement that they are able to operate a commercial vehicle from a vision standpoint.

The following seven applicants were denied for multiple reasons:

McVay Chambers (LA)

Narciso L. Ferreira (ID)

Nicholas Piscitelli (NJ)

Louis J. Scheele (IN)

Terry A. Smith (IA)

James H. Ward (NC)

Dana J. York (PA)

The following two applicants have not had stable vision for the preceding three-year period:

Plynie A. Deen (GA); and Bret A. Herbolsheimer (WA)

The following three applicants drove interstate while restricted to intrastate driving:

Raul Alcalde (CA); Joseph N. Fulton (SC); and Heriberto R. Perez (TX)

Issued on: November 5, 2018.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2018–24849 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2018–0094]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System

Under part 235 of Title 49 of the Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that on October 31, 2018, Canadian National Railway Company (CN) petitioned the Federal Railroad Administration (FRA) seeking approval to discontinue or modify a signal system. FRA assigned the petition Docket Number FRA–2018–0094.

Applicant: Canadian National Railway Company, Mr. Tom Hilliard, Assistant Chief S&C—Southern Region, 17641 S Ashland Avenue, Homewood, IL 60430.

The U.S.-based operating railroad subsidiary of CN, Illinois Central Railroad Company requests approval to permanently remove the Automatic Block Signal (ABS) system between Mile Post (MP) 725.9 on the Canton Subdivision and MP 728.6 on the McComb Subdivision, located near Jackson, Mississippi.

CN states the reason for the proposed change is that the track connection with Yazoo and McComb Subdivisions has been retired so the Canton Subdivision does not connect with Yazoo Subdivision or McComb Subdivision at this location. This makes the ABS system unnecessary for a stub track. Operation over this territory will be conducted using Yard Limit United States Operating Rule requirements.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by December 31, 2018 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. 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.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

Robert C. Lauby,

Associate Administrator for Railroad Safety Chief Safety Officer.

[FR Doc. 2018–24826 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2018–0008–N–9]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, FRA seeks approval of the Information Collection

Requests (ICRs) abstracted below. Before submitting these ICRs to the Office of Management and Budget (OMB) for approval, FRA is soliciting public comment on specific aspects of the activities identified below.

DATES: Interested persons are invited to submit comments on or before January 14, 2019.

ADDRESSES: Submit written comments on the ICRs activities by mail to either: 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; 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. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, ''Comments on OMB Control Number 2130–XXXX,'' (the relevant OMB control number for each ICR is listed below) and should also include the title of the ICR. Alternatively, comments may be faxed to (202) 493–6216 or (202) 493–6497, or emailed to Mr. Brogan at *Robert.Brogan@dot.gov,* or Ms. Toone at *Kim.Toone@dot.gov*. Please refer to the assigned OMB control number in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

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: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to provide 60-days' notice to the public to allow comment on information collection activities before seeking OMB approval of the activities. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. Specifically, FRA invites interested parties to comment on the following ICRs regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways for FRA to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology. *See* 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1).

FRA believes that soliciting public comment may reduce the administrative and paperwork burdens associated with the collection of information that Federal regulations require. In summary, FRA reasons that comments received will advance three objectives: (1) Reduce reporting burdens; (2) organize information collection requirements in a ''user-friendly'' format to improve the use of such information; and (3) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

The summaries below describe the ICRs that FRA will submit for OMB clearance as the PRA requires:

Title: State Safety Participation Regulations and Reporting of Remedial Actions.

OMB Control Number: 2130–0509.

Abstract: The collection of information is set forth under 49 CFR part 212, and requires qualified state inspectors to provide various reports to FRA for monitoring and enforcement purposes concerning state investigative, inspection, and surveillance activities regarding railroad compliance with Federal railroad safety laws and regulations. Additionally, under 49 CFR part 209, subpart E, railroads are required to report to FRA actions taken to remedy certain alleged violations of law.

Form Number(s): FRA F 6180.33/61/67/96/96A/109/110/111/112/144.

Affected Public: Businesses.

Respondent Universe: States and Railroads.

Frequency of Submission: On occasion.

REPORTING BURDEN

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Burden hours dollar equivalent cost [1]
Application for Participation	16 States	16 updates	2.5 hours	40	$2,960
State Railroad Technical Training Funding Agreement.	32 States	32 agreements	1 hour	32	2,368
Inspector Travel Planning and Reimbursement.	32 States	400 vouchers	1 hour	400	29,600
212.109—Annual Work Plan	32 States	1,862 reports	5 hours	9,310	688,940
Inspection Form (FRA F 6180.96)	32 States	69,885 forms	15 minutes	17,471	1,292,854
Violation Report—Motive, Power, and Equipment Regulations (Form FRA F 6180.109).	19 States	1,862 reports	4 hours	7,448	551,152
Violation Report—Operating Practices Regulations (Form FRA F 6180.67).	19 States	868 reports	4 hours	3,472	256,928
Violation Report—Hazardous Materials Regulations (Form FRA F 6180.110).	17 States	856 reports	4 hours	3,424	253,376
Violation Report—Hours of Service Law (F 6180.33).	19 States	103 reports	4 hours	412	30,488

REPORTING BURDEN—Continued

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Burden hours dollar equivalent cost [1]
Violation Report—Accident/Incident Reporting Rules (Form FRA F 6180.61).	19 States	146 reports	4 hours	584	43,216
Violation Report—Track Safety Regulations (Form FRA F 6180.111).	26 States	667 reports	4 hours	2,668	197,432
Violation Report—Signal and Train Control Regulations (Form FRA F 6180.112).	14 States	440 reports	4 hours	1,760	130,240
209.405—Remedial Actions Reports	566 Railroads	4,050 reports	15 minutes	1,013	74,962
209.407—Violation Report Challenge	566 Railroads	810 challenges	1 hour	810	59,940
209.407—Delayed Reports	695 Railroads	405 reports	30 minutes	203	15,022

[1] To determine the dollar equivalent cost for the estimated burden hours under OMB No. 2130–0509, FRA used an average hourly wage rate of $74. FRA derived this estimate from Bureau of Labor Statistics (BLS) data for management occupations, NAICS 99920—State Government, excluding schools and hospitals (OES Designation). To calculate the mean hourly wage of $42.17 for this category of workers, FRA included a 75-percent charge for overhead costs. The calculation is $42.17 per hour × 1.75 = $73.7975 or $74 per hour (rounded). The Web address for this data is: *https://www.bls.gov/oes/current/naics4_999200.htm#11-0000.*

Total Estimated Annual Responses: 82,402.

Total Estimated Annual Burden: 49,047 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $3,629,478.

Title: Use of Locomotive Horns at Highway-Rail Grade Crossings.

OMB Control Number: 2130–0560.

Abstract: Under 49 CFR part 222, FRA seeks to collect information from railroads and public authorities in order to increase safety at public highway-rail grade crossings nationwide by requiring that locomotive horns be sounded when trains approach and pass through these crossings or by ensuring that a safety level at least equivalent to that provided by routine locomotive horn sounding exists for quiet zone corridors in which horns are silenced. FRA reviews applications by public authorities intending to establish new quiet zones or, in some cases, continue pre-rule quiet zones to ensure the necessary level of safety is achieved.

Form Number(s): N/A.

Affected Public: Businesses.

Respondent Universe: 728 railroads/340 Public Authorities.

Frequency of Submission: On occasion.

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Burden hours dollar equivalent cost
222.15—Waiver Petitions	784 Railroads/531 Public Authorities.	2 petitions	4 hours	8	$584
222.39—Applications to Establish Quiet Zone.	531 Public Authorities	15 applications	80 hours	1,200	88,800
—Diagnostic Team Review	531 Public Authorities	3 team reviews	16 hours	48	3,504
—Updated Crossing Inventory Forms	531 Public Authorities	75 updated forms	1 hour	75	5,550
—Copies of Quiet Zone Application	531 Public Authorities	90 copies	10 minutes	15	1,110
—Comments to FRA on Quiet Zone Application.	784 Railroads/State Agencies.	30 comments	1.5 hours	45	3,285
222.43—Written Notice of Public Authority Intent to Create New Quiet Zone and Notification to Required Parties.	216 Communities/ Public Authorities.	60 notices + 180 notifications.	40 hours + 10 minutes.	2,430	179,820
—Updated Crossing Inventory Forms	216 Communities	300 updated forms	1 hour	300	22,200
—Comments on proposed Quiet Zone	784 Railroads/State Agencies.	120 comments	4 hours	480	35,040
—Notice of Quiet Zone Establishment + Notification to Required Parties.	531 Public Authorities	60 notices + 360 notifications.	40 hours + 10 minutes.	2,460	182,040
—Updated Crossing Inventory Forms	531 Public Authorities	300 updated forms	1 hour	300	22,200
—Certification by CEO of Public Authority Regarding Accuracy of Information.	531 Public Authorities	60 certifications	5 minutes	5	370
222.47—Periodic Updates: Written Affirmation that Supplementary Safety Measures Implemented w/in Quiet Zone Conform to Rule or Terms of Approval.	531 Public Authorities	213 written affirmations + 1,278 copies (to required parties).	30 minutes + 2 minutes.	150	11,100
—Updated Crossing Inventory Forms	531 Public Authorities	810 updated forms	1 hour	810	59,940
222.51—Written Commitment to Lower Risk to Traveling Public in Quiet Zones Exceeding Nationwide Significant Risk Threshold.	15 Public Authorities	10 written commitments.	5 hours	50	3,700
—Comments Upon FRA Review of Quiet Zone Status.	3 Public Authorities	2 comments	30 minutes	1	74

CFR section	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Burden hours dollar equivalent cost
222.55—Request for FRA Approval of New Supplementary Safety Measures/Alternative Safety Measures (ASMs) for Quiet Zone.	265 Interested Parties/.	1 letter	30 minutes	1	74
—Comments on New SSMs or ASMs	265 Interested Parties/General Public.	5 comments	30 minutes	3	222
—Request for SSM/ASM Approval –Demo.	265 Interested Parties	1 letter	30 minutes	1	74
222.57—Petition for FRA Review of Decision Granting or Denying a New SSM or ASM; Petition Copies to Relevant Parties.	531 Public Authorities/Interested Parties.	1 petition + 5 petition copies.	60 minutes + 2 minutes.	1	74
—Request for FRA Reconsideration of Disapproval of Quiet Zone + Party Copies.	531 Public Authorities	1 letter + 6 letter copies.	5 hours + 2 minutes.	5	370
—Additional Documents to FRA as Follow-up to Petition for Reconsideration.	531 Public Authorities	1 additional document/set of materials.	2 hours	2	148
—Letter Requesting FRA Informal Hearing.	531 Public Authorities	1 letter	30 minutes	1	74
222.59—Written Notice of Use of Wayside Horn at Grade Crossing within Quiet Zone + Party Copies.	531 Public Authorities	5 notices + 30 notice copies.	2.5 hours + 10 minutes.	18	1,332
—Notice of Wayside Horn Outside Quiet Zone.	531 Public Authorities	5 notices + 30 notice copies.	2.5 hours + 10 minutes.	18	1,332
Appendix B—Public Authority Record Relating to Monitoring and Sampling Efforts at Grade Crossing in Quite Zone with Programmed Enforcement.	531 Public Authorities	1 record	500 hours	500	37,000
—Public Authority Record Relating to Monitoring and Sampling Efforts at Grade Crossing in Quite Zone with Photo Enforcement.	531 Public Authorities	1 record	9 hours	9	666
222.129—Written Reports/Records of Locomotive Horn Testing.	784 Railroads	300 reports/records	60 minutes	300	21,900

Total Estimated Responses: 4,362.

Total Estimated Annual Burden: 9,236 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $681,983.

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. 2018–24716 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2009–0078]

Petition for Waiver of Compliance

Under part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that on September 20, 2018, the American Short Line Railroad Association (ASLRRA) petitioned the Federal Railroad Administration (FRA) for an amended waiver of compliance from certain provisions of the Federal hours of service laws contained at 49 U.S.C. 21103(a)(4), which, in part, require a train employee to receive 48 hours off duty after initiating an on-duty period for six consecutive days. FRA assigned the petition Docket Number FRA–2009–0078.

ASLRRA's waiver of 49 U.S.C. 21103(a)(4)(A), granted under the terms and conditions contained in FRA's initial March 5, 2010 decision letter, and extended by FRA's decision letter dated February 27, 2012, permits participating railroads to allow train employees to work six consecutive days followed by 24 hours of rest before returning to work. One condition of the waiver excludes work occurring between the hours of midnight and six a.m. ASLRRA requests to expand the waiver to include work between the hours of midnight and six a.m. for those railroads identified in the petition who agree to participate in this Pilot Project. ASLRRA contends ''the data justifies a pilot project to test its preliminary conclusion that appropriate mitigation techniques can adequately offset fatigue risks associated with extending the waiver from midnight to six a.m.''

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the

appropriate docket number and may be submitted by any of the following methods:

- *website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by December 31, 2018 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. 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 *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

Robert C. Lauby,

Associate Administrator for Railroad Safety Chief Safety Officer.

[FR Doc. 2018–24825 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2017–0002–N–20]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA), 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 March 14, 2017, FRA published a notice providing a 60-day period for public comment and on September 13, 2017, published a notice providing a 30-day period for public comment on the ICR.

DATES: Interested persons are invited to submit comments on or before December 14, 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. Michael Jones, Information Collection Clearance Officer, Office of Research, Development, and Technology, Human Factors Division, RPD–34, Federal Railroad Administration, 1200 New Jersey Avenue SE, Room W38–119, Washington, DC 20590 (telephone: (202) 493–6106); 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 paperwork packages. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. The required 60- and 30-Day **Federal Register** Notices were published in the **Federal Register** on March 14, 2017 (see 82 FR 20530) and September 13, 2017 (see 82 FR 43078), respectively. FRA received comments from the Association of American Railroads (AAR) in a letter dated October 13, 2017, outlining some concerns with the research approach in the human error study. FRA replied by letter clarifying the research approach.

Specifically, AAR commented that it was concerned that the proposed study on automated locomotive technology was not fully developed and that results of such a study might lead to unnecessary roadblocks to the development of the technology positive train control (PTC). Further, AAR stated ''FRA should also include in the study a control group demonstrating the number of errors that occur in locomotives absent autonomous technology.'' In response, FRA explained that under the planned research approach at the time, it was not necessary to include a manual operation condition as FRA did not intend to compare performance with vs. without automation. The purpose of the study was to understand the nature of possible design-induced errors for existing system automation in the locomotive cab, with an eye toward future improved systems. These errors are likely, absent of any human factors engineering in the system design and development process. For this examination, a control group was unnecessary. However, FRA now proposes to expand the study approach to address AAR's concern and include a manual condition control group. In this context, FRA's reference to automation means an operation assisted by autonomous technology that offers some level of automation less than full automation. This condition will provide a baseline of performance to address two hypotheses:

(H1) Automation provides specific performance benefits (*e.g.,* an energy management software system reduces fuel usage; PTC prevents overspeeding and transgressions into workzones or past a red signal) compared with manual control, but does not reduce workload in the locomotive cab compared with manual control.

(H2) Automation usage results in more errors in high workload situations than in low workload situations (*e.g.,* distractions lead to failure to notice mode transitions) and these errors have no direct counterpart in manual conditions.

Workload is defined as task loading, or the number of tasks in a scenario. The high workload scenarios have more tasks than the low workload scenarios. Based on the initial FRA pilot study, preceding the current study, and on research and operational experiences in other industries, high workload is often associated with error, thus, FRA's concern and interest in conducting the current study.

Before OMB decides whether to approve this proposed collection of information, an additional 30 days is being provided 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 1320.10(b); *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 44983, Aug. 29, 1995. 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: Experimental Investigation of Automation-Induced Human Error in Locomotive Cab.

OMB Control Number: 2130–XXXX.

Abstract: The purpose of this collection is to identify and evaluate the potential for human error associated with the operation of systems and automation in the locomotive cab. This research addresses DOT's strategic goal of safety. Once the nature and risk of the human error in locomotive cab systems and automation is better understood, error mitigating steps can be taken to provide safer systems and reduce the risk of accidents or incidents involving these systems. FRA will use the research's results to identify training, operational procedures, or automation design standards that will improve the safety of automated systems in locomotive cabs.

Type of Request: New information collection request.

Affected Public: Railroad Engineers and Conductors.

Form(s): FRA F 6180.3.

Respondent Universe: 24.

Frequency of Submission: Once.

Total Estimated Annual Responses: 24.

Total Estimated Annual Burden: 48 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. 2018–24715 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Saint Lawrence Seaway Development Corporation Advisory Board—Notice of Public Meetings

AGENCY: Saint Lawrence Seaway Development Corporation (SLSDC); USDOT.

ACTION: Notice of Public Meeting.

SUMMARY: This notice announces the public meeting via conference call of the Saint Lawrence Seaway Development Corporation Advisory Board.

DATES: The public meeting will be held on (all times Eastern):

- Tuesday, December 4, 2018 from 2:00 p.m.–4:00 p.m. EST

ADDRESSES: The meeting will be held via conference call at the SLSDC's Headquarters, 55 M Street, SE, Suite 930, Washington, DC 20003.

FOR FURTHER INFORMATION CONTACT: Wayne Williams, Chief of Staff, Saint Lawrence Seaway Development Corporation, 1200 New Jersey Avenue SE, Washington, DC 20590; 202–366–0091

SUPPLEMENTARY INFORMATION:

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463; 5 U.S.C. App. I), notice is hereby given of a meeting of the Advisory Board of the Saint Lawrence Seaway Development Corporation (SLSDC). The agenda for this meeting will be as follows:

December 4, 2018 from 2:00 p.m.–4:00 p.m. EST

1. Opening Remarks
2. Consideration of Minutes of Past Meeting
3. Quarterly Report
4. Old and New Business
5. Closing Discussion
6. Adjournment

Public Participation

Attendance at the meeting is open to the interested public but limited to the space available. With the approval of the Administrator, members of the public may present oral statements at the meeting. Persons wishing further information should contact the person listed under the heading, **FOR FURTHER INFORMATION CONTACT**, not later than Monday, November 19, 2018. Any member of the public may present a written statement to the Advisory Board at any time.

Carrie Lavigne,

Chief Counsel, Saint Lawrence Seaway Development Corporation.

[FR Doc. 2018–24789 Filed 11–13–18; 8:45 am]

BILLING CODE 4910–61–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[Docket ID OCC–2018–0036]

Mutual Savings Association Advisory Committee

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

ACTION: Notice.

SUMMARY: The OCC has determined that the renewal of the charter of the OCC Mutual Savings Association Advisory Committee (MSAAC) is necessary and in the public interest. The OCC hereby gives notice of the renewal of the charter.

DATES: The charter of the OCC MSAAC has been renewed for a two-year period that began on September 19, 2018.

FOR FURTHER INFORMATION CONTACT: Michael R. Brickman, Designated Federal Officer, 202–649–5420, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Notice of the renewal of the MSAAC charter is hereby given, with the approval of the Secretary of the Treasury, pursuant to section 9(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. 2. The Comptroller of the Currency has determined that the renewal of the MSAAC charter is necessary and in the public interest in order to provide advice and information concerning the condition of mutual savings associations, the regulatory changes or other steps the OCC may be able to take to ensure the health and viability of mutual savings associations, and other issues of concern to mutual savings associations, all in accordance with the goals of Section 5(a) of the Home Owners' Loan Act, 12 U.S.C. 1464.

Dated: November 7, 2018.

Joseph M. Otting,

Comptroller of the Currency.

[FR Doc. 2018–24723 Filed 11–13–18; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, 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 continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning procedure for waiver of right to consistent agreement of partnership items and partnership-level determinations as to penalties, additions to tax, and additional amounts.

DATES: Written comments should be received on or before January 14, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *Kerry.Dennis@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Waiver of Right to Consistent Agreement of Partnership Items and Partnership-Level Determinations as to Penalties, Additions to Tax, and Additional Amounts.

OMB Number: 1545–1969.

Form Number: 13751.

Abstract: The information requested on Form 13751 will be used to determine the eligibility for participation in the settlement initiative of taxpayers related through TEFRA partnerships to ineligible applicants. Such determinations will involve partnership items and partnership-level determinations, as well as the calculation of tax liabilities resolved under this initiative, including penalties and interest.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households, Business or other for-profit organizations, not-for-profit institutions.

Estimated Number of Respondents: 100.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 100.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 7, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–24730 Filed 11–13–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, 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 continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning procedure for filing forms W–2 in certain acquisitions.

DATES: Written comments should be received on or before January 14, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form should be directed to Kerry Dennis, at (202) 317–5751 or Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *Kerry.Dennis@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Procedure for filing Forms W–2 in certain acquisitions.

OMB Number: 1545–1510.

Revenue Procedure Number: Revenue Procedure 2004–53.

Abstract: The information is required by the Internal Revenue Service to assist predecessor and successor employers in complying with the reporting requirements under Internal Revenue Code sections 6051 and 6011 for Forms W–2 and 941.

Current Actions: There are no changes being made to the revenue procedure at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 553,500.

Estimated Time per Respondent: 12 minutes.

Estimated Total Annual Burden Hours: 110,700.

The following paragraph applies to all of the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 6, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–24729 Filed 11–13–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Notice 2018–81

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, 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. The IRS is soliciting comments concerning Notice 2018–81, Notice Regarding Certain Church Plan Clarifications under Section 336 of the PATH Act.

DATES: Written comments should be received on or before January 14, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to L. Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the collection tools should be directed to Sara Covington at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or at (202) 317–6038 or through the internet at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Notice Regarding Certain Church Plan Clarifications under Section 336 of the PATH Act.

OMB Number: 1545–2279.

Regulation Project Number: Notice–2018–81.

Abstract: Notice 2018–81 describes the manner in which taxpayers notify the Internal Revenue Service (IRS) of revocation of an election to aggregate or disaggregate certain church-related organizations from treatment as a single employer under section 414(c)(2)(C) and (D). Churches and church-related organizations are allowed to make elections to aggregate or disaggregate for this purpose under section 414(c)(2)(C) and (D), which were added to the Code by section 336(a) of the Protecting Americans from Tax Hikes Act of 2015 (Pub. L. 114–113 (129 Stat. 2242 (2015)) (PATH Act).

Current Actions: There are changes in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection. The number of respondents have been corrected to represent the annual number of respondents.

Affected Public: Business or other Not-for-profit; Individuals or households.

Estimated Number of Respondents: 3.

Estimated Time per Respondent: 2 hours.

Estimated Total Annual Burden Hours: 6.1 hours.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 6, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–24831 Filed 11–13–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, 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. Currently, the IRS is soliciting comments concerning required distributions from retirement plans.

DATES: Written comments should be received on or before January 14, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Laurie Brimmer, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to LaNita Van Dyke, at (202) 317–6009, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Required Distributions from Retirement Plans.

OMB Number: 1545–0996.

Regulation Project Number: REG–130477–00; REG–130481–00.

Abstract: These regulations relate to the required minimum distributions from qualified plans, individual retirement plans, deferred compensation plans under section 457, and section 403(b) annuity contracts, custodial accounts, and retirement income accounts.

Current Actions: There are no changes to these existing regulations.

Type of Review: Extension of currently approved collection.

Affected Public: Business or other for-profit institutions, and state, local, or tribal governments.

Estimated Number of Respondents: 42,000.

Estimated Time per Respondent: 12 minutes.

Estimated Total Annual Burden Hours: 8,400.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 6, 2018.

Laurie Brimmer,

Senior Tax Analyst.

[FR Doc. 2018–24731 Filed 11–13–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request for Form 5213

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the 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. Currently, the IRS is soliciting comments concerning Form 5213, Election to Postpone Determination as To Whether the Presumption Applies That an Activity Is Engaged in for Profit.

DATES: Written comments should be received on or before January 14, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Carolyn Brown, Internal Revenue Service, Room 6236, 1111 Constitution Avenue NW, Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to R. Joseph Durbala, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Election to Postpone Determination as To Whether the Presumption Applies That an Activity Is Engaged in for Profit.

OMB Number: 1545–0195.

Form Number: 5213.

Abstract: Section 183 of the Internal Revenue Code allows taxpayers to elect to postpone a determination as to whether an activity is entered into for profit or is in the nature of a nondeductible hobby. The election is made on Form 5213 and allows taxpayers 5 years (7 years for breeding, training, showing, or racing horses) to show a profit from an activity.

Current Actions: There is no change to the burden previously approved.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 3,541.

Estimated Time per Respondent: 47 min.

Estimated Total Annual Burden Hours: 2,762.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: November 6, 2018.

R. Joseph Durbala,

IRS Tax Analyst.

[FR Doc. 2018–24735 Filed 11–13–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Excise Tax; Tractors, Trailers, Trucks, and Tires; Reporting and Recordkeeping Requirements

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the 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. Currently, the IRS is soliciting comments concerning floor stocks credits or refunds and consumer credits or refunds with respect to certain tax-repealed articles; excise tax on heavy trucks, and excise tax on heavy trucks, truck trailers, semitrailers, and tractors; reporting and recordkeeping requirements.

DATES: Written comments should be received on or before January 14, 2019 to be assured of consideration.

ADDRESSES: Direct all written comments to Carolyn Brown, Internal Revenue Service, Room 6236, 1111 Constitution Avenue NW, Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to R. Joseph Durbala, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW, Washington DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Excise Tax; Tractors, Trailers, Trucks, and Tires; Reporting and Recordkeeping.

OMB Number: 1545–0745.

Regulation Project Number: TD 7882, TD 8050, and REG–103380–05.

Abstract: Before April 1, 1983, section 4061 imposed a tax on the manufacturer's sale of certain highway-type tractors, chassis, and bodies for highway-type trailers and trucks, and related parts and accessories for these articles. The Highway Revenue Act of 1982, Public Law 97–424 (96 Stat. 2097) (the 1982 Act), changed this tax to a 12 percent tax under section 4051(a)(1) on the first retail sale of certain highway-type tractors and chassis and bodies for highway-type trailers and trucks.

On April 4, 1983, temporary regulations were published in the **Federal Register** (48 FR 14361; TD 7882) to implement this new retail tax. Subsequent amendments to these regulations were published in the **Federal Register** on September 13, 1985 (50 FR 37350; TD 8050); May 12, 1988 (53 FR 16867; TD 8200); and July 1, 1998 (63 FR 35799; TD 8774). REG 103380–05 (81 FR 18544), published March 31, 2016, contains proposed regulations relating to the excise taxes imposed on the sale of highway tractors, trailers, trucks, and tires; the use of heavy vehicles on the highway; and the definition of highway vehicle related to these and other taxes. These proposed regulations reflect legislative changes and court decisions regarding these topics. These proposed regulations affect manufacturers, producers, importers, dealers, retailers, and users of certain highway tractors, trailers, trucks, and tires.

Current Actions: There is no change to the burden previously approved.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and Individuals.

Estimated Number of Respondents: 7,100.

Estimated Time per Respondent: 1 hr. 16 min.

Estimated Total Annual Burden Hours: 4,890.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: November 6, 2018.

R. Joseph Durbala,

IRS Tax Analyst.

[FR Doc. 2018–24734 Filed 11–13–18; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0674]

Agency Information Collection Activity: Notice of Disagreement

AGENCY: Board of Veterans' Appeals, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Board of Veterans' Appeals, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: Comments must be submitted on or before December 14, 2018.

ADDRESSES: Submit written comments on the collection of information through *www.Regulations.gov*, or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW, Washington, DC 20503 or sent through electronic mail to *oira_submission@omb.eop.gov.* Please refer to ''OMB Control No. 2900–0674'' in any correspondence.

FOR FURTHER INFORMATION CONTACT: Sue Hamlin, BVA, (01C2), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 632–5100 or email *sue.hamlin@va.gov.* Please refer to ''OMB Control No. 2900–0674'' in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 115–55; 38 U.S.C. 5104B, 5108, 5701, 5901, 7103, 7104, 7105, 7107.

Title: Decision Review Request: Board Appeal (Notice of Disagreement) and Appeal to the Board of Veterans' Appeals, VA Form 10182 and VA Form 9

OMB Control Number: 2900–0674.

Type of Review: Reinstatement with Change of a currently approved collection.

Abstract: Appellate review of the denial of VA benefits may only be initiated by filing a Notice of Disagreement with the Board. 38 U.S.C. § 7105(a). The VA Form 9, ''Appeal to Board of Veterans' Appeals,'' is required to complete a legacy appeal to the Board. The completed form becomes the ''substantive appeal'' (or ''formal appeal''), which is required by 38 U.S.C. §§ 7105(a) and (d)(3) in order to complete an appeal to the Board. Additionally, the proposed information collections allow for withdrawal of services by a representative, requests for changes in hearing dates and methods under 38 U.S.C. § 7107, and motions for reconsideration pursuant to 38 U.S.C. § 7103(a). The Board is requesting to revise the currently approved OMB Control No. 2900–0674, adding four information collections previously approved under OMB Control No. 2900–0085, and one new information collection. Revised Control No. 2900–0674 would contain all appeals-related information collections for the legacy and new systems. 2900–0085 will be discontinued upon approval of this request to renew 2900–0674.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 83 No. 164 on Thursday, August 23, 2018, pages 42769 and 42770.

Affected Public: Individuals and households.

Estimated Annual Burden: 114,877.78 hours.

Estimated Average Burden per Respondent: 40.83 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 168,800.

- VA Form 10182: Notice of Disagreement (new) = 40,000.
- Nonstandard Form: Notice of Disagreement (legacy) = 60,000.
- VA Form 9: Appeal to the Board of Veterans' Appeals (legacy) = 64,500.
- Nonstandard Form: Withdrawal of Services by a Representative = 500.
- Nonstandard Form: Requests for Changes in Hearing Dates or Methods = 2,800.
- Nonstandard Form: Motions for Reconsideration =1000.

By direction of the Secretary.

Cynthia D. Harvey-Pryor,

Government Information Specialist, Department of Veterans Affairs.

[FR Doc. 2018–24759 Filed 11–13–18; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Rehabilitation Research and Development Service Scientific Merit Review Board; Notice of Meetings

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that the subcommittees of the Rehabilitation Research and Development Service Scientific Merit Review Board will meet from 8:00 a.m. to 5:00 p.m. on the dates indicated below:

Subcommittee	Date(s)	Location
Center and Research Enhancement Award Program	January 17, 2019	Crystal City Marriott.
Chronic Medical Conditions and Aging	February 26, 2019	20 F Conference Center.
Sensory Systems & Communication Disorders	February 26, 2019	20 F Conference Center.
Career Development Program	February 26–27, 2019	20 F Conference Center.
Rehabilitation Engineering & Prosthetics/Orthotics	February 27, 2019	20 F Conference Center.
Spinal Cord Injury/Disorders & Neuropathic Pain	February 27, 2019	20 F Conference Center.
Musculoskeletal Health & Function	February 27–28, 2019	20 F Conference Center.
Behavioral Health & Social Reintegration	February 28, 2019	20 F Conference Center.
Regenerative Rehabilitation	February 28, 2019	20 F Conference Center.
Brain Health and Injury	February 28–March 1, 2019	20 F Conference Center.

The address of the meetings sites are: 20 F Conference Center, 20 F Street NW, Washington, DC 20001.

Crystal City Marriott at Reagan National Airport, 1999 Jefferson Davis Highway, Arlington, VA 22202.

The purpose of the Board is to review rehabilitation research and development applications and advise the Director, Rehabilitation Research and Development Service, and the Chief Research and Development Officer on the scientific and technical merit, the mission relevance, and the protection of human and animal subjects.

The subcommittee meetings will be open to the public for approximately one-half hour at the start of each meeting to cover administrative matters and to discuss the general status of the program. Members of the public who wish to attend the open portion of the teleconference sessions may dial 1 (800) 767–1750, participant code 35847. The remaining portion of each subcommittee meeting will be closed to the public for the discussion, examination, reference to, and oral review of the research applications and critiques. During the closed portion of each subcommittee meeting, discussion and recommendations will include qualifications of the personnel conducting the studies (the disclosure of which would constitute a clearly unwarranted invasion of personal privacy), as well as research information (the premature disclosure of which would likely compromise significantly the implementation of proposed agency action regarding such research projects). As provided by subsection 10(d) of Public Law 92–463, as amended by Public Law 94–409, closing the meeting is in accordance with 5 U.S.C. 552b(c)(6) and (9)(B).

No oral or written comments will be accepted from the public for either portion of the meetings. Those who plan to attend (by phone or in person) the open portion of a subcommittee meeting must contact Tiffany Asqueri, Designated Federal Officer, Rehabilitation Research and Development Service, at Department of Veterans Affairs (10P9R), 810 Vermont Avenue NW, Washington, DC 20420, or email *Tiffany.Asqueri@va.gov,* at least five days before the meeting. For further information, please call Mrs. Asqueri at (202) 443–5757.

Dated: November 8, 2018.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2018–24758 Filed 11–13–18; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 83 Wednesday,
No. 220 November 14, 2018

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413 and 414

[CMS–1691–F]

RIN 0938–AT28

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates and makes revisions to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year (CY) 2019. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury (AKI). In addition, it updates and rebases the ESRD market basket for CY 2019. This rule also updates requirements for the ESRD Quality Incentive Program (QIP), and makes technical amendments to correct existing regulations related to the Competitive Bidding Program (CBP) for certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS). Finally, this rule finalizes changes to bidding and pricing methodologies under the DMEPOS competitive bidding program; adjustments to DMEPOS fee schedule amounts using information from competitive bidding for items furnished from January 1, 2019 through December 31, 2020; new payment classes for oxygen and oxygen equipment and a new methodology for ensuring that new payment classes for oxygen and oxygen equipment are budget neutral; payment rules for multi-function ventilators or ventilators that perform functions of other durable medical equipment (DME); and revises the payment methodology for mail order items furnished in the Northern Mariana Islands. This rule also includes a summary of the feedback received for the request for information related to establishing fee schedule amounts for new DMEPOS items and services.

DATES: These regulations are effective January 1, 2019, except the amendments to 42 CFR 413.234, which are effective January 1, 2020.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov, for issues related to the ESRD PPS and coverage and payment for renal dialysis services furnished to individuals with AKI.

Delia Houseal, (410) 786–2724, for issues related to the ESRD QIP.

DMEPOS@cms.hhs.gov, for issues related to DMEPOS payment policy.

Julia Howard, (410) 786–8645, for issues related to DMEPOS CBP technical amendments only.

SUPPLEMENTARY INFORMATION:

Electronic Access

This **Federal Register** document is also available from the **Federal Register** online database through *Federal Digital System* (*FDsys*), a service of the U.S. Government Printing Office. This database can be accessed via the internet at *http://www.gpo.gov/fdsys/*.

Addenda Are Only Available Through the internet on the CMS website

The Addenda for the annual ESRD PPS proposed and final rules will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet on the CMS website at *http://www.cms.gov/ESRDPayment/PAY/list.asp*. In addition to the Addenda, limited data set (LDS) files are available for purchase at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html*. Readers who experience any problems accessing the Addenda or LDS files, should contact *ESRDPayment@cms.hhs.gov*.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents. Some of the issues discussed in this preamble affect the payment policies, but do not require changes to the regulations in the Code of Federal Regulations (CFR).

I. Executive Summary

A. Purpose

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14) (F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule updates and makes revisions to the ESRD PPS for CY 2019.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with acute kidney injury (AKI). Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This rule updates the AKI payment rate for CY 2019.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized under section 1881(h) of the Social Security Act (the Act) and is the most recent step in fostering improved patient outcomes by establishing incentives for dialysis facilities to meet or exceed performance standards established by the Centers for Medicare & Medicaid Services (CMS). This rule finalizes a number of updates for the ESRD QIP.

4. Changes to the DMEPOS Competitive Bidding Program and Fee Schedule Payment Rules

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP): This rule finalizes revisions to the DMEPOS CBP by implementing lead item pricing based on maximum winning bid amounts.

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP: This rule finalizes fee schedule adjustment methodologies for DMEPOS items and services furnished on or after January 1, 2019, in areas that are currently CBAs and in areas that are currently not CBAs. Altogether, this rule finalizes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous United States (U.S.); and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes: This rule finalizes new, separate payment classes for portable gaseous oxygen equipment, portable liquid oxygen equipment, and high flow portable liquid oxygen contents. This rule also finalizes a new methodology for ensuring that all new payment classes for oxygen and oxygen equipment are budget neutral in accordance with section 1834(a)(9)(D)(ii) of the Act.

iv. Payment for Multi-Function Ventilators: This rule finalizes payment rules for certain ventilators that are classified under section 1834(a)(3) of the Act but also perform the functions of other items of DME that are subject to payment rules other than those at section 1834(a)(3) of the Act.

v. Northern Mariana Islands in Future National Mail Order CBPs: This rule finalizes changes to 42 CFR 414.210(g)(7) indicating that, beginning on or after the date that contracts take effect for a national mail order competitive bidding program that includes the Northern Mariana Islands, the fee schedule adjustment methodology under this paragraph will no longer apply.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2019:* The final CY 2019 ESRD PPS base rate is $235.27. This amount reflects a productivity-adjusted market basket increase as required by section 1881(b)(14)(F)(i)(I) of the Act (1.3 percent), and application of the wage index budget-neutrality adjustment factor (0.999506), equaling $235.27 ($232.37 × 1.013 × 0.999506 = $235.27).
- *Annual update to the wage index:* We adjust wage indices on an annual basis using the most current hospital wage data and the latest core-based statistical area (CBSA) delineations to account for differing wage levels in areas in which ESRD facilities are located. For CY 2019, we are increasing the wage index floor, for areas with wage index values below the floor, to 0.50 and we are updating the wage index values to the latest available data.
- *Update to the outlier policy:* We are updating the outlier policy using the

most current data, as well as updating the outlier services fixed-dollar loss (FDL) amounts for adult and pediatric patients and Medicare Allowable Payment (MAP) amounts for adult and pediatric patients for CY 2019 using CY 2017 claims data. Based on the use of the latest available data, the final FDL amount for pediatric beneficiaries will increase from $47.79 to $57.14 and the MAP amount will decrease from $37.31 to $35.18, as compared to CY 2018 values. For adult beneficiaries, the final FDL amount will decrease from $77.54 to $65.11 and the MAP amount will decrease from $42.41 to $38.51. The 1 percent target for outlier payments was not achieved in CY 2017. Outlier payments represented approximately 0.8 percent of total payments rather than 1.0 percent. We believe using CY 2017 claims data to update the outlier MAP and FDL amounts for CY 2019 will increase payments for ESRD beneficiaries requiring higher resource utilization in accordance with a 1 percent outlier percentage.

- *Update to the drug designation process:* We are updating and revising our drug designation process and expanding the transitional drug add-on payment adjustment (TDAPA) to all new renal dialysis drugs and biological products, not just those in new ESRD PPS functional categories. We are also changing the basis of payment for the TDAPA from pricing methodologies under section 1847A of the Act, which includes ASP+6, to ASP+0. These changes to the drug designation process and TDAPA will be effective January 1, 2020.
- *Update to the low-volume payment adjustment:* We are finalizing revisions to the low-volume payment adjustment regulations to allow for more flexibility with regard to attestation deadlines and cost reporting requirements, as well as updating the requirements for eligibility with respect to certain changes of ownership.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

We are updating the AKI payment rate for CY 2019. The final CY 2019 payment rate is $235.27, which is the same as the base rate finalized under the ESRD PPS for CY 2019.

3. ESRD QIP

This rule finalizes a number of new requirements for the ESRD QIP beginning with PY 2021, including the following:

- We are updating the ESRD QIP's measure removal criteria, which we now refer to as ''factors,'' so that they are more closely aligned with the measure removal factors we have adopted for other quality reporting and pay for performance programs, as well as the priorities we have adopted as part of the Meaningful Measures Initiative.
- We are removing four measures: Healthcare Personnel Influenza Vaccination, Pain Assessment and Follow-Up, Anemia Management, and Serum Phosphorus. The removal of these measures will align the ESRD QIP measure set more closely with the priorities we have adopted as part of our Meaningful Measures Initiative.
- We are finalizing several changes to the domains that we use for purposes of our scoring methodology to more closely align the ESRD QIP with the priorities we have adopted as part of our Meaningful Measures Initiative. We are removing the Reporting Domain from the Program and moving each reporting measure currently in that domain (and not being removed) to another domain that is better aligned with the focus area of that measure. Additionally, we are finalizing that the Patient and Family Engagement/Care Coordination Subdomain and the Clinical Care Subdomain, both of which are currently subdomains in the Clinical Measure Domain, will become their own domains. As a result, the ESRD QIP will be scored using four domains instead of three. Furthermore, we are finalizing new domain and measure weights that better align with the priority areas we have adopted as part of our Meaningful Measures Initiative.
- We are updating our policy governing when newly opened facilities must start reporting ESRD QIP data. Under our updated policy, new facilities will begin reporting ESRD QIP data beginning with the month that begins 4 months after the month during which the CMS Certification Number (CCN) becomes effective (for example, a facility with a CCN effective date of January 15th will be required to begin reporting ESRD QIP data collected in May). The policy will provide facilities with a longer time period to learn how to properly report ESRD QIP data.
- We are increasing the number of facilities that we select for validation under the National Healthcare Safety Network (NHSN) data validation study from 35 to 150 facilities. We are also increasing the number of records that each selected facility must submit to 20 records for each of the first 2 quarters of CY 2019 (for a total of 40 records). This will improve the overall accuracy of the study.
- We are converting the current Consolidated Renal Operations in a Web-Enabled Network (CROWNWeb) data validation study into a permanent program requirement using the methodology we first adopted for PY 2016 because an analysis demonstrated that this methodology produced reliable validation results. We are also finalizing that the 10-point deduction for failure to comply with the data request, which was first adopted for PY 2017, will become a permanent program requirement.

This rule also finalizes a number of new requirements for the ESRD QIP beginning with PY 2022, including the following:

- We are adopting the Percentage of Prevalent Patients Waitlisted (PPPW) Measure and placing it in the Care Coordination Measure Domain.
- We are adopting the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) Measure (NQF #2988) and placing it in the Safety Measure Domain.
- We are increasing the number of facilities that we select for validation under the NHSN data validation study from 150 to 300 facilities. This will further improve the overall accuracy of the study.

Finally, we are codifying in our regulations several previously finalized requirements for the ESRD QIP by revising § 413.177 and adopting a new § 413.178.

4. Changes to the DMEPOS Competitive Bidding Program and Fee Schedule Payment Rules

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP): The rule finalizes changes to the DMEPOS CBP to implement lead item pricing based on maximum winning bid amounts, including revisions to certain definitions under 42 CFR 414.402. The definition of bid is revised to mean an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items. The definition of composite bid is revised to mean the bid submitted by the supplier for the lead item in the product category. The definition of lead item is revised to mean the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition.

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information from the DMEPOS CBP: This rule finalizes methodologies for using the payment determined under the DMEPOS CBP to adjust fee schedule

amounts for DMEPOS items and services furnished on or after January 1, 2019. Altogether, this rule finalizes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous U.S.; and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes: This rule establishes new, separate payment classes for portable gaseous oxygen equipment, portable liquid oxygen equipment, and high flow portable liquid oxygen contents. This rule also finalizes a new methodology for ensuring that all new payment classes for oxygen and oxygen equipment are budget neutral in accordance with section 1834(a)(9)(D)(ii) of the Act.

iv. Payment for Multi-Function Ventilators: This rule finalizes payment rules for certain ventilators that are classified under section 1834(a)(3) of the Act but also perform the functions of other items of DME that are subject to payment rules other than those at section 1834(a)(3) of the Act.

v. Northern Mariana Islands in Future National Mail Order CBPs: This rule finalizes changes to § 414.210(g)(7) to indicate that, beginning on or after the date that contracts take effect for a national mail order competitive bidding program that includes the Northern Mariana Islands, the fee schedule adjustment methodology under this paragraph will no longer apply.

C. Summary of Costs and Benefits

In section XV of this final rule, we set forth a detailed analysis of the impacts of the finalized changes for affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact chart in section XV of this final rule displays the estimated change in payments to ESRD facilities in CY 2019 compared to estimated payments in CY 2018. The overall impact of the CY 2019 changes are projected to be a 1.6 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.7 percent increase in payments compared with freestanding facilities with an estimated 1.6 percent increase.

We estimate that the aggregate ESRD PPS expenditures will increase by approximately $210 million in CY 2019 compared to CY 2018. This reflects a $170 million increase from the payment rate update and a $40 million increase due to the updates to the outlier threshold amounts. As a result of the projected 1.6 percent overall payment increase, we estimate that there will be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2019, which translates to approximately $50 million.

2. Impacts of the Final Payment for Renal Dialysis Services Furnished to Individuals With AKI

The impact chart in section XV of this final rule displays the estimated change in payments to ESRD facilities in CY 2019 compared to estimated payments in CY 2018. The overall impact of the CY 2019 changes are projected to be a 1.3 percent increase in payments. Hospital-based ESRD facilities have an estimated 1.2 percent increase in payments compared with freestanding facilities with an estimated 1.3 percent increase.

We estimate that the aggregate payments made to ESRD facilities for renal dialysis services furnished to AKI patients at the final CY 2019 ESRD PPS base rate will increase by less than $1 million in CY 2019 compared to CY 2018.

3. Impacts of the Finalized Updates to the ESRD QIP

We estimate that the overall economic impact of the ESRD QIP will be approximately $213 million in PY 2021. The $213 million figure for PY 2021 includes costs associated with the collection of information requirements, which we estimate will be approximately $181 million. In PY 2022, we estimate that the overall economic impact of the ESRD QIP will be approximately $234 million. The $234 million figure for PY 2022 includes costs associated with the collection of information requirements, which we estimate will be approximately $202 million.

4. Impacts of the Final Changes to the DMEPOS Competitive Bidding Program and Fee Schedule Payment Rules

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

The rule finalizes changes to the DMEPOS CBP to implement lead item pricing based on maximum winning bid amounts. The impacts of this rule are estimated by rounding to the nearer 5 million dollars and are expected to cost $10 million in Medicare benefit payments for the 5-year period beginning January 1, 2019, and ending September 30, 2023. The impact on the Medicare beneficiary cost sharing is roughly $3 million over this 5-year period. We estimate that the average per Medicare beneficiary increase in cost-sharing from median-priced SPAs to maximum-bid priced SPAs will be about $1.50. This average increase is based on 2017 claims data which divides the aggregate $3 million dollar cost-sharing impact by the number of Medicare beneficiaries residing in CBAs in 2017 of about 2 million beneficiaries. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to both be $0 million.

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

This rule finalizes fee schedule adjustment methodologies for DMEPOS items and services furnished on or after January 1, 2019. Altogether, this rule finalizes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous U.S.; and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

The estimated impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are made consistent with the rules in place

as of January 1, 2018, which establish payment for items furnished in CBAs based on fee schedule amounts fully adjusted in accordance with regulations at § 414.210(g). The impacts are expected to cost $1.05 billion in Medicare benefit payments and $260 million in Medicare beneficiary cost sharing for the 2-year period beginning January 1, 2019, and ending December 31, 2020. In other words, the average per Medicare beneficiary increase in cost-sharing is about $65.00 dollars. This average increase is based on 2017 claims data which divides the aggregate $260 million cost-sharing impact by the number of beneficiaries residing in CBAs and non-CBAs of about 4 million beneficiaries. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to be $45 million and $30 million, respectively. Section 503 of the Consolidated Appropriations Act of 2016 (Pub. L. 114–113), and section 5002 of the 21st Century Cures Act (the Cures Act) (Pub. L. 114—255), added section 1903(i)(27) to the Act, which prohibits federal Medicaid reimbursement to states for certain DME expenditures that are, in the aggregate, in excess of what Medicare would have paid for such items. The requirement took effect January 1, 2018. We note that the costs for the Medicaid program and beneficiaries could be higher depending on how many state agencies adopt the higher Medicare adjusted fee schedule amounts for rural areas for use in paying claims under the Medicaid program. We are not able to quantify this impact.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

This rule establishes new payment classes for oxygen and oxygen equipment and will be budget neutral to the Medicare program and its beneficiaries.

iv. Payment for Multi-Function Ventilators

This rule establishes new rules to address payment for certain ventilators that are classified under section 1834(a)(3) of the Act but also perform the functions of other items of durable medical equipment (DME) that are subject to payment rules other than those at section 1834(a)(3) of the Act. The impacts are estimated by rounding to the nearer 5 million dollars and are expected to cost $15 million in Medicare benefit payments and $3 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019, and ending September 30, 2023. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to both be $0 million.

v. Northern Mariana Islands in Future National Mail Order CBPs

This change will not have a fiscal impact because the amount paid for mail order items furnished in the Northern Mariana Islands will be the same as it would have been had the policy not changed.

II. Calendar Year (CY) 2019 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, we implemented the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act), established that beginning with calendar year (CY) 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014 to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals (excluding oral-only ESRD-related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. And section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for—(1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Finally, on December 19, 2014, the President signed the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295). Section 204 of ABLE amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis services cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single, per-treatment payment is made to an ESRD facility for all of the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to individuals for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definitions of renal dialysis services at 42 CFR

413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies. The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, four comorbidity categories, and pediatric patient-level adjusters consisting of two age categories and two dialysis modalities (§ 413.235(a) and (b)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second adjustment reflects differences in area wage levels developed from core based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

The ESRD PPS provides a training add-on for home and self-dialysis modalities (§ 413.235(c)) and an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable (§ 413.237).

The ESRD PPS also provides for a transitional drug add-on payment adjustment (TDAPA) to pay for a new injectable or intravenous product that is not considered included in the ESRD PPS bundled payment, meaning a product that is used to treat or manage a condition for which there is not an existing ESRD PPS functional category (§ 413.234). The ESRD PPS functional categories represent distinct groupings of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. New injectable or intravenous products that are not included in a functional category in the ESRD PPS base rate are paid for using the TDAPA for a minimum of 2 years, until sufficient claims data for rate setting analysis are available. At that point, utilization would be reviewed and the ESRD PPS base rate modified, if appropriate, to account for these products. The TDAPA is based on pricing methodologies under section 1847A of the Act (§ 413.234(c)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule was published on August 12, 2010 in the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011 in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

On November 1, 2017, we published a final rule in the **Federal Register** titled, ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program'' (82 FR 50738 through 50797) (hereinafter referred to as the CY 2018 ESRD PPS final rule). In that rule, we updated the ESRD PPS base rate for CY 2018, the wage index, the outlier policy, and pricing outlier drugs. For further detailed information regarding these updates, see 82 FR 50738.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on the Calendar Year (CY) 2019 ESRD PPS

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS'' (83 FR 34304 through 34415), hereinafter referred to as the ''CY 2019 ESRD PPS proposed rule'', was published in the **Federal Register** on July 19, 2018, with a comment period that ended on September 10, 2018. In that proposed rule, for the ESRD PPS, we proposed to make a number of annual updates for CY 2019, including updates to the ESRD PPS base rate, wage index, and outlier policy. We also proposed to revise the drug designation process and expand the TDAPA to all new renal dialysis drugs and biologicals, not just those in new ESRD PPS functional categories, and change the basis for determining the TDAPA from pricing methodologies under section 1847A of the Act (which includes ASP+6) to ASP+0. We also proposed revisions to the low-volume payment adjustment (LVPA) regulations. We received approximately 156 public comments on our proposals, including comments from ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; health care systems; and nurses.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the CY 2019 ESRD PPS.

1. Drug Designation Process

a. Protecting Access to Medicare Act of 2014

Section 217(c) of PAMA requires the Secretary to implement a process for: (1) Determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the bundled payment under the ESRD PPS. Therefore, in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027), we finalized a process, which we refer to as the drug designation process, that allows us to recognize when an oral-only renal dialysis service drug or biological product is no longer oral only and to include new injectable and intravenous products into the ESRD PPS bundled payment, and when appropriate, modify the ESRD PPS payment amount.

In accordance with section 217(c)(1) of PAMA, we established § 413.234(d), which provides that an oral-only drug is no longer considered oral-only if an injectable or other form of administration of the oral-only drug is approved by the Food and Drug Administration (FDA). Additionally, in accordance with section 217(c)(2) of PAMA, we codified the drug designation process at § 413.234(b). As discussed in the CY 2016 ESRD PPS final rule (80 FR 69017 through 69022), effective January 1, 2016, if a new injectable or intravenous product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new injectable or intravenous product is considered included in the ESRD PPS bundled payment and no separate payment is available. The new injectable or intravenous product qualifies as an outlier service. The ESRD bundled market basket updates the PPS base rate annually and accounts for price changes of the drugs and biological products reflected in the base rate.

Under § 413.234(b)(2), if the new injectable or intravenous product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new injectable or intravenous product is not considered included in the ESRD PPS bundled payment and the following

steps occur. First, an existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new injectable or intravenous product is used to treat or manage. Next, the new injectable or intravenous product is paid for using the transitional drug add-on payment adjustment (TDAPA). Then, the new injectable or intravenous product is added to the ESRD PPS bundled payment following payment of the TDAPA.

Under § 413.234(c), the TDAPA is based on pricing methodologies under section 1847A of the Act and is paid until sufficient claims data for rate setting analysis for the new injectable or intravenous product are available, but not for less than 2 years. During the time a new injectable or intravenous product is eligible for the TDAPA, it is not eligible as an outlier service. Following payment of the TDAPA, the ESRD PPS base rate would be modified, if appropriate, to account for the new injectable or intravenous product in the ESRD PPS bundled payment.

b. Renal Dialysis Drugs and Biological Products Reflected in the Base Rate (ESRD PPS Functional Categories)

In the CY 2016 ESRD PPS final rule (80 FR 69024), we finalized the drug designation process as being dependent upon the functional categories, consistent with our policy since the implementation of the PPS in 2011. We provided a detailed discussion on how we accounted for renal dialysis drugs and biological products in the ESRD PPS base rate since its implementation on January 1, 2011 (80 FR 69013 through 69015). In the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053) we explained that in order to identify drugs and biological products that are used for the treatment of ESRD and therefore meet the definition of renal dialysis services (defined at § 413.171) that would be included in the ESRD PPS base rate, we performed an extensive analysis of Medicare payments for Part B drugs and biological products billed on ESRD claims and evaluated each drug and biological product to identify its category by indication or mode of action. Categorizing drugs and biological products on the basis of drug action allows us to determine which categories (and therefore, the drugs and biological products within the categories) would be considered used for the treatment of ESRD (75 FR 49047). We grouped the injectable and intravenous drugs and biological products into functional categories based on their action (80 FR 69014). This was done for the purpose of adding new drugs or biological products with the same functions to the ESRD PPS bundled payment as expeditiously as possible after the drugs become commercially available so that beneficiaries have access to them. We finalized the definition of an ESRD PPS functional category in § 413.234(a) as a distinct grouping of drugs or biologicals, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD.

Using the functional categorization approach, we established categories of drugs and biological products that are *not* considered used for the treatment of ESRD, categories of drugs and biological products that are *always* considered used for the treatment of ESRD, and categories of drugs and biological products that *may be* used for the treatment of ESRD but are also commonly used to treat other conditions (75 FR 49049 through 49051). The drugs and biological products that were identified as *not* used for the treatment of ESRD were *not* considered renal dialysis services and were *not* included in computing the base rate. The functional categories of drugs and biological products that are *not* included in the base rate can be found in the CY 2011 ESRD PPS final rule (75 FR 49049). The functional categories of drugs and biological products that were *always* and *may be* considered used for the treatment of ESRD were considered renal dialysis services and were included in computing the base rate. Subsequent to the CY 2011 discussion about the always and may be functional categories (75 FR 49050 through 49051), we also discussed these categories in the CY 2016 ESRD PPS final rule (80 FR 69015 through 69018) and clarified the medical conditions or symptoms that indicate the drugs are used for the treatment of ESRD. See Table 1.

TABLE 1—ESRD PPS FUNCTIONAL CATEGORIES

Category	Rationale for association
Access Management	Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
Anemia Management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Bone and Mineral Metabolism.	Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics.
Cellular Management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
Antiemetic	Used to prevent or treat nausea and vomiting related to dialysis. Excludes antiemetics used for purposes unrelated to dialysis, such as those used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Used to treat vascular access-related and peritonitis infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs in this classification have multiple clinical indications. Use within an ESRD functional category includes treatment for itching related to dialysis.
Anxiolytic	Drugs in this classification have multiple actions. Use within an ESRD functional category includes treatment of restless leg syndrome related to dialysis.
Excess Fluid Management	Drug/fluids used to treat fluid excess/overload.
Fluid and Electrolyte Management Including Volume Expanders.	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs used to treat vascular access site pain and to treat pain medication overdose, when the overdose is related to medication provided to treat vascular access site pain.

In computing the ESRD PPS base rate, we used the payments in 2007 for drugs and biological products included in the always functional categories, that is, the injectable forms (previously covered under Part B) and oral or other forms of

administration (previously covered under Part D) (75 FR 49050). For the oral or other forms of administration for those drugs that are always considered used for the treatment of ESRD, we determined that there were oral or other forms of injectable drugs only for the bone and mineral metabolism and cellular management categories. Therefore, we included the payments made under Part D for oral vitamin D (calcitriol, doxercalciferol and paricalcitol) and oral levocarnitine in our computation of the base rate (75 FR 49042).

In the CY 2011 ESRD PPS final rule (75 FR 49050 through 49051), we explained that drugs and biological products that may be used for the treatment of ESRD may also be commonly used to treat other conditions. We used the payments made under Part B in 2007 for these drugs in computing the ESRD PPS base rate, which only included payments made for the injectable version of the drugs. We excluded the Part D payments for the oral (or other form of administration) substitutes of the drugs and biological products described above because they were not furnished or billed by ESRD facilities or furnished in conjunction with dialysis treatments (75 FR 49051). For those reasons, we presumed that these drugs and biological products that were paid under Part D were prescribed for reasons other than for the treatment of ESRD. However, we noted that if these drugs and biological products paid under Part D are furnished by an ESRD facility for the treatment of ESRD, they would be considered renal dialysis services and not be billed or paid under Part D.

In the CY 2011 ESRD PPS final rule (75 FR 49075 through 49076), Table 19 provides the Medicare allowable payments for all of the components of the ESRD PPS base rate for CY 2007, inflated to CY 2009, including payments for drugs and biological products and the amount each contributed to the base rate, except for the oral-only renal dialysis drugs where payment under the ESRD PPS was delayed. A list of the specific Part B drugs and biological products that were included in the final ESRD PPS base rate is located in Table C of the Appendix of the CY 2011 ESRD PPS final rule (75 FR 49205 through 49209). A list of the former Part D drugs that were included in the final ESRD PPS base rate is located in Table D of the Appendix of that rule (75 FR 49210). As discussed in section II.3.d of this final rule, the ESRD PPS base rate is updated annually by the ESRD bundled (ESRDB) market basket.

c. Section 1847A of the Social Security Act (the Act) and Average Sales Price (ASP) Methodology Under the ESRD PPS

In the CY 2005 Physician Fee Schedule (PFS) final rule, published on November 15, 2004 (69 FR 66299 through 66302) in the **Federal Register**, we discussed that section 303(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added section 1847A to the Act and established the Average Sales Price (ASP) methodology for certain drugs and biological products not paid on a cost or prospective payment basis furnished on or after January 1, 2005. The ASP methodology is based on quarterly data submitted to CMS by drug manufacturers. The ASP amount is based on the manufacturer's sales to all purchasers (with certain exceptions) net of all manufacturer rebates, discounts, and price concessions. Sales that are nominal in amount are exempted from the ASP calculation, as are sales excluded from the determination of ''best price'' in the Medicaid drug rebate program. Each drug with a Healthcare Common Procedure Coding System (HCPCS) code has a separately calculated ASP. To allow time to submit and calculate these data, the ASP is updated with a two-quarter lag.[1]

Section 1847A(b)(1)(A) of the Act requires that the Medicare payment allowance for a multiple source drug included within the same HCPCS code be equal to 106 percent of the ASP for the HCPCS code. Section 1847A(b)(1)(B) of the Act also requires that the Medicare payment allowance for a single source drug HCPCS code be equal to the lesser of 106 percent of the ASP for the HCPCS code or 106 percent of the wholesale acquisition cost (WAC) of the HCPCS code.

Section 1847A(c)(4) of the Act further provides a payment methodology in cases where the ASP during first quarter of sales is unavailable, stating that in the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological are not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on (A) the WAC; or (B) the methodologies in effect under Medicare Part B on November 1, 2003, to determine payment amounts for drugs or biologicals. For further guidance on how Medicare Part B pays for drugs and biological products under section 1847A of the Act, see Pub. 100–04, Chapter 17, section 20 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf*).

In the CY 2018 ESRD PPS final rule (82 FR 50742 through 50743), we discussed how we have used the ASP methodology since the implementation of the ESRD PPS when pricing ESRD-related drugs and biological products previously paid separately under Part B (prior to the ESRD PPS) for purposes of ESRD PPS policies or calculations. In the CY 2016 ESRD PPS final rule (80 FR 69024), we adopted § 413.234(c), which requires that the TDAPA is based on pricing methodologies available under section 1847A of the Act (including 106 percent of ASP). We also use such pricing methodologies for Part B ESRD-related drugs or biological products that qualify as an outlier service (82 FR 50745).

d. Revision to the Drug Designation Process Regulation

As noted above, in prior rulemakings we addressed how new drugs and biological products are implemented under the ESRD PPS and how we have accounted for renal dialysis drugs and biological products in the ESRD PPS base rate since its implementation on January 1, 2011. Accordingly, the drug designation process we finalized is dependent upon the functional categories we developed and is consistent with the policy we have followed since the inception of the ESRD PPS. However, since PAMA only required the Secretary to establish a process for including new injectable and intravenous drugs and biological products in the ESRD PPS bundled payment, such new products were the primary focus of the regulation we adopted at § 413.234. We did not codify our full policy for other renal dialysis drugs, such as drugs and biological products with other forms of administration, including oral, which by law are included under the ESRD PPS (though oral-only renal dialysis drugs are excluded from the ESRD PPS bundled payment until CY 2025).

In the CY 2019 ESRD PPS proposed rule (83 FR 34311 through 34312), we proposed to revise the drug designation process regulations at § 413.234 to reflect that the process applies for all new renal dialysis drugs and biological products that are approved regardless of the form or route of administration, that is, new injectable, intravenous, oral, or

[1] Sheingold, S., Marchetti-Bowick, E., Nguyen, N., Yabrof, K.R. (2016, March). Medicare Part B Drugs: Pricing and Incentives. Retrieved from *https://aspe.hhs.gov/system/files/pdf/187581/PartBDrug.pdf.*

other route of administration, or dosage form. We noted in the proposed rule that for purposes of the ESRD PPS drug designation process, we use the term form of administration interchangeably with the term route of administration. We proposed these revisions so that the regulation reflects our longstanding policy for all new renal dialysis drugs and biological products, regardless of the form or route of administration, with the exception of oral-only drugs. Specifically, we proposed to replace the definition of ''new injectable or intravenous product'' at § 413.234(a) with a definition for ''new renal dialysis drug or biological,'' which is ''an injectable, intravenous, oral or other form or route of administration drug or biological that is used to treat or manage a condition(s) associated with ESRD,'' to encompass the broader scope of the drug designation process. Under the proposed definition, a new renal dialysis drug or biological ''must be approved by the Food and Drug Administration (FDA) on or after January 1, 2019 under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs or biologicals are excluded until January 1, 2025.''

In our proposal to replace the definition of ''new injectable or intravenous product'' in § 413.234(a) with the proposed definition of ''new renal dialysis drug or biological,'' we included the clause, ''have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures.'' We explained that this would be a change from the existing policy of requiring that the new product be assigned an HCPCS code. We proposed that new renal dialysis drugs or biologicals are no longer required to be assigned an HCPCS code before the TDAPA can apply, instead we would require that an application has been submitted in accordance with the Level II HCPCS coding procedures. This would allow the application of the TDAPA to happen more quickly than under our current process, wherein a lag occurs when a drug or biological product is approved but is waiting for the issuance of a code. Information regarding the HCPCS process is available on the CMS website at *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Application_Form_and_Instructions.html.*

We stated that this proposed definition would also address prior concerns that we narrowly defined ''new'' in the context of the functional categories (that is, the drug designation process primarily addresses ''new'' drugs that fall outside of the functional categories for purposes of being newly categorized and eligible for the TDAPA). As we noted in section II.B.1.f of the CY 2019 ESRD PPS proposed rule, even though we were maintaining the functional categories to determine whether or not to potentially adjust or modify the ESRD PPS base rate (that is, those renal dialysis drugs and biological products that do not fall within an existing category), we proposed to expand the TDAPA policy based on whether the renal dialysis drug or biological product is new, that is, any renal dialysis drug or biological product newly approved on or after January 1, 2019.

We solicited comment on the proposed revisions to § 413.234(a), (b), and (c).

The comments and our responses to the comments on our proposal to revise the drug designation process regulations are set forth below.

Comment: Some commenters were supportive of the proposed change to the drug designation process regulation to allow all new drugs and biological products, regardless of form or route of administration, to be eligible for the TDAPA. A drug manufacturer asserted that the proposal recognizes that new innovative products in the treatment of ESRD need not be injectables and that limiting the TDAPA to any particular category of products (for example, by mode of action, cost, or inclusion in a functional category) would be arbitrary and impair access of patients to new therapeutic agents.

Response: We appreciate the commenters' support and note that the change codifies our drug designation policy with regard to all drugs.

Comment: A national dialysis association commented that CMS should implement the proposed drug designation process consistent with the limitations in the Medicare Improvements for Patients and Providers Act of 2009 (MIPPA) on including drugs and biological products in the ESRD PPS. The association stated it is imperative to return to the statutory text of MIPPA to review precisely what categories of drugs and biological products have and have not been authorized for inclusion within the ESRD PPS. The association believes the Congress was clear that only those drugs and biological products that are furnished for the treatment of ESRD and were separately paid prior to implementation of MIPPA—specified by CMS in regulation as of January 1, 2011—are defined as ''renal dialysis services''. The association maintains that drugs and biological products approved after January 1, 2011, that are not erythropoietin stimulating agents (ESAs) or composite rate drugs, are specifically excluded from ''renal dialysis services'' as defined in statute and cannot be included in the ESRD PPS without a legislative change.

Response: We disagree with the commenter that section 1881(b)(14) of the Act excludes drugs and biological products approved after January 1, 2011 from being included in the ESRD PPS. As we explained in the CY 2016 ESRD PPS final rule (80 FR 69016), we have the authority to add new renal dialysis services to the bundle under section 1881(b)(14)(B) of the Act and Congress recognized this authority under section 217(c)(2) of PAMA. First, we interpret section 1881(b)(14)(B)(iii) of the Act as requiring the inclusion of a specific category of drugs in the ESRD PPS bundled payment—that is, drugs and biological products, including those with only an oral form, furnished to individuals for the treatment of ESRD and for which separate payment was made prior to January 1, 2011. We also interpret section 1881(b)(14)(B)(iv) of the Act as specifying a different category of items that must be included in the bundle—that is, items and services, which includes drugs and biological products, not specified by sections 1881(b)(14)(B)(i), (ii), or (iii) of the Act. Second, we read the language of section 217(c)(2) of PAMA—''the Secretary of Health and Human Services . . . shall establish a process for . . . including new injectable and intravenous products into the bundled payment system''—as more than a directive to simply develop an inoperative scheme but that Congress recognized that this authority to include new drug products existed. As we discussed in the CY 2016 ESRD PPS final rule, we believe the provision required us to both define and implement a drug designation process for including new injectable and intravenous products into the bundle.

Comment: A large dialysis organization (LDO) and a national dialysis association expressed concern that the proposed regulatory text, which defines a ''new drug or biological'' as one ''used to treat or manage a condition(s) associated with ESRD,'' exceeds the statutory and regulatory definition of ''renal dialysis services,'' which requires that drugs and biological products included in the ESRD PPS be ''for the treatment'' of ESRD and be

''essential for the delivery of maintenance dialysis'' respectively.

Response: We did not intend to expand the definition of ''new renal dialysis drug or biological'' beyond use in the treatment of ESRD, and we do not believe the proposed definition in § 413.234 does that. With regard to limiting the definition to those drugs and biological products that are essential to the delivery of maintenance dialysis, we believe all drugs that fit into our existing ESRD PPS functional categories are essential to the delivery of maintenance dialysis because they are necessary to treat or manage conditions associated with the beneficiary's ESRD, and thus, help the beneficiary to remain sufficiently healthy to continue receiving maintenance dialysis.

Comment: A drug manufacturer stated that CMS should avoid uncertainty about whether the definition of ''new renal dialysis drug or biological'' applies to oral-only drugs. The commenter recommended revising the last sentence in the proposed definition of ''new renal dialysis drug or biological'' in § 413.234(a) from ''Oral-only drugs and biologicals are excluded until January 1, 2025,'' to ''Oral-only drugs and biologicals will be included after December 31, 2024.'' The commenter believed this would clarify that oral-only drugs qualify for the TDAPA payment for new drugs and biological products once the statutory carve-out for oral-only drugs ends.

Response: We believe the proposed definition of ''new renal dialysis drug or biological'' with regard to oral-only drugs is sufficiently clear regarding the timing of when oral-only drugs will be included in the ESRD PPS bundled payment. As specified in § 413.174(f)(6), oral-only renal dialysis drugs and biologicals will be included in the ESRD PPS bundled payment amount effective January 1, 2025. That is, oral-only drugs will be treated in the same manner as other renal dialysis drugs and biological products with other routes of administration, beginning January 1, 2025. However, we are making a technical change to revise the definition from ''Oral-only drugs and biologicals are excluded until January 1, 2025,'' to ''Oral-only drugs are excluded until January 1, 2025,'' because ''oral-only drugs'' is a defined term in § 413.234(a) that includes biological products.

Comment: A drug manufacturer recommended that CMS revise the criterion pertaining to the date of FDA approval from January 1, 2019 to January 1, 2018, to include the most current drug therapy innovations. The commenter explained that the proposals in the CY 2019 ESRD PPS proposed rule are significant changes from last year's rule, which was the first application of the new drug designation process. Specifically, the commenter recommended CMS define new renal dialysis drugs or biological products as drugs or biological products that were FDA-approved on or after January 1, 2018, that are commercialized, and designated by CMS as a renal dialysis service under § 413.171. The commenter explained that its recommended policy should not affect the past application of the payment, that is, it would be prospective from January 1, 2019 onward.

Response: We believe that when the commenter refers to the proposals in the CY 2019 proposed rule as being ''significant changes from last year's rule, which was the first application of the new drug designation process,'' the commenter is confusing the original effective date for the TDAPA policy (January 1, 2016) with the date when the TDAPA was first implemented with respect to certain drugs (January 1, 2018). Specifically, we believe the commenter is referring to the January 1, 2018 date when ESRD facilities began to receive the TDAPA for calcimimetics, the first drugs to meet the criteria for the TDAPA. We finalized the policies for the drug designation process, including the applicability of TDAPA, in our regulations at § 413.234 in the CY 2016 ESRD PPS final rule (80 FR 69013 through 69027). Furthermore, the proposed CY 2019 revisions to the drug designation process regulations are an expansion of those finalized in the CY 2016 ESRD PPS final rule since all new drugs would be eligible for the TDAPA, whereas before only new drugs that did not fall within an existing ESRD PPS functional category were eligible for the payment adjustment. We disagree with the commenter that the policy should be effective January 1, 2018 because with prospective rulemaking under the ESRD PPS, we generally do not finalize retroactive policies. That is, we generally use historical data, behaviors, and trends to make data-driven changes for the future year(s). In addition, as we discussed in the CY 2019 ESRD PPS proposed rule, the purpose of the TDAPA eligibility expansion is to give the new renal dialysis drugs and biological products a foothold in the market so that when the TDAPA timeframe is complete, they are able to compete with the existing drugs and biologicals under the outlier policy, if applicable. Making the policy retroactive to drugs that are FDA-approved as of January 1, 2018 would create an uneven playing field because those drugs would have a 2-year head start for uptake compared to drugs that are FDA-approved and commercialized as of January 1, 2020 (which, as discussed below, is the effective date we are finalizing for the TDAPA expansion). We believe that drugs with FDA approval and commercialization in 2018 would already have achieved that foothold if the dialysis centers saw the advantage of utilizing these new drugs. Therefore, we do not believe it would be appropriate to finalize this policy retroactively to apply to drugs or biological products FDA-approved on or after January 1, 2018.

Comment: A drug manufacturer requested clarification on the term ''new biological'' and questioned if this term would also include biosimilars as defined in § 414.902, ''a biosimilar biological product approved under an abbreviated application for a license of a biological product.''

Response: The proposed definition of ''new renal dialysis drug or biological'' specified that the drug or biological is required to be ''approved by the Food and Drug Administration (FDA) on or after January 1, 2019 under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act.'' Section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act (PHS Act) include applications for all new drugs and biological products, including generic drugs approved under 505(j) of the FD&C Act and biological products approved under section 351(k) of the PHS Act, the abbreviated pathway created by the Biologics Price Competition and Innovation Act of 2009.

We are finalizing a revision at § 413.234(a) to change ''new renal dialysis drug or biological'' to ''new renal dialysis drug or biological product,'' to be consistent with FDA nomenclature. For the same reason, we are changing the references to ''biological'' within the proposed definition to refer to ''biological product'' instead.

Comment: We received several comments regarding the proposed clause, ''have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures.'' One drug manufacturer expressed support for the proposed definition and agreed with CMS's rationale that referring to submission of a HCPCS code application versus assignment of a code allows for quicker application of the TDAPA.

MedPAC recommended that the proposed revisions to the drug

designation process, discussed in section II.B.1 of this final rule, should only apply to new renal dialysis drugs and biological products that have been assigned a HCPCS code. MedPAC explained that applying the proposed policy to new drugs that have not been assigned a HCPCS code could undermine the HCPCS process. MedPAC further explained that the proposed policy could result in overpayments by beneficiaries and taxpayers for a drug that the CMS HCPCS workgroup concludes fits into an existing HCPCS code. MedPAC stated that if CMS proceeds with this proposal, the agency should establish a policy for addressing situations in which an application does not lead directly to the assignment of a new HCPCS code.

Several commenters pointed out that under the proposal, submission of a Level II HCPCS application could initiate the data collection period for drugs or biological products for TDAPA. As such, the commenters asserted data collection could begin prior to a drug or biological product's launch, effectively shortening the period and decreasing available data. The commenters requested that CMS confirm that a Level II HCPCS application would trigger eligibility for the TDAPA, but that the data collection period commences when the drug or biological product receives the HCPCS code. The commenters further requested that concurrent with the code being issued, CMS release detailed clinical and billing guidance regarding the drug or biological product.

Response: We understand from these comments that the main concern with the proposed clause, ''have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures'' is how it relates to the duration of the TDAPA for the particular drug or biological product. We note that the definition of a ''new renal dialysis drug or biological product'' includes other requirements that must be met in addition to the submission of a HCPCS application, and we therefore believe beginning our review of the drug when the HCPCS application is received does not undermine the HCPCS process. The other requirements include that the drug must have FDA approval, be commercially available, and be designated by CMS as a renal dialysis service. Also, as discussed on our website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/ESRD-Transitional-Drug.html*, stakeholders must notify the Division of Chronic Care Management in our Center for Medicare of the interest for eligibility for the TDAPA and provide the information requested. We plan to work collaboratively with the CMS HCPCS workgroup when determining whether a drug or biological product is a renal dialysis service and how it should be coded. The materials submitted with the HCPCS application also assist in determining if the new drug or biological product fits into an existing ESRD PPS functional category or if it represents a new functional category. The submission of a Level II HCPCS code application is simply one criterion for the drug or biological product to be eligible for the TDAPA. Once the information is received and reviewed, we will issue a change request with billing guidance that will provide notice that the drug is eligible for TDAPA as of a certain date and guidance on how to report the new drug or biological product on the ESRD claim for purposes of TDAPA. The effective date of this change request will initiate the TDAPA payment period and, for drugs that do not fall within a functional category, the data collection period. Information regarding the duration of the TDAPA period is discussed in section II.B.1.g of this final rule. CMS will issue any applicable clinical guidance when necessary.

With regard to the suggestion that the definition should only recognize new renal dialysis drugs and biological products that have been assigned a HCPCS code, we note that in section II.B.1.g of this final rule, we are finalizing a policy that the TDAPA will apply for all new renal dialysis drugs and biological products regardless of whether they fall within a functional category. That is, we are finalizing a policy where eligibility for TDAPA is based upon the definition of a new renal dialysis drug or biological product rather than a new HCPCS code. We therefore believe that our approach should shift away from requiring the assignment of an HCPCS code to the submission of an HCPCS application. The final policy does not depend on assignment of a new HCPCS code. We do not believe this would lead to overpayments because the final TDAPA policy recognizes all new renal dialysis drugs and biological products, and we do not agree that using the HCPCS process in this way undermines or weakens the process. As noted previously, we will issue further billing guidance for drugs and biological products that are eligible for the TDAPA, including those that are not assigned a unique HCPCS code.

We believe it is appropriate for the definition to require the submission of a HCPCS application since we will use that information to evaluate whether the new renal dialysis drug or biological product falls into an existing ESRD PPS functional category or a new functional category. We will evaluate whether any additional operational changes are needed in light of the new TDAPA eligibility criteria we are finalizing, and issue guidance, as needed.

Final Rule Action: We are finalizing the revisions to the drug designation process regulations at § 413.234(a), (b), and (c) to reflect that the process applies for all new renal dialysis drugs and biological products that are FDA approved regardless of the form or route of administration, that is, new injectable, intravenous, oral, or other form or route of administration,'' that are ''used to treat or manage a condition(s) associated with ESRD.'' We are finalizing a revision at § 413.234(a) to the term we are defining, from ''new renal dialysis drug or biological'' to ''new renal dialysis drug or biological product'' to be consistent with FDA nomenclature. We are also finalizing the definition for ''new renal dialysis drug or biological product'' in § 413.234(a) to encompass the broader scope of the drug designation process with three revisions. First, we are revising the timing of the FDA approval to begin January 1, 2020, for consistency with our decision to finalize the policy for the TDAPA expansion with an effective date of January 1, 2020, for the reasons discussed in detail in section II.B.1.d of this final rule. This delay will provide an opportunity to engage in education and coordination with other CMS programs, including Medicare Parts C and D and Medicaid. The second revision is to refer to ''biological product,'' which is FDA's preferred nomenclature, within the definition instead of ''biological.'' The third revision is to reflect the defined term ''oral-only drugs'' in § 413.234(a). Therefore, a new renal dialysis drug or biological product ''must be approved by the Food and Drug Administration (FDA) on or after January 1, 2020 under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official HCPCS Level II coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.''

e. Basis for Expansion of the TDAPA Eligibility Criteria

In the CY 2016 ESRD PPS final rule (80 FR 69017 through 69024), we

acknowledged that there are unique situations identified by the commenters during rulemaking regarding the eligibility criteria for the TDAPA. For example, commenters stated that they believed the drug designation process was too restrictive, could hinder innovation, and prevent new treatment options from entering the marketplace, and that CMS should contemplate the cost of new drugs and biological products that fall within the ESRD PPS functional categories. In the following paragraphs we have summarized key concerns commenters have raised. We indicated in the CY 2016 ESRD PPS final rule that we anticipated addressing these situations in future rulemaking and stated that we planned to consider the issues of ESRD facility resource use, supporting novel therapies, and balancing the risk of including new drugs for both CMS and the dialysis facilities.

As described in the CY 2016 ESRD PPS final rule, commenters seemed concerned about the cost of new drugs that fit into the functional categories, rather than the process of adding new drugs to existing categories (80 FR 69017 through 69024). For example, a drug manufacturer suggested that in order to promote access to new therapies and encourage innovation in ESRD care, the TDAPA should apply to all new drugs, not just those drugs that are used to treat or manage a condition for which we have not adopted a functional category. The commenter pointed out that the functional categories are very comprehensive and capture every known condition related to ESRD. The commenter indicated that under the proposed approach to TDAPA, CMS would make no additional payment regardless of whether the drug has a novel mechanism of action, new FDA approval, or other distinguishing characteristics and suggested that such distinguishing characteristics provided rationale for additional payment. The commenter believed the CMS proposal sent conflicting messages to manufacturers about the importance of developing new treatments for this underserved patient population (80 FR 69020).

An organization of home dialysis patients commented with a similar concern, noting that the functional categories are too broad and could prevent people on dialysis from receiving needed care, and be detrimental to innovation (80 FR 69022). The commenter stated that in the future there could be a new medication to help with fluid management but patients would be shut out of ever having the option for a new fluid management therapy since there is an existing functional category for excess fluid management and therefore, these drugs are considered to be included in the ESRD PPS base rate. We interpreted the comment to mean that drug manufacturers would be less likely to develop a new fluid management drug knowing it would never qualify for additional payment under the ESRD PPS. The commenter asked that CMS provide additional payment for new drugs that fit into the functional categories in order to incentivize new medications to come to market and to ensure patients have the opportunity for better care, choices and treatment.

A national dialysis patient advocacy organization explained that if new products are immediately added to the ESRD PPS bundle without additional payment it would curtail innovation in treatments for people on dialysis. The organization believed clinicians should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes, and that the CY 2016 ESRD PPS proposed rule did not allow for this. The commenter explained that Kidney Disease Improving Global Outcomes (KDIGO) and Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines are often updated when evidence of improved therapies on patient outcomes are made available and that this rigorous and evidence-based process is extremely important in guiding widespread treatment decisions in nephrology. The commenter expressed concern that under the CY 2016 ESRD PPS proposed rule, reimbursement and contracting arrangements could instead dictate utilization of a product before real world evidence on patient outcomes is ever generated (80 FR 69021).

The comments we received regarding the drug designation process in the CY 2016 ESRD PPS rulemaking indicated that commenters were also concerned about the cost of the new drugs and biological products, and in particular, new drugs and biological products that fall within the functional categories, and therefore, are considered by CMS to be reflected in the ESRD PPS base rate (80 FR 69017 through 69024).

A national dialysis organization strongly recommended that CMS adopt the same drug designation process for all new drugs and biological products (as opposed to only those that do not fall within a functional category) unless they are substantially the same as drugs or biological products currently paid for under the ESRD PPS payment rate. For new drugs or biological products that are substantially the same as drugs or biological products currently paid under the ESRD PPS, the organization supported incorporating them into the PPS on a case-by-case basis using notice-and-comment rulemaking and foregoing the transition period if it can be shown that the PPS rate is adequate to cover the cost of the drug or biological product. The organization believed if the rate is inadequate to cover the cost of the new drug then the TDAPA should apply (80 FR 69016 through 69017). An LDO stated that, if implemented, the proposed drug designation process could jeopardize patient access to drugs that are clinically superior to existing drugs in the same functional category. For example, the commenter stated, if a new substantially more expensive anemia management drug is released and is clinically proven to be more effective than the current standard of care, under the CY 2016 ESRD PPS proposed rule, the ESRD PPS base rate would remain stagnant. The commenter stated that it is not reasonable for CMS to expect that all dialysis facilities would incur frequent and substantial losses in order to furnish the more expensive, although more clinically effective, drug.

A dialysis organization and a professional association asked that CMS consider a pass-through payment, meaning Medicare payment in addition to the ESRD PPS base rate for all new drugs that are considered truly new. They recommended a rate of 106 percent of ASP, minus the portion of the ESRD PPS base rate that CMS determines is attributable to the category of drugs that corresponds to a truly new drug (80 FR 69019). An LDO stated that defining new drugs requires special consideration of cost. The LDO suggested a similar approach by stating that rather than comparing the cost of the new drug to the ESRD PPS base rate, we should compare it to the cost of the existing drugs in the same CMS-defined ''mode of action'' category. In such a case, a drug might qualify for payment of the TDAPA on the basis that its cost per unit or dosage exceeds a specified percentage (for example 150 percent) of the average cost per unit or dosage of the top three most common drugs in the same category (based on utilization data). This comparison would demonstrate that the amount allocated to that category in the ESRD PPS base rate is insufficient to cover the cost of the new drug (80 FR 69020).

Other commenters referred to pathways in other payment systems that provide payment for new drugs and biological products to account for their associated costs. For example, the Outpatient Prospective Payment System

(OPPS) provides a pass-through payment and the Inpatient Prospective Payment System (IPPS) provides a new technology add-on payment. Commenters indicated that we should decouple the TDAPA from the functional categories and provide the additional payment for all new injectable and intravenous drugs and biological products and oral equivalents for 2 to 3 years, similar to the IPPS or the OPPS (80 FR 69020).

f. Expansion of the TDAPA Eligibility Criteria

As we discussed in the CY 2019 ESRD PPS proposed rule (83 FR 34313 through 34314), we continue to believe that the drug designation process does not prevent ESRD facilities from furnishing available medically necessary drugs and biological products to ESRD beneficiaries. Additionally, our position has been that payment is adequate for ESRD facilities to furnish new drugs and biological products that fall within existing ESRD PPS functional categories. The per treatment payment amount is a patient and facility level adjusted base rate plus any applicable adjustments, such as training adjustment add-ons or outlier payments. In addition, the ESRD PPS includes the ESRDB market basket, which updates the PPS base rate annually for input price changes for providing renal dialysis services and accounts for price changes of the drugs and biological products that are reflected in the ESRD PPS base rate (80 FR 69019). However, in the CY 2016 ESRD PPS final rule, we also acknowledged that the outlier policy would not fully cover the cost of furnishing a new drug and that newer drugs may be more costly (80 FR 69021). Consequently, in the CY 2019 ESRD PPS proposed rule, we discussed a number of reasons why we were reconsidering our previous policy on the drug designation process.

First, we recognized the unique situations identified by the commenters discussed in section II.B.1.e of this final rule, and how they are impacted by the eligibility criteria for the TDAPA. We stated that concerns regarding inadequate payment for renal dialysis services and hindrance of high-value innovation, among others, are important issues that we contemplate while determining appropriate payment policies. Additionally, we noted that subsequent to the issuance of the CY 2016 ESRD PPS final rule, we continued to hear concerns that the drug designation process is restrictive in nature; and received requests from the dialysis industry and stakeholders that we reconsider the applicability of the TDAPA.

We acknowledged that ESRD facilities have unique circumstances with regard to implementing new drugs and biological products into their standards of care. For example, when new drugs are introduced to the market, ESRD facilities need to analyze their budget and engage in contractual agreements to accommodate the new therapies into their care plans. Newly launched drugs and biological products can be unpredictable with regard to their uptake and pricing which makes these decisions challenging for ESRD facilities. Furthermore, practitioners should have the ability to evaluate the appropriate use of a new product and its effect on patient outcomes. We noted that we agreed this uptake period would be best supported by the TDAPA pathway because it would help facilities transition or test new drugs and biological products in their businesses under the ESRD PPS. We stated that the TDAPA provides flexibility and targets payment for the use of new renal dialysis drugs and biological products during the period when a product is new to the market so that we can evaluate if resource use can be aligned with payment. As explained in section II.B.1.b of this final rule, the ESRD PPS base rate includes dollars allocated for drugs and biological products that fall within a functional category, but those dollars may not directly address the total resource use associated with the newly launched drugs trying to compete in the renal dialysis market.

We explained in the CY 2019 ESRD PPS proposed rule that we believe we need to be conscious of ESRD facility resource use and the financial barriers that may be preventing uptake of innovative new drugs and biological products that, while are already accessible to them, may be under-prescribed because the new drugs are priced higher than currently utilized drugs (as recommended by commenters). Therefore, we proposed that beginning January 1, 2019, we would add § 413.234(b)(1)(i), and (ii) and revise § 413.234(c) to reflect that the TDAPA, under the authority of section 1881(b)(14)(D)(iv) of the Act, would apply to all new renal dialysis injectable or intravenous products, oral equivalents, and other forms of administration drugs and biological products, regardless of whether or not they fall within an ESRD PPS functional category. New renal dialysis drugs and biological products that do not fall within an existing functional category would continue to be paid under the TDAPA and the ESRD PPS base rate would be modified, if appropriate, to reflect the new functional category. We proposed to revise § 413.234(b)(2)(ii) and § 413.234(c)(2), removing § 413.234(c)(3), and adding § 413.234(c)(2)(i) to reflect that we would continue to provide the TDAPA, collect sufficient data, and modify the ESRD PPS base rate, if appropriate, for these new drugs and biologicals that do not fall within an existing functional category.

We proposed to revise § 413.234(c)(1) to reflect that for new renal dialysis drugs and biological products that fall within a functional category, the TDAPA would apply for only 2 years. We explained that while we would not collect claims data for purposes of analyzing utilization to result in a change to the base rate, we would still monitor renal dialysis service utilization for trends and we believed that this timeframe is adequate for payment. We also noted that we believed 2 years is a sufficient timeframe for facilities to set up system modifications, and adjust business practices so that there is seamless access to these new drugs within the ESRD PPS base rate. In addition, we stated that when we implement policy changes whereby facilities need to adjust their system modifications or protocols, we have provided a transition period. We believe that this 2-year timeframe is similar in that facilities are making changes to their systems and care plan to incorporate the new renal dialysis drugs and biological products into their standards of care and this could be supported by a transition period. Also, we noted that providing the TDAPA for 2 years would address the stakeholders concerns regarding additional payment to account for higher cost of more innovative drugs that perhaps may not be adequately captured by the dollars allocated in the ESRD PPS base rate. That is, this transitional payment would give the new renal dialysis drugs and biological products a foothold in the market so that when the timeframe is complete, they are able to compete with the existing drugs and biological products under the outlier policy, if applicable. Meaning, once the timeframe is complete, drugs would then qualify as outlier services, if applicable, and the facility would no longer receive the TDAPA for any one particular drug. Instead, in the outlier policy space, there is a level playing field where drugs could gain market share by offering the best practicable combination of price and quality. We stated that we believed the proposed timeframe is long enough to be

meaningful but not too long as to improperly incentivize high cost items without more value, for example, substitutions of those drugs that already exist in the functional category.

We noted that this proposal would increase Medicare expenditures, which would result in increases to ESRD beneficiary cost sharing, since we have not previously provided the TDAPA for new renal dialysis drugs and biological products in the past. We stated that we understand there are new drugs and biological products in the pipelines, for example, we are aware that there are new drugs that would fall within the anemia management, bone and mineral, and pain management categories. We noted that we would continue to monitor the use of the TDAPA and carefully evaluate the new renal dialysis drugs and biological products that qualify. We stated that we would address any concerns through future refinements to the TDAPA policy.

We also proposed that when a new renal dialysis drug or biological product falls within an existing functional category at the end of the TDAPA period we would not modify the ESRD PPS base rate, but at the end of the 2 years, as consistent with the existing outlier policy, the drug would be eligible for an outlier payment. However, as discussed in section II.B.1.h of this final rule, if the new renal dialysis drug or biological product is considered to be a composite rate drug, it would not be eligible for an outlier payment. The intent of the TDAPA for a new renal dialysis drug or biological product that falls within an existing functional category is to provide a transition period for the unique circumstances experienced by ESRD facilities and to allow time for the uptake of the new drug. We explained that it would not be appropriate to add dollars to the ESRD PPS base rate for new renal dialysis drugs and biological products that fall within existing functional categories and that doing so would be in conflict with the fundamental principles of a PPS. Under a PPS, Medicare makes payments based on a predetermined, fixed amount that reflects the average patient, and the facility retains the profit or suffers a loss resulting from the difference between the payment rate and the facility's cost, which creates an incentive for cost control. It is not the intent of a PPS to add dollars to the base whenever something new is made available. We explained that the proposal to make no change to the base rate at the end of the TDAPA period for new renal dialysis drugs and biological products that fall within an existing functional category would maintain the overall goal of a bundled PPS, that is, the limitation of applying the TDAPA would not undermine the bundle since there is no permanent adjustment to the base rate. We also noted that this proposal would strike a balance of maintaining the existing functional category scheme of the drug designation process and not adding dollars to the ESRD PPS base rate when the base rate may already reflect costs associated with such services, while still promoting high-value innovation and allowing facilities to adjust or factor in new drugs through a short-term transitional payment. We proposed to add § 413.234(c)(1)(i) to reflect that when a new renal dialysis drug or biological falls within an existing functional category at the end of the TDAPA period, we would not modify the ESRD PPS base rate. We solicited comment on this proposal.

We proposed to operationalize this proposed policy no later than January 1, 2020. We stated that this deadline would provide us with the appropriate time to prepare the necessary changes to our claims processing systems.

We solicited comment on the proposal to revise § 413.234(c) and (c)(1) to reflect that the TDAPA would apply for all new renal dialysis drugs and biological products regardless of whether they fall within a functional category. Then, for a new renal dialysis drug or biological product that falls within an existing functional category, that payment would apply for 2 years and there would be no modification to the ESRD PPS base rate. We also solicited comment on the appropriateness of the 2-year timeframe for the TDAPA for new renal dialysis drugs and biological products that fall within existing functional categories.

We note that the nature of these proposals was to expand the applicability of TDAPA to new renal dialysis drugs and biological products that fall within an ESRD PPS functional category since we had already established a policy in the CY 2016 ESRD PPS final rule regarding the applicability of TDAPA to new renal dialysis drugs and biological products that do not fall within an ESRD PPS functional category. Therefore, the purpose of the proposal was supporting innovation, but geared solely toward those drugs and biological products that are considered reflected in the ESRD PPS base rate.

The CY 2019 ESRD PPS proposed rule did not propose any changes with regard to how CMS determines if a new renal dialysis drug or biological product is reflected in the ESRD PPS base rate. That is, we did not propose a change in the basic structure of the drug designation process, which is based on the ESRD PPS functional categories. New renal dialysis drugs and biological products that fall within an existing functional category are considered to be reflected in the ESRD PPS base rate. As proposed, the purpose of providing the TDAPA for these drugs that fall into an existing functional category is to help ESRD facilities to incorporate new drugs and make appropriate changes in their businesses to adopt such drugs; provide additional payment for such associated costs, as well as promote competition among drugs and biological products within the ESRD PPS functional categories. New renal dialysis drugs and biological products that do not fall within an existing functional category are not considered to be reflected in the ESRD PPS base rate, and the purpose of TDAPA for those drugs is to be a pathway toward a potential base rate modification.

We received many comments on the proposed revisions to the drug designation process regulations from all sectors of the dialysis industry, and each had their view on the direction the policy needed to go to support innovation. Commenters generally agreed that more drugs and biological products should be eligible for the TDAPA, that is, they agreed that drugs and biological products that fall within a functional category should be eligible for a payment adjustment when they are new to the market. However, the commenters had specific policy recommendations for each element of the drug designation process. Specifically, we received comments regarding which drugs should qualify for the TDAPA, the duration of the application of the adjustment, post-TDAPA base rate modifications, and basis of payment for the TDAPA. While a couple of commenters cautioned against implementing any changes in the drug designation process, overall, the general consensus from commenters was to expand the payment adjustment to new renal dialysis drugs and biological products that fall into an existing functional category and have clinical value with the intent to modify the ESRD PPS base rate, if applicable.

The comments and our responses to the comments on our proposals regarding the expansion of the TDAPA eligibility criteria are set forth below.

Comment: Two commenters supported the proposals. A professional association expressed support for CMS's efforts to foster innovation of new renal dialysis drugs and biological products by revising its TDAPA policy and recommended that CMS keep the special needs of children with ESRD in

mind and consider policies to foster the innovation of new therapies for this population.

A drug manufacturer supported CMS' flexibility and willingness to consider new approaches to improve access to innovative medicines. The commenter stated that CMS' proposed expansion of TDAPA eligibility will incentivize competition and innovation that encourages quality and cost-savings. The commenter appreciates CMS's acknowledgement of and willingness to take action to address uptake in innovations in treatment for ESRD patients through changes to the TDAPA for new drugs. The commenter also stated that these proposals encourage renal dialysis providers to consider the appropriate use of new drugs and biological products to improve the outcomes of their patients.

Response: We appreciate the support of the stakeholders.

Comment: Two commenters did not support the proposals. MedPAC expressed concern about the importance of maintaining the structure of the ESRD PPS and not creating policies that would unbundle services covered under the ESRD PPS or creating incentives that encourage high launch prices of new drugs and technologies. MedPAC stated that access to new dialysis products is favorable under the ESRD PPS. For example, in 2015, nearly one-quarter of all dialysis beneficiaries received epoetin beta, which was introduced to the U.S. market in that year. Consequently, MedPAC recommended that CMS should not proceed with its proposal to apply the TDAPA policy to new renal dialysis drugs that fit into a functional category (including composite rate drugs, which have never been paid separately by Medicare) for the following reasons:

- Although new dialysis drugs could improve patient outcomes, the proposal does not require that the new drugs be more effective than current treatment to qualify for the TDAPA.
- Paying the TDAPA for new dialysis drugs that fit into a functional category would be duplicative of the payment that is already made as part of the ESRD bundle. Beneficiaries and taxpayers already pay for drugs in each functional category because they are included in the ESRD PPS payment bundle.
- Applying the TDAPA to new dialysis drugs that fit into a functional category undermines the competition with existing drugs included in the PPS payment bundle. By bundling drugs with similar function together, CMS encourages providers to make decisions about each drug's clinical effectiveness for individual patients while also attempting to constrain costs. MedPAC pointed out that it has documented the changes in drug use due to increased price competition with the vitamin D and ESA therapeutic classes in both its 2016 and 2018 Reports to the Congress. MedPAC asserted that finalizing the TDAPA proposal would unbundle all new dialysis drugs, removing all cost constraints during the TDAPA period and encouraging the establishment of high launch prices. MedPAC explained that under the proposal, after the 2-year TDAPA period concluded, the new, potentially high-priced dialysis drugs would be included in the PPS payment bundle and could thereby further increase dialysis spending through the periodic process of rebasing the ESRDB market basket.
- The proposed policy would increase spending for beneficiaries and taxpayers, as CMS acknowledges. However, the proposed rule did not include an estimate of expected spending changes in the ''detailed economic analysis'' section.

An LDO also did not support the TDAPA proposal. The commenter explained that it has observed significant issues for both patients and providers under the current TDAPA program, which support delaying expansion until the process can be better evaluated. The commenter further explained that under the TDAPA, patients will experience substantial increases in cost-sharing, as these drugs will be subject to Part B's 20 percent co-insurance, instead of being part of the PPS bundle. The commenter pointed to its experience under the current TDAPA period for calcimimetics, stating that this cost-shifting to vulnerable ESRD patients has had a detrimental effect on them, as many have had to refuse necessary medications due to their high costs. In addition, the commenter stated that providers frequently provide the medications to patients and then are unable to fully recoup the 20 percent coinsurance from them, resulting in considerable amounts of unreimbursed bad debt, which places additional burden on dialysis facilities.

This LDO identified other significant issues encountered by patients and providers including revenue loss from the inability to bill Medicare for full prescriptions; payers not recognizing an oral medication under the medical benefit; Medicare paying for drugs consumed, for which dialysis facilities have little to no visibility, and not for drugs dispensed (a particular problem for oral drugs); payers experiencing system update problems that have resulted in incorrect or no reimbursement for current medications subject to TDAPA; lack of Medicaid secondary coverage for Medicare primary patients; pricing power shifting to pharmaceutical manufacturers; and an absence of reimbursement from Medicare Advantage plan contractors.

Some commenters used their experience with the current TDAPA policy to express that due to the difficulties related to the transition of oral drugs from payment under Medicare Part D to Medicare Part B, CMS should obtain 2-full calendar years of claims data before engaging in rulemaking to incorporate the new drug or biological product into the ESRD PPS bundled payment. Again, referring to calcimimetics as the example, the commenters stressed how important it is for dialysis facilities to receive timely and clear clinical and billing guidance. A national LDO organization stated the current policy creates a disconnect between oral calcimimetics, which are prescribed for daily use, including days that do not include a dialysis treatment, and the per treatment payment methodology. The LDO stated this disconnect can result in dialysis facilities being unable to claim all the days when the patient took the oral calcimimetic.

The LDO also stressed that further steps are needed to address confusion among plans regarding their coverage and payment responsibilities for new renal dialysis oral drugs under the MA program. The commenter further explained that CMS needs to take additional action to ensure that all MA enrollees with ESRD have good access to the drug formulation that meets their needs by issuing guidance that reiterates coverage and reimbursement for these drugs.

The LDO further stated that it is premature to expand the TDAPA before data and experience from the first period is analyzed and thoughtfully considered, and strongly recommended that CMS not move forward on expanding TDAPA at this time. While the organization stated that it supports and encourages CMS's interest in developing a process to incentivize significant innovation in dialysis treatment, the organization believes the proposal may undermine investment in treatment advances that significantly improve outcomes or quality of life for vulnerable patients.

Response: We understand and appreciate the concerns expressed by the commenters. With regard to MedPAC's concern that the proposal does not require that the new drugs be more effective than current treatment to qualify for the TDAPA, we believe that allowing all new drugs to be eligible for

TDAPA will provide an opportunity for the new drugs to compete with other similar drugs in the market which could mean lower prices for all drugs. We believe drug manufacturers understand that if they are to compete with drugs currently in the ESRD PPS bundle, they need to not only be better, but they also must come in at a lower price in order to continue to be utilized by the facilities in the post-TDAPA period. The 2-year TDAPA period gives the innovative product an opportunity to demonstrate its clinical value and financial worth, while buffering the risk to both the manufacturer and the facility. If the facility finds the product sufficiently worthy of use among its patients, then the manufacturer has an incentive to keep the price lower than the drug it is replacing that is currently in the bundle. In addition, the effectiveness of drugs can depend on age, gender, race, genetic predisposition and comorbidities. Innovation can provide options for those that do not respond to a certain preferred treatment regimen the same way the majority of patients respond. However, we appreciate MedPAC's feedback and will consider the comment for future refinements to the TDAPA policy.

With respect to MedPAC's concern regarding duplicate payment for new drugs that fit into a functional category, as noted previously, we believe the TDAPA would help facilities to incorporate new drugs and make appropriate changes in their businesses to adopt such drugs; provide additional payment for such associated costs, as well as promote competition among other drugs and biological products in the same ESRD PPS functional categories. We do not view the expanded TDAPA as duplicative payment because at the end of the TDAPA time period, there is no additional money added to the base rate for those drugs that already fall within functional category. This TDAPA is a separate, temporary payment adjustment for the reasons discussed above. We believe the TDAPA expansion will encourage innovative products to come into the market, by facilitating the introduction of more drug options to the functional categories. We also believe this TDAPA expansion will enhance treatment options for those population subsets that currently may not respond optimally to what is available in the bundle. We have heard from ESRD facilities that newer drugs may carry higher financial risk for the centers due to inventory issues with higher cost drugs, and this may cause uneven access to the newer products. We note that the TDAPA for new drugs considered to be included in the functional categories would be temporary. In addition, we believe that in order for the new drugs to obtain a long-term market share, they will need to show better clinical results and be available at a competitive price once those drugs are bundled into the ESRD PPS. Some of the drugs currently in the bundle effectively target a specific condition but have side effects that manifest themselves differently across the population of ESRD patients. If a third or fourth generation product achieves the same clinical effect, and does not have those side effects, then it would be a clinically superior product for that population.

With regard to MedPAC's assertion that finalizing the TDAPA proposal would unbundle all new dialysis drugs, remove all cost constraints during the TDAPA period and encourage the establishment of high launch prices, we believe that we are mitigating these issues by paying ASP+0 for a limited amount of time (2 years) and by not making modifications to the base rate. If manufacturers choose to respond with an even higher launch price, then there is a possibility their product will not be used as much because the beneficiary co-pays will also be increased. This could increase bad debt for the facilities. We believe as stated above that our policy could lead to lower drug prices during the TDAPA period and once the TDAPA period expires. We note that TDAPA is a transitional payment, and under this expansion does not result in a permanent addition to the base rate. Rather, this payment will help facilities to incorporate new drugs and make appropriate changes in their businesses to adopt such drugs; provide additional payment for such associated costs, as well as promote competition with other drugs and biological products within the same ESRD PPS functional categories. We believe paying the TDAPA for all new drugs will foster competition, and actually encourage the companies with existing drugs in the functional categories to produce a newer, better product, at a lower cost in order to retain their market share.

With regard to MedPAC's concern regarding the ESRDB market basket rebasing, we believe that any impact that would result from the proposed TDAPA expansion is unknown at this time. We will continue to monitor the impact that these changes have on the relative cost share weights in the ESRDB market basket, over time, as reported in cost report data. When appropriate we will rebase the ESRDB market basket to reflect observed shifts in cost weights.

In response to MedPAC's comment that we did not include an estimate of expected spending changes in the ''detailed economic analysis'' section for the proposal, we were unable to provide such impacts because the policy addresses drugs and biological products that have not been developed and therefore we would not be able to address hypothetical usage and project impacts accurately.

With regard to the comments about beneficiary coinsurance, we acknowledge there will be increases; however, we believe that access to innovative new drugs that could provide better clinical outcomes and fewer side effects will be valuable to beneficiaries and help to offset the coinsurance obligation. In addition, we believe drug pricing information and coinsurance amounts should be a part of the discussion between the beneficiary and his or her physician regarding the decision to use new drugs. For this reason, we believe that concerns about what beneficiaries have to pay for coinsurance and whether ESRD facilities are able to obtain these payments from other payers versus directly from the ESRD beneficiary, would have an impact on the drugs that are used for treatment.

We are finalizing the expansion of TDAPA to encourage development of new drugs within the current functional categories. However, we understand and acknowledge the concerns expressed by the LDO about operational difficulties and patient access issues experienced for the current drugs paid for using the TDAPA. In recognition of those concerns, we are making the changes to the drug designation process under § 413.234 and the expansion of TDAPA eligibility effective January 1, 2020, as opposed to January 1, 2019, to address as many of those concerns as possible. We believe that the small dialysis organizations and rural facilities have a more difficult time developing processes than LDOs, and delaying the effective date of the expansion of TDAPA by 1 year would benefit both types of facilities. This additional year would also provide us with the opportunity to address issues such as transitioning payment from Part D to Part B, and coordination issues involving Medicaid and new Medicare Advantage policies. Finally, the additional year will allow more time for provider and beneficiary education about this new policy.

In addition, regarding the previous discussion on HCPCS codes, we will need to work with the current HCPCS

process as it applies to the ESRD PPS to accommodate the initial influx of new drugs and biological products. In collaboration with the HCPCS workgroup we will make the determination of whether a drug or biological product is a renal dialysis service. We will also determine if the new renal dialysis drug or biological product falls within an existing functional category or if it represents a new functional category. We discuss the operational concerns that warrant a 1-year delay of the TDAPA expansion in section II.B.1.f of this final rule.

Comment: A national kidney organization, a national dialysis association, a clinical association, a dialysis provider organization, as well as drug manufacturers, expressed support for the application of TDAPA to all new drugs and biological products approved on or after January 1, 2019, but they recommended that CMS not apply TDAPA to generic drugs or to biosimilars. The commenters explained that they believe the rationale for TDAPA is to allow the community and CMS to better understand the appropriate utilization of new products and their pricing. The commenters asserted that generic drugs and biosimilars seek to provide the same type of treatment and patient outcomes as existing drugs in the ESRD PPS bundled payment. Thus, the additional time is unnecessary for these drugs and biological products.

A drug manufacturer further stated that a generic drug clearly is not innovative because it must have the same active ingredient, strength, dosage form, and route of administration as the innovator drug; a biosimilar also is not innovative because it is required under statute to be highly similar and have no clinically meaningful differences to the reference product and must be administered in the same manner to treat the same conditions that the reference product is licensed to treat. The commenter stated that because they have no clinically meaningful differences, biosimilars and reference products should be treated equally in payment and coverage policies; a biosimilar should not be eligible for the TDAPA when its reference product would not qualify for the payment.

A different drug manufacturer made a similar comment and stated that while it appears clear that the proposal would exclude generic drugs, it appears to allow biosimilars to receive TDAPA. The commenter stated that it does not believe biosimilars need to be treated differently than generic drugs and recommended that CMS not extend TDAPA to these products as those dollars would be better spent adjusting the bundled rate to ensure adequate funding for truly innovative products.

Response: We proposed to allow all new drugs in current functional categories, including generic drugs, and biosimilar biological products approved under 351(k) of the PHS Act, to receive the TDAPA because we want to foster a competitive marketplace in which all drugs within a functional category would compete for market share. We believe this will mitigate or discourage high launch prices. We believe including generic drugs and biosimilar biological products under the TDAPA expansion will foster innovation of drugs within the current functional categories. We also believe including these products will give a financial boost to support their utilization, and ultimately lower overall drug costs since these products generally have lower prices. Because of this, generic drugs and biosimilar products will provide cost-based competition for new higher priced drugs during the TDAPA period and also afterward when they are bundled into the ESRD PPS.

Comment: Some commenters also recommended that CMS require that the new renal dialysis drug or biological have a clinical superiority over the existing drugs in the bundle and provided suggestions on clinical value criteria. For example, several commenters indicated that the following are examples of when a new drug has high clinical value:

- Drugs and biologicals that fill a treatment gap (address an unmet medical need) in an existing functional category;
- Drugs or biologicals that treat conditions in dialysis patients for which no FDA-approved product in an existing functional category may be used consistent with the drug's label;
- Drugs or biologicals for which there are multiple clinical outcomes as stated in the FDA labeling material approved by the FDA (including within the clinical pharmacology and study portion of the label approved by the FDA);
- Drugs and biologicals that are approved by the FDA (if appropriate to add to a functional category based on the indications listed in FDA-approved labeling) that have demonstrated clinical superiority to existing products in the bundle; or
- Drugs and biologicals that improve priority outcomes, such as:

++ Decreasing hospitalizations;

++ Reducing mortality;

++ Improving quality of life (based on a valid and reliable tool);

++ Creating clinical efficiencies in treatment (including but not limited to reducing the need for other items or services within the ESRD PPS);

++Addressing patient-centered objectives (including patient reported outcomes once they are developed and assessed by the FDA in its review of drugs and biologicals);

++Reducing in side effects or complications; or

++Drugs and biologicals that have a significantly better safety profile than existing products.

An LDO recommended that CMS limit TDAPA to significantly innovative drug products that substantially advance the treatment and management of conditions associated with ESRD or have demonstrated safety advances. The LDO requested the opportunity to work with CMS and interested stakeholders to develop a uniform definition of significant innovation.

Response: We believe that allowing all new drugs and biological products to be eligible for the TDAPA will provide an ability for new drugs to compete with other drugs in the market, which could mean lower prices for all drugs. We further believe, categorically limiting or excluding any group of drugs from TDAPA would reduce the competitiveness because there would be less incentive for manufacturers to develop lower-priced drugs, such as generic drugs, to be able to compete with higher priced drugs during the TDAPA period. In addition, the question of drugs being more effective can be subjective since effectiveness of drugs can depend on age, gender, race, genetic pre-disposition and comorbidities. Innovation can provide options for those patient who do not respond to a certain preferred treatment regimen the same way the majority of patients respond. However, we appreciate the commenters' feedback and will consider these suggestions for future refinement of the drug designation process.

Comment: A patient advocacy organization applauded the revisions to the drug designation process regulations and stated that while any innovations in treatment that improve quality of life or tolerability of dialysis have great value to patients, they do not support adding dollars to the base rate for more expensive ''me-too'' substitute drugs or biological products that add no value for patients or for the Medicare program.

A dialysis provider organization also expressed concern that the proposed policy would encourage promotion of so called ''me too'' drugs and higher launch prices, even if moderated after 2 years. The organization stated that

developers need to have a clear roadmap and set of criteria based on whether a new drug is a significant clinical improvement that warrants a higher cost to the program, and beneficiaries, as well as possible financial tradeoffs to providers. Rather than an open-ended policy, several commenters recommended that CMS consider a new drug policy more in line with those in other parts of the Medicare program, such as the policies for new technologies under the hospital inpatient PPS which includes a substantial clinical improvement test and for devices under the outpatient PPS.

Response: We understand drugs characterized as ''me too'' drugs are new drugs that are in the same product class as other drugs currently in the functional categories. We agree with the commenter that recommended not adding dollars to the base rate for more expensive ''me-too'' substitute drugs or biological products and note that we did not propose such a policy. However, we believe the introduction of new drugs in the functional categories promotes competition that lowers prices, while frequently improving on the quality of the first-in-class drugs.

With regard to the comment on significant clinical improvement, we did not propose this criteria because our goal was to be expansive regarding the applicability of TDAPA. In general, manufacturers compete on the basis of cost, and it is that competition that ignites negotiating. We believe when there is more than one choice of drug, ESRD facilities have the ability for bargaining, obtaining lower drug prices, and taking their drug needs to another manufacturer. When there is a monopoly by one drug company, the ability to bargain is removed. With respect to physicians, we note that those physicians prescribing drugs in the functional categories should not only be interested in their patient's clinical well-being and safety, but also take into consideration the patient's financial resources.

With regard to other Medicare payment systems, although the systems are noteworthy, under the ESRD PPS there is a different programmatic approach to new drugs and biological products. We believe the TDAPA would apply for more new drugs and biological products than if we utilized a policy similar to the other payment systems. Under the final policy, the expanded TDAPA will apply to all new renal dialysis drugs and biological products and will be paid for 2 years, and these drugs and biological products will not need to meet clinical improvement or cost criteria. In addition, our goal in this approach is to assist ESRD facilities in incorporating these products and promote development of new renal dialysis drugs and biological products to compete with other drugs in the ESRD PPS functional categories with the aim of lowering drug prices.

Comment: A drug manufacturer recommended that CMS consider when the FDA may re-profile a drug. The commenter further explained that re-profiling a drug may occur when its utility and efficacy are further elucidated or expanded once on-market. The commenter recommended that CMS establish a pathway as part of the drug designation process that would allow for manufacturers or other stakeholders to request that CMS reconsider how a particular drug is classified with regard to the functional categories and, if appropriate, adjust the base rate when there is a change in the label approved by FDA.

Response: When the commenter discusses re-profiling, we presume the commenter is referring to the FDA's approval of changes to the labeling of already approved drugs to add new indications for additional diseases or conditions. Under the current ESRD PPS functional categories, in that circumstance the drug would be automatically included in the ESRD PPS bundled payment amount when it is identified as a renal dialysis service based on its FDA approved labeling. We appreciate this feedback and will consider these recommendations for future refinements to the policy.

Comment: A drug manufacturer commented that it is vitally important that CMS does not exclude new drugs from TDAPA that have been FDA approved for the treatment of ESRD since the bundled payment became active in 2011. The commenter stated there is no basis for excluding these drugs, and pointed out that Triferic is the only drug CMS would need to consider during that time period because CMS approved the TDAPA for the other drug (calcimimetics). The commenter stated that excluding this one drug from TDAPA would be unfair and prevent patients from gaining access to a new innovative therapy that is available and can improve their lives.

Response: We generally are precluded from retroactively implementing regulations and therefore, we are unable to provide TDAPA payments for new drugs approved by the FDA since 2011. We apply the policy that was in effect when the drug is launched which, in the case of Triferic, was to provide no add-on payment for drugs in the existing ESRD PPS functional categories beyond the ESRD PPS bundled payment amount.

The next set of comments and responses address the proposal regarding the 2-year duration of TDAPA for new renal dialysis drugs and biological products that fall within a functional category. Commenters had two main concerns with this aspect of the proposal. First, commenters were concerned with how long ESRD facilities would receive the payment adjustment. Second, commenters wanted clarification on the specific timeframe CMS would use to evaluate utilization for rate-setting purposes.

The comments and our responses to the comments on this proposal are set forth below:

Comment: Many commenters suggested that CMS retain the flexibility to extend the TDAPA period beyond 2 years to ensure that accurate and complete data are available to make determinations about bundling new products and adjustments to the bundled rate. One commenter noted that a ''new'' drug or biological product that falls within an existing functional category, including composite rate drugs, could be one that has a relatively familiar mode of action in the body to drugs and biological products that are already included in this category. This type of drug could be appropriate for a 2-year TDAPA period, however, if the ''new'' drug or biological product has an entirely new mode of action with which clinicians are unfamiliar (including but not limited to new benefits, side-effects, or safety profile) that product could deserve a longer TDAPA period. The commenters explained that if the language in the drug designation regulations stated ''at least two years,'' consistent for both existing functional category drugs and new functional category drugs and biological products, CMS would maintain the flexibility to use a 2-year period in those instances where there is sufficient claims data to move a drug or biological product into the bundle, but also have the ability to extend that period when warranted.

A few commenters requested for CMS to clarify it will evaluate at least 24-consecutive months of claims data prior to bundling any new drug or biological product into the ESRD PPS.

A drug manufacturer recommended the TDAPA apply for 3 years to better protect access to new drugs and to increase the amount of data collected for rate setting. The commenter explained that when a new drug becomes available, it can take months for dialysis facilities to incorporate it into their treatment protocols and implement the required changes in coding and billing

to reflect use of the drug on their claims. A national provider association supported this statement and described situations that can slow the rate of uptake of new products. For example, this commenter stated that physicians, nurses and administrative staff must receive education and training from the drug manufacturer so that the drug or biological product can be safely and effectively administered. Eligible patients must receive education on the medication prior to prescription and administration. The facility staff must review all patient insurance plans to initiate the authorization process to start the new drug. And, facilities must negotiate with vendors for the supply and pricing of the item so it can be purchased and administered to patients. The commenter further explained that the particular acuity and severity of the ESRD patient population generally results in facilities more gradually increasing use of novel therapies in these patients over time.

One commenter explained that due to the length of the rulemaking cycle, CMS typically has a 1-year lag between collecting claims data and implementing any reimbursement changes based on that data. The commenter asserted that if CMS extended a drug's TDAPA beyond 2 years, it would have more than 1 year of data available to use to adjust the base rate, and those data would be more likely to reflect mature utilization patterns in clinical practice. In addition, the commenter noted that when a drug does not qualify for an adjustment to the base rate, a longer TDAPA period would give facilities more time to determine how to accommodate use of the drug under the base rate.

A different drug manufacturer and a clinical association recommended that CMS apply TDAPA for whatever the period of time required to obtain 2 full years of claims data, not just 2 calendar years. The commenters explained that while they appreciated the concern noted in the preamble to the proposed rule that a longer TDAPA period ''could improperly incentivize high cost items without more value,'' they believed 2-calendar years of TDAPA would not provide adequate data to assess the information CMS has identified is necessary when new drugs come to market. They further explained that it is also important to have 2-full years of claims data to assess whether a new renal dialysis drug or biological product should be added to the bundle (or alternatively an add-on or adjuster be used to account for drugs not used in the average patient) and, if so, whether new dollars should be added to the base rate as well. They stated that depending on the variability in the prescribing protocols and general uptake in utilization, the data available at the end of 2-calendar years would not provide an adequate picture of utilization or cost.

A drug manufacturer and a national dialysis association noted that both CMS and Congress have recognized the need for a longer transitional payment period than 2 years for new drugs in the OPPS setting. They explained that while initially pass-through payment for new drugs was provided for 2 years, the period was extended by CMS in 2017 to 3 years. The commenters also indicated that in the Bipartisan Budget Act of 2018, Congress extended the pass-through period for certain outpatient drugs for an additional 2 years beyond the 3-year period CMS had implemented. The drug manufacturer estimated that the TDAPA period could be needed for up to 4 years to collect 2 full calendar years of claims data.

An LDO indicated that sufficient time is needed to evaluate new drugs as they come onto the market and also recommended that CMS obtain 2 full calendar years of claims data. The commenter recalled its experiences with an ESA and an iron replacement therapy product to illustrate concerns that may arise during the transition period. The commenter explained that since phase 3 studies are small, adverse events may not be recognized until a promising new drug is more widely used. The commenter went on to describe its experience with specific new drugs, identifying a higher rate of adverse effects in comparison to other products for these drugs, which resulted in its medical directors recommending discontinuing use of the drugs.

Response: In expanding TDAPA to new renal dialysis drugs and biological products that fall within the existing ESRD PPS functional categories, we did not propose to incorporate these drugs into the ESRD PPS base rate when the TDAPA period ends. Rather, we proposed to apply TDAPA for 2 years to support access to the new drug during its uptake period. The purpose for this expanded TDAPA is to help ESRD facilities incorporate these drugs and foster competition and innovation for ESRD drugs. At the end of the TDAPA period, we expect that the drug would achieve its foothold and would be able to compete with other drugs in the functional category. We continue to believe providing TDAPA for 2 years is appropriate for drugs in the current functional categories and that a longer timeframe to establish the drug's utilization is not necessary for drugs in a functional category, particularly since the ESRD PPS payment includes money for the drugs in these categories. With respect to the specific recommendation that we collect sufficient claims data, there is no data collection period for new renal dialysis drugs and biological products that fall within the existing functional categories for the purpose of modifying the base rate. However, we monitor utilization of all items and services available under the ESRD PPS. We will also use claims data to monitor for increased costs related to use of the new TDAPA drugs. We are not expanding the duration of TDAPA for these drugs because we believe that 2 years strikes the appropriate balance of supporting innovation while protecting the Medicare Trust Fund.

Under our final policy, beginning January 1, 2020, for new renal dialysis drugs and biological products that fall within an existing functional category, the application of TDAPA will begin with the effective date of subregulatory billing guidance and end 2 years from that date.

For new renal dialysis drugs and biological products that do not fall within an existing functional category, the application of TDAPA will begin with the effective date of subregulatory billing guidance and end after we determine, through notice-and-comment rulemaking, how the drug will be recognized in the ESRD PPS bundled payment.

The next set of comments and responses address our proposal that when a new renal dialysis drug or biological product falls within an existing functional category, at the end of the TDAPA period, we would not modify the ESRD PPS base rate. In general, commenters expressed that there is a need to consider a base rate modification for all new renal dialysis drugs and biological products to support their long term use. The comments and our responses to the comments on this proposal are set forth below:

Comment: We received several comments expressing concern that the functional categories are too broad to be the determining factor for when a drug or biological product is included in the ESRD PPS bundled payment. A national dialysis association asserted that the distinction CMS has drawn between drugs and biological products within an existing functional category, including composite rate drugs, and those outside an existing functional category is artificial and may not correspond to clinician, patient, or provider experience in the real world. The commenter recommended that all new renal dialysis drugs and biological

products, regardless of functional category, should have its utilization and price patterns evaluated before decisions are made with regard to the ESRD PPS bundled payment. The commenter believes CMS should consistently apply the review of utilization prior to making decisions about bundling drugs and biological products because this ensures that the bundling of a drug or biological product is based on the actual review of real and reliable data.

Several commenters, including a national dialysis association, noted that there are several new drugs in the pipeline that are not generic drugs or biosimilars and, while likely to have an indication for which a product is labeled and approved focused on treating conditions in an existing functional category, will not be clinically substituted with drugs currently in the functional categories or will provide a more effective treatment option, that is, true innovations. The national dialysis association stated that while current funding within the ESRD PPS may be sufficient to cover the costs for some new drugs or biological products within an existing functional category, it may not be sufficient for all new drugs and biological products. For these other drugs and biological products, the commenter noted, having guaranteed access to the TDAPA is only part of the solution. The association stated that innovation requires appropriate and sustainable long-term funding as well.

The commenters stated if CMS were to adopt a blanket policy of not adding new money to the bundle for any drug or biological product that comes within one of these categories, it will stifle innovation and leave patients with the same standard of care that existed in the 1990s. The commenters noted that unless there is adequate reimbursement for new products, they simply will not be used. Patients will lose access to them, even if these products are used during the TDAPA period. A drug manufacturer with a similar concern explained that if the cost will not be covered afterward in the bundle or via some other payment mechanism, it is highly likely that a dialysis facility will not convert to the new therapy with just 2 years of TDAPA. Commenters noted that an investment in what could be a temporary payment adjustment could adversely affect the financial aspects of the company, and may affect prescribing decisions after the TDAPA period.

A patient advocacy organization disagreed with our statement in the proposed rule that adding dollars to the ESRD PPS base rate for new renal dialysis drugs and biological products that fall within existing functional categories would be in conflict with the fundamental principles of a PPS and stated that a treatment that provides either longevity gain or improves quality of life or tolerability of treatment has great value to patients and is worthy of increased reimbursement. The commenter stated that if there is a colorable claim that a new treatment adds value, the cost of that treatment should be built into the base rate for year 3 while further developing evidence. Then, if the claims prove exaggerated and the new drug or biological product falls into disuse, CMS would have the option of reducing or eliminating the additional expenditure.

While many commenters suggested that CMS implement a rate-setting exercise at the end of TDAPA for all new renal dialysis drugs and biological products, other commenters expressed concern that we would add dollars to the base rate for drugs and biological product without significant clinical value. Given that new drugs for dialysis patients are expected in 2019, some commenters encouraged CMS to develop a final rule with comment period, that describes the process and criteria it will use to evaluate drugs for functional category consideration and determine when additional money will be added to the bundle, particularly when the drug is considered a significant clinical improvement over existing drugs.

Response: We appreciate the concerns raised by the stakeholders with regard to our proposal to not adjust the base rate after the end of the TDAPA period for new drugs or biological products that fall within an existing ESRD PPS functional category. We continue to believe that because the existing functional categories account for renal dialysis services in the ESRD PPS bundled payment, 2 years is long enough to be meaningful and to allow these new drugs to gain a foothold in the market, but not too long as to improperly incentivize high cost items without added value, for example, substitutions of those drugs that already exist in the functional category. The functional categories were designed to be broad because, when a new drug becomes available, it is added to the therapeutic armamentarium of the treating physician.

With regard to the commenter stating that CMS should consider continuing the TDAPA for a third year while developing further evidence, we do not intend to modify the base rate for new renal dialysis drugs and biological product in existing functional categories. With regard to the longevity gain, we do not believe that 2 years would provide the experience to assess longevity, and further, the intent of the TDAPA for new drugs is to be a short term payment to help facilities to incorporate new drugs and make appropriate changes in their businesses to adopt such drugs; provide additional payment for such associated costs, as well as promote competition with other drugs and biological products within the same ESRD PPS functional categories. Regarding the suggestion that increasing the base rate would be in keeping with the purpose of the ESRD PPS and would increase the quality of life of the ESRD beneficiary, we note that quality of life is a highly subjective determinant and is outside the purview of a PPS, however we believe this policy expands options which could enhance quality of life.

We are concerned about the comment stating that there will be beneficiary access issues at the end of the TDAPA period for new renal dialysis drugs or biological products that fall within a functional category. As we noted above, these drugs will be paid under the ESRD PPS bundle and become eligible under the outlier policy, if they are not considered to be a composite rate drug. We expect that if a beneficiary is responding well to a drug or biological product paid for using the TDAPA that they will continue to have access to that therapy after the TDAPA period ends. We plan to monitor the use of the TDAPA and carefully evaluate the new renal dialysis drugs and biological products that qualify.

We appreciate the suggestion of undergoing a rate-setting exercise wherein we compare the dollars allocated to a functional category to the cost of the new drugs to determine if reimbursement is appropriate. However, we did not propose to modify the base rate for new drugs that fall into the functional categories given that the purpose of the TDAPA for these drugs is to provide a short term boost to help ESRD facilities implement these products and to support innovation. We will consider this suggestion in future rulemaking.

With regard to the functional categories, we note that they were established based on the drugs and biological products that were included in the ESRD composite rate or billed on claims in conjunction with a dialysis treatment when the ESRD PPS was developed. The functional categories are a mechanism for adding new drugs and biological products to the bundle and designed to capture all renal dialysis

services. Since the PPS began, we have routinely and consistently monitored the utilization and pricing of all drugs furnished to ESRD patients and will continue to do so as new drugs are developed. We appreciate the viewpoints expressed by the commenters and will take the comments into consideration.

Comment: An LDO noted that CMS characterized the proposed TDAPA expansion as a means to give new renal dialysis drugs and biological products footholds in the market so that they can compete with existing drugs and biological products. The LDO stated that it is naïve to conclude that after achieving a market foothold, a manufacturer would simply lower the cost of a drug or biological product whose development required additional financial support through the TDAPA. Rather, manufacturers will still have incentive to continue to recoup those development costs, giving them significant negotiating leverage over dialysis facilities. The commenter further explained that given that scenario and existing financial constraints, it will be difficult for dialysis facilities to offer such new drugs and biological products during the TDAPA period as well as after it expires.

Response: We appreciate this feedback, however we believe that the TDAPA will incentivize competition, which will ultimately lower drug prices after the TDAPA period since there will be more drugs available to treat each condition. We believe that having more drug choices in the existing functional categories will increase both the negotiating power for facilities and their ability to obtain a competitive price after the TDAPA period ends. For example, we believe it is reasonable to conclude that once a lower cost drug, such as a generic drug, obtains a market foothold that dialysis providers will embrace the opportunity to switch to that drug's lower cost while maintaining quality of care. Under the ESRD PPS, ESRD facilities are responsible for furnishing all renal dialysis services either directly or under arrangement. As noted previously, we will monitor the application of the TDAPA adjustment and utilization during the TDAPA period, along with the utilization of the drugs that qualified for TDAPA, after the TDAPA period ends.

Comment: Several commenters suggested that we uniformly apply the TDAPA and provided suggestions on how CMS should recognize new renal dialysis drugs and biological products in the ESRD PPS bundled payment after the TDAPA period ends. For example, commenters recommended that CMS clearly state when a drug or biological product, even if it were to qualify for a functional category, will not be bundled if it is not provided to the average patient. The commenters referred to the language in the CY 2019 ESRD PPS proposed rule where CMS stated that ''the bundle is based on the costs incurred by the average patient.'' The commenters explained that if only a small portion of patients use the product, then it should not be added to the bundle because that would create the wrong incentives. The commenters further explained that providers who use the product will always be reimbursed less than it costs to provide the product and providers who do not use the product will receive a windfall (albeit a small one). The commenters asserted that bundling a product that is medically necessary for only a small percentage of patients only disincentivizes its use.

Response: We disagree with the commenter that the TDAPA should be applied uniformly, because the purpose of the TDAPA is different depending on whether the new drug or biological product falls or does not fall within an existing functional category. That is, if the new drug falls within an existing functional category, the purpose of the TDAPA is to support its uptake period. For new drugs that do not fall within an existing functional category, the purpose of the TDAPA is a pathway to a potential base rate modification. When we describe the PPS as a payment system based on the ''average patient,'' that means based on the costs of the average patient, not that the majority of patients utilize specific drugs, items, or services.

Comment: We received several comments expressing concern about the duration and sufficiency of data collection for calcimimetics and requesting clarification from CMS. Several commenters questioned whether paying the TDAPA for 2 years means CMS would be making utilization and pricing decisions based on a year or less of data due to CMS's rulemaking cycle. They maintained that the first year of utilization is not reflective of how the new drug will actually be used, and expressed concern about the impact of the thus far low and uneven utilization of calcimimetics on the data and any subsequent pricing decisions. To determine the appropriate duration for data collection, a drug manufacturer urged CMS to first consider the rate at which dialysis facilities incorporate new drugs into their treatment regimens. Several commenters also requested that CMS work with ESRD stakeholders to develop the methods CMS will use to evaluate the data as well as an approach to accounting for calcimimetics in the base rate. The commenters want to ensure that beneficiaries continue to have access to these drugs once the TDAPA period ends. In particular, an LDO noted the importance of recognizing the uniqueness of the oral calcimimetic in that it is taken daily when the payment system is designed for 3 treatments per week. A few commenters specifically requested that CMS outline its methodology in this final rule, with a comment period.

Response: As we stated in the CY 2019 proposed rule (83 FR 34309 through 34310), under § 413.234(c), for new injectable or intravenous products that are not included in a functional category, the TDAPA is based on pricing methodologies under section 1847A of the Act and is paid until sufficient claims data for rate setting analysis for the new injectable or intravenous product are available, but not for less than 2 years. We note that this period begins with the effective date of a change request and, after at least 2 years of data collection, ends with rulemaking to modify the ESRD PPS base rate, if appropriate. After 2 years of data collection, we will evaluate the data, and if we determine that we need further data collection, we will continue TDAPA payments until data collection is sufficient. We further thank the commenters for their suggestions of methods we should employ when evaluating the data. We will keep these in mind and will provide further discussion about our methods in future rulemaking.

Final Rule Action: After consideration of public comments, for CY 2019 we are finalizing the revisions to the drug designation process regulations to reflect the proposed policy but are delaying the effective date of the policy revisions until January 1, 2020. The purpose of the delay is to mitigate the launch issues of the TDAPA expansion particularly for CMS programs (HCPCS, Medicaid and Medicare Part C). Also, many state Medicaid programs offer the same scope of services available under Part C and may need additional time to ensure proper communication so that dual eligible beneficiaries have access to drugs receiving the TDAPA. In addition, states may need time to modify their systems to adopt new renal dialysis drugs and biological products. For stakeholders (particularly small dialysis organizations and rural facilities) we believe the delay will be beneficial so that they can adapt and streamline processes to support a seamless transfer

between Agency programs when new drugs are launched and are eligible for the TDAPA. For example, facilities will have more time during this year to develop software to accommodate the diverse nature of all drugs receiving TDAPA so that they can be flexible and communicate with Medicare and Medicaid system requirements.

Specifically, we are finalizing the addition of § 413.234(b)(1)(i), (ii) and revision of § 413.234(c) with one revision to proposed § 413.234(b)(1)(ii), to reflect that the TDAPA, under the authority of section 1881(b)(14)(D)(iv) of the Act, will apply to all new renal dialysis injectable or intravenous products, oral equivalents, and other forms of administration drugs and biological products, regardless of whether or not they fall within a functional category, effective January 1, 2020. We also note the revision to refer to ''biological product,'' which is FDA's preferred nomenclature, within the definition instead of ''biological''.

We are finalizing the revision of § 413.234(b)(2)(ii) and § 413.234(c)(2), removal of § 413.234(c)(3), and addition of § 413.234(c)(2)(i) to reflect that we will continue to provide the TDAPA, collect sufficient data, and modify the ESRD PPS base rate, if appropriate, for new renal dialysis drugs and biological products that do not fall within an existing functional category.

We are finalizing the revision to § 413.234(c)(1) to reflect that for new renal dialysis drugs and biological products that fall within a functional category, the TDAPA applies for only 2 years, effective January 1, 2020.

We are finalizing the addition of § 413.234(c)(1)(i) to reflect that when a new renal dialysis drug or biological product falls within an existing functional category at the end of the TDAPA period we will not modify the ESRD PPS base rate, but at the end of the 2 years, as consistent with the existing outlier policy, the drug is eligible for outlier payment, effective January 1, 2020. However, as discussed in section II.B.1.h of this final rule, if the new renal dialysis drug or biological product is considered to be a composite rate drug, it will not be eligible for an outlier payment.

Commenters did not specifically comment on the proposal to operationalize this proposed policy no later than January 1, 2020. Therefore, we are finalizing this proposal as proposed. We note that this action coincides with the delayed effective date to January 1, 2020 to better coordinate with CMS and stakeholders as noted above. For CY 2019, the current regulations (and drug designation process) will remain in place and will apply to new renal dialysis drugs and biological products that come on the market, but beginning January 1, 2020, the new regulations (and drug designation process) will take effect.

g. Basis of Payment for the TDAPA

Currently, under § 413.234(c), the TDAPA is based on pricing methodologies under section 1847A of the Act, including 106 percent of ASP (ASP+6). As we explained in the CY 2019 ESRD PPS proposed rule (83 FR 3414), if we adopt the proposals discussed in section II.B.1.f of this final rule using the same pricing methodologies, Medicare expenditures would increase, which would result in increases of cost sharing for ESRD beneficiaries, since we have not previously provided the TDAPA for all new renal dialysis drugs and biological products.

The TDAPA is a payment adjustment under the ESRD PPS and is not intended to be a mechanism for payment for new drugs and biological products under Medicare Part B, and under section 1881(b)(14)(D)(iv) of the Act, we believe it may not be appropriate to base the TDAPA strictly on section 1847A of the Act methodologies. For CY 2019, we considered options for basing payment under the TDAPA, for example, maintaining the policy as is and facility cost of acquiring drugs and biological products. As we explained in the proposed rule, we found that the while ASP could encourage certain unintended consequences (discussed below), it continues to be the best data available since it is commonly used to facilitate Medicare payment across care settings and, as described in section II.B.1.c of this final rule, is based on the manufacturer's sales to all purchasers (with certain exceptions) net of all manufacturer rebates, discounts, and price concessions.

We further noted that, since the implementation of section 1847A of the Act, stakeholders and executive policy advisors have analyzed this section of the statute and issued their respective critiques on the purpose of the ASP add-on percentage. On March 8, 2016, the Assistant Secretary for Planning and Evaluation (ASPE) issued an Issue Brief titled, ''Medicare Part B Drugs: Pricing and Incentives'' (*https://aspe.hhs.gov/pdf-report/medicare-part-b-drugs-pricing-and-incentives*). In this brief ASPE notes several concerns with the ASP methodology. Two of those concerns relate to the economic incentives of cost and value. ASPE stated that the ASP methodology for Part B drugs falls short of providing value based incentives in several ways. Specifically, ASPE noted physicians can often choose between several similar drugs for treating a patient and although the current system may encourage providers and suppliers to pursue the lowest price for drugs that are multiple source, payment based on drug specific ASP provides little incentive to make choices among the therapeutic options with an eye towards value and choose among the lowest price among all drugs available to effectively treat a patient. ASPE noted that rationale for the 6 percent add-on has been to cover administrative and overhead costs, but such costs are not proportional to the price of the drug. The fixed 6 percent of ASP provides a larger ''add-on'' for higher priced drugs than for lower priced drugs, resulting in increased profit margins for the physicians' office and hospitals creating a perverse incentive to choose the high priced drugs as opposed to lower priced alternatives of similar effectiveness.

We also noted in the proposed rule that in MedPAC's June 2015 Report to Congress (*http://medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf*), MedPAC discussed the meaning of the 6 percent that is added to the ASP and stated: ''There is no consensus on the original intent of the 6 percent add-on to ASP. A number of rationales have been suggested by various stakeholders. Some suggest that the 6 percent is intended to cover drug storage and handling costs. Others contend that the 6 percent is intended to maintain access to drugs for smaller practices and other purchasers who may pay above average prices for the drugs. Another view is that the add-on to ASP was intended to cover factors that may create a gap between the manufacturers' reported ASP and the average purchase price across providers (for example, prompt-pay discounts). Another rationale for the percentage add-on may be to provide protection for providers when price increases occur and the payment rate has not yet caught up.''

Finally, we stated in the CY 2019 ESRD PPS proposed rule that with regard to acquisition costs in a 2006 Report to Congress titled, ''Sales of Drugs and Biological products to Large Volume Producers (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/LVP_RTC_2_09_06.pdf*), the Secretary was tasked to submit a Report to Congress (RTC) to include recommendations as to whether sales to large volume purchasers should be excluded from the computation of

manufacturer's ASP. The contractor made extensive efforts to collect and analyze data regarding large volume drug purchasers, but was unable to obtain data on ASP by type of purchaser from the drug manufacturers, and was unable to determine net acquisition costs. The sensitive and proprietary nature of prescription drug pricing data made it extremely difficult to obtain the data necessary for the report. Given that ASP was designed to broadly reflect market prices without data on net acquisition cost, it is not possible to accurately analyze the impact of large volume purchasers on overall ASP. We noted that in 2018, we remain unable to obtain contractual information regarding drug pricing and ESRD PPS, which is especially pertinent since the dialysis stage is dominated by two large dialysis organizations who administer drugs and biological products to the majority of ESRD beneficiaries.

We explained in the proposed rule that to balance the price controls inherent in any PPS we believe that we need to take all of these issues into consideration to revise the basis for TDAPA payment. We noted that we are, and will continue to be, conscious of ESRD facility resource use and recognize the financial barriers that may be preventing uptake of innovative new drugs and biological products. Therefore, we proposed to revise § 413.234(c) under the authority of section 1881(b)(14)(D)(iv) of the Act, to reflect that we would base the TDAPA payments on 100 percent of ASP (ASP+0) instead of the pricing methodologies available under section 1847A of the Act (which includes ASP+6).

We noted that this proposal would apply to new renal dialysis drugs and biological products that fall within an existing functional category and to those that do not fall within an existing functional category. We stated that we believe ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category because there are already dollars in the per treatment base rate for a new drug's respective category. We also noted that we believe ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that do not fall within the existing functional category because the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products. We noted that there is no clear statement from Congress as to why the payment allowance is required to be 106 percent of ASP (ASP+6) as opposed to any other value from 101 to 105 percent, and, as MedPAC discussed in its June 2015 report, there is no consensus amongst stakeholders.

We further explained that we believe moving from pricing methodologies available under section 1847A of the Act, (which includes ASP+6) to ASP+0 for all new renal dialysis drugs and biological products regardless of whether they fall within an ESRD PPS functional category strikes a balance between the increase to Medicare expenditures (subsequently increasing beneficiary coinsurance) and stakeholder concerns discussed in section II.B.1.e of this final rule. That is, we proposed to provide the TDAPA for new drugs that are within an existing functional category, which is an expansion of the existing policy. We stated that this proposal would also aim to promote innovation and bring more high-value drugs to market. This proposal would further address concerns about incentivizing use of high cost drugs in ESRD facilities, also discussed in section II.B.1.e of this final rule. We solicited comment on the proposal to revise § 413.234(c) to reflect that we would base the TDAPA payments on ASP+0. While we proposed to change the basis of payment for the TDAPA from pricing methodologies available under section 1847A of the Act, (which includes ASP+6) to ASP+0, we also solicited comment on other add-on percentages to the ASP amount, that is, ASP+1 to 6 percent for commenters to explain why it may be appropriate to have a higher percentage.

We stated in the proposed rule that there are times when the ASP is not available. For example, when a new drug or biological product is brought to the market, sales data is not sufficiently available for the manufacturer to compute an ASP. Therefore, when the ASP is not available, we proposed that the TDAPA payment would be based on 100 percent of Wholesale Acquisition Cost (WAC) and, when WAC is not available, the TDAPA payment would be based on the drug manufacturer's invoice. We solicited comment on this proposal.

We noted that this proposal to use ASP+0 as the basis for the TDAPA payments, if adopted, would apply prospectively to new drugs and biological products as of January 1, 2019. Currently, calcimimetics are eligible for the TDAPA and payment for both the injectable and oral versions are based on pricing methodologies under section 1847A of the Act. We explained that this proposal would not affect calcimimetics, which would continue to be eligible for the TDAPA payment based on ASP+6.

The comments and our responses to the comments on the basis of payment for the TDAPA proposal are set forth below:

Comment: MedPAC commented that if CMS decides to finalize the proposed policy and apply TDAPA to new renal dialysis drugs that fit into an existing functional category, CMS should not make duplicative payments for a new product (assigned to a functional category) by paying the TDAPA for 2 years and paying for its functional category under the ESRD PPS base rate. For example, the agency could reduce the TDAPA amount to reflect the amount already included in the base rate. In addition, CMS could consider paying a reduced percentage of the estimated incremental cost of the new drug as a way to share risk with dialysis providers and provide some disincentive for the establishment of high launch prices.

A drug manufacturer disagreed with MedPAC, pointing out that its product is an advance that substantially improves beneficiary outcomes and that CMS's assessment of the cost of other drugs in its functional category is trivial (the commenter asserted that there appears to be approximately 59 cents currently allocated in the ESRD PPS rate for the functional category). The manufacturer stated that the amount currently in the ESRD PPS rate does not account for the hundreds of millions of dollars it costs to develop a new, breakthrough drug; thus, a TDAPA would not be duplicative.

Response: We understand MedPAC's suggestion is to base the TDAPA payment amount on a value that takes into account the dollars already included in the ESRD PPS base rate for the functional category. While we did not propose this approach, we can consider this mechanism in the future. With regard to the commenter that disagreed with MedPAC's comment, we appreciate the concern and understand there could be new renal dialysis drugs and biological products that have a high cost which is not directly accounted for by the functional category. However, as we mentioned previously, we did not propose to change the determinant on how a new renal dialysis drug or biological product is considered reflected in the ESRD PPS base rate, therefore, in the situation described by the commenter, this new high cost drug would be considered reflected in the base rate since it falls within an existing functional category. The ESRD PPS is a payment system that takes into account

the resource use of the ESRD facility for furnishing renal dialysis services to Medicare beneficiaries. We will, however, consider this situation in the future.

Comment: Although MedPAC did not support the proposal to expand the TDAPA to all new dialysis drugs that fit into a functional category, MedPAC believed there was good rationale for CMS's proposal to change the basis for the TDAPA from ASP+6 percent to ASP with no percentage add-on. MedPAC pointed out that the ASP+6 percent policy was developed to reimburse physicians for the cost of drugs that they purchase directly and commonly administer in their offices. While the policy never stated what cost the ''+6 percent'' was intended to cover, MedPAC noted that applying the policy to dialysis facilities is considerably different from reimbursing physicians. First, the variation in physicians' purchasing power, whether they practice solo, as part of a group, or in a health system, is likely to result in considerably more variation in the acquisition price for a drug compared to the acquisition prices for dialysis facilities. If the intent of the ''+6 percent'' was to address acquisition price variation, MedPAC believes that rationale is diminished for dialysis facilities. Second, MedPAC noted that the TDAPA is in addition to the ESRD base rate, which already includes reimbursement for the cost of storage and administration of ESRD-related drugs. Therefore, if the intent of the ''+6 percent'' was to address storage and administration costs, MedPAC believes these costs are already addressed through the ESRD PPS bundled payment and do not contribute to the rationale for paying ASP+6 percent for the TDAPA. MedPAC stated that, overall, the proposal to change the basis of the TDAPA to ASP with no percentage add-on appears to be well founded.

Response: We appreciate MedPAC's support for this proposal and agree that ASP+0 is appropriate as the basis for the TDAPA, particularly in light of the administrative costs included in the ESRD PPS bundled payment amount.

Comment: Some commenters referenced an analysis completed by an analytic organization, stating that if CMS were to finalize the 100 percent ASP policy for TDAPA, and that amount were used to fold drugs and biological products into the ESRD PPS, there will be insufficient dollars available to provide access to these products for patients. They stated that the actual payment amount would be closer to ASP − 1.6 or lower.

Some commenters expressed concern that the ASP+0 proposal will result in a provider reimbursement falling far below that amount given: (1) The exclusion of the 20 percent coinsurance from bad debt recovery; (2) the fact that many states fail to fulfill their cost sharing obligations for dual-eligible beneficiaries; and (3) the budget sequestration. The commenter further explained that this considerable underpayment will challenge dialysis facilities' ability to offer a new drug or biological product during the TDAPA period.

Response: We appreciate all of the feedback we received from the commenters with regard to basing payment for TDAPA at ASP+0 as opposed to using the pricing methodologies available under section 1847A of the Act.

With regard to the concerns that ASP+0 will effectively yield a reimbursement below ASP after sequestration and bad debt reductions are applied, as discussed previously, the TDAPA policy is for purposes of the ESRD PPS and not designed to offset or mitigate other statutorily required cuts and instances in which facilities cannot recover beneficiary cost sharing.

The TDAPA is a payment adjustment under the ESRD PPS, and we continue to believe it is not intended to be a mechanism for payment for new drugs and biological products under Medicare Part B. We believe that we have flexibility to determine the basis for payment for TDAPA on a methodology outside of how Part B pays because we need to take into account impacts to the Medicare Trust Fund when there are already administrative costs reflected in the ESRD PPS base rate. As a result we have reconsidered the use of pricing methodologies under section 1847A of the Act and proposed ASP+0, as discussed above in section II.B.1.f of this final rule. We agree with MedPAC that the ASP+6 percent policy was developed to reimburse physicians for the cost of drugs and that the TDAPA is in addition to the ESRD base rate, which already includes reimbursement for the cost of storage and administration of ESRD-related drugs. Therefore, we believe basing the TDAPA payment on ASP+0 is appropriate and we are finalizing the proposal.

Comment: Some commenters explained that the ESRD PPS is unique and fragile and operates at razor-thin margins, with many facilities operating with negative Medicare margins. One commenter stated that it is not appropriate to assume that because a functional category exists there is sufficient funding for all future drugs and biological products developed to treat such conditions. One commenter expressed strong concern about the proposal and explained that facilities will have to reconcile potential differences in the amount that CMS reimburses in TDAPA and the amount that the facilities actually pay for new prescription drugs and associated costs of administering them to patients (overhead). The commenter stated that this discrepancy could have the unintended consequence of discouraging dialysis providers from including new therapies on their formularies.

Some commenters expressed concern regarding the impact the proposal would have on medium and small dialysis organizations. One commenter stated that payment at ASP+0 may create a disincentive for medium and small dialysis organizations to acquire the product and provide it in their facilities because they may be under-reimbursed. This could lead to patient access issues in obtaining the drug as clinicians may be hesitant to prescribe a new therapy if they know the dialysis facilities are not stocking it.

Many commenters expressed concern that ASP+0 is not sufficient to cover the cost of administering the drug or biological product during the transition period. One commenter stated that it is inappropriate to assume that new drugs and biological products will have the same administrative and overhead cost profile, or that dialysis facilities can simply cover these costs for multiple drugs or biologics with the current dollars. Commenters explained that drugs and biological products require support for costs related to storage, management, delivery, packaging, administration, and dispensing. Further, the availability of novel drugs and biological products will necessitate the dedication of resources to develop clinical protocols, educate and train staff, and change medical record and billing systems. Another commenter explained that some dialysis providers face unique and significant costs associated with implementing the TDAPA, including setting up and paying for pharmacy systems and substantially updating internal billing systems to comply with the TDAPA regulations. The commenter also stated that fulfillment, distribution and waste costs paid to dispensing pharmacies, as well as billing and administrative costs for these providers are examples of unique costs that would be better addressed with an ASP+6 policy. Another commenter stated that some dialysis providers face additional hurdles, such as state pharmacy laws,

which make more complex their ability to ''dispense'' medication. This commenter further explained that the consequence of adding new drugs, especially oral drugs, to the ESRD PPS is that an elaborate operational and clinical system is required when a new oral medication is approved and qualifies for the TDAPA in order to ensure patients receive the product and that dialysis providers can bill for the product. This commenter noted that these drugs were not included in the ESRD PPS at the outset or in the composite rate and therefore the administrative costs of developing the infrastructure to deliver new pharmaceutical products, especially oral drugs, is not built into the ESRD PPS.

Another commenter explained that there are costs associated with establishing pilot programs, typically the manner in which dialysis organizations would evaluate the benefits and risks of newly approved therapies. This commenter further explained that pilot programs often involve chart reviews, selection of patients to initiate therapy, titration of dosing, additional lab monitoring, evaluation of outcomes, and ultimately incorporation into modified treatment protocols, if facilities determine there is value to the utilization of a new therapy. This would occur after a thorough evidence review of registration trials, peer reviewed literature and other clinical outcomes data.

Some commenters noted that setting the TDAPA at ASP+0 will not likely have any impact on the drug or biological product's price. One commenter explained that there are challenges of delivering care with limited resources when the cost of prescription pharmaceuticals is outside of its control and frequently on the rise. The commenter expressed concern that none of the systemic issues that the Administration seeks to address regarding pharmaceutical prices will be changed by reducing the payment rate for drugs and biological products in the ESRD PPS from ASP+6 to ASP+0 because this change does not affect the actual price of pharmaceuticals. Instead, it only affects what Medicare will reimburse providers for the price they still have to pay to pharmaceutical companies. The commenter indicated that this reduction have a negative impact on dialysis facilities and further limit their ability to provide quality care to Medicare beneficiaries.

Some commenters explained that ASP is driven by the ''average'' sales price for a drug to all purchasers, including hospitals and large purchasing groups, net of all manufacturer rebates, discount, and price concessions. A few commenters noted that while the drugs and biological products contained within the ESRD PPS are required to be ''renal dialysis services'' that are ''furnished for the treatment of ESRD,'' it is not necessarily the case that dialysis facilities are the only—or largest—purchasers of the drugs and biological products in question. The commenters asserted that it is therefore faulty logic to assume that dialysis providers are necessarily the entities whose purchase price is represented by ASP. Commenters stated that many dialysis facilities are unable to acquire some drugs and biological products at or below ASP and may find that even ASP+6 does not adequately cover their costs to acquire and deliver drugs to beneficiaries.

Another commenter stated that many dialysis facilities may not have the leverage or capacity to purchase the drug or biological product at or below the ASP, for example, small ESRD facilities and ESRD facilities in rural areas do not have the buying power of large dialysis organizations. The commenter further explained that for these facilities, the cost to provide drugs and biological products is higher than the average and includes additional costs such as transportation to the rural area. Often a drug is shipped to a central location and then transported to rural facilities which adds both transportation and administrative costs. Another commenter noted that drug manufacturers do not give small and mid-sized facilities the same discounts received by the two largest dialysis providers.

Response: With regard to the concerns that ASP+0 will not cover the administrative costs associated with bringing a new drug or biological product as a therapeutic option in a facility, we point out that under the current ESRD PPS, new renal dialysis drugs that are considered to be in a functional category do not receive any additional payment. Payment for these drugs has been included in the ESRD PPS bundled payment amount since the inception of the ESRD PPS. We note that with this new policy, effective January 1, 2020, ESRD facilities will now get a payment adjustment for 2 years for new renal dialysis drugs and biological products, whereas before they did not. We continue to believe that ASP+0 is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category because there are already dollars in the per treatment base rate for a new drug's respective category. Beyond just capturing administrative costs in the base rate, there are also payment dollars for the respective functional category included in the base rate which, we believe, mitigates the financial risk to the facilities.

We are concerned with the comment regarding that the discrepancy between ASP+0 and ASP+6 could have an unintended consequence of discouraging dialysis providers from including new therapies on their formularies. Under the ESRD PPS, ESRD facilities are responsible for furnishing all renal dialysis services directly or under arrangement. We understand that small, medium, and rural facilities may have additional challenges related to acquisition costs, transportation, and delivery which could lead to inequitable access for beneficiaries served by those communities. Again, we note that currently new renal dialysis drugs have entered the market since the implementation of the ESRD PPS in 2011 and were immediately rolled into the bundled payment rate. We believe the same would be true for new drugs and biological products and we believe the dollars included in the base rate for the specific functional groups would mitigate these challenges. Effective January 1, 2020, ESRD facilities will now get a payment adjustment for 2 years for new renal dialysis drugs and biological products, whereas before they did not.

With regard to pilot programs, we believe the issues that were mentioned are addressed by FDA clinical trials for new drug applications. For generic drugs, part of the reason they are approved in the section 505(j) program is that these safety and drug response issues have been addressed. It would seem that what the commenter is asking us to pay for is an evaluative business model and that is not considered payment for the treatment of a medical condition.

With regard to the comment asserting that the consequence of adding new drugs, especially oral drugs, to the ESRD PPS is that an elaborate operational and clinical system is required when a new oral medication is approved and qualifies for the TDAPA in order to ensure patients receive the product and that dialysis providers can bill for the product, we believe this issue should be mitigated with the 1-year delay finalized in section II.B.1.e of this final rule. We note that there are oral equivalent drugs that have been bundled in the ESRD PPS since its inception.

Comment: One commenter noted that patient's out-of-pocket costs may be higher with an ASP+6 TDAPA than under the ASP+0 proposal, however the

commenter believed the trade-off of spurring innovation in new treatments warrants the cost. The commenter stated that while it would prefer that the coinsurance would not be applied to TDAPA given this is a facility-level adjuster to the PPS, they recognize that CMS has stated it does not have the authority to waive the coinsurance.

Response: We do not agree with the commenter that the TDAPA is a facility-level adjustment to the ESRD PPS. The TDAPA is a patient-level adjustment because it is only applicable if the patient is furnished the drug or biological product. We appreciate that coinsurance is a concern, but as the commenter noted, we do not have the authority to waive coinsurance requirements.

Comment: While some commenters appreciated CMS working to reduce drug pricing, they expressed concern that changing the basis of payment for the TDAPA from ASP+6 to ASP+0 will not encourage innovation despite CMS's intent. Commenters stated that there has been little innovation in new ESRD therapies in over 2 decades and they requested that CMS not apply this untested new pricing policy to the TDAPA under the ESRD PPS.

Several commenters discussed the Kidney Accelerator (KidneyX) project. The commenters noted that the Department of Health and Human Services (HHS) indicated that the project ''sends an important message to investors and innovators regarding the desire and demand for new therapies.'' Commenters explained that in addition to the activities around KidneyX, CMS needs to make sure that its policies also promote innovation and advances in case across these stakeholder groups and that properly aligning the payment component is essential to advancing innovation as well. The commenters stated that the ASP+0 proposal could result in creating a disincentive for the adoption and development of new drugs and biological products and undermines the KidneyX initiative. The commenters explained that promoting innovation in kidney care requires taking into account patients, providers, and manufacturers and that CMS should provide ASP+6 percent via TDAPA so that the cost of evaluation, training and implementation is cost-neutral and providers will be eager to evaluate and utilize new therapies, and innovation of new products will be spurred in the renal space.

Response: We agree with commenters that innovation and the KidneyX project are important and necessary for the development of new therapies. We believe that basing the TDAPA at ASP+0 provides sufficient resources to incentivize the development of new, innovative therapies and is a supplement to the KidneyX project. We believe that ASP+0 is sufficient because the ESRD PPS provides on a per treatment basis payment for administrative activities, including packaging and handling of drugs and staff costs. This per treatment payment along with the TDAPA is a reasonable basis for payment because we believe it mitigates the financial risk to the ESRD facilities. One of the objectives of KidneyX is to bring to market not only medications that will slow the progression and/or reverse kidney disease, but also drugs and biological products that will cure kidney disease. We believe providing the TDAPA for all new renal dialysis drugs and biological products provides an incentive for innovation as part of the treatment pathway for mitigating, reversing and ultimately curing ESRD.

Comment: A few commenters referred to CMS' experience in the hospital outpatient setting when it tried to shift to ASP+4 percent. The commenter asserted that between 2009 and 2012, CMS worked to establish the appropriate payment rate for separately paid drugs in the hospital outpatient setting. During this time, CMS made various shifts in the percentage added to the ASP, but eventually for CY 2013 concluded that the only way to establish a predictable and accurate payment for these drugs that recognized the real overhead costs associated with providing them was to set the amount at ASP+6 percent. The commenter noted that none of the proposals in the outpatient setting over the years ever suggested setting the rate at 100 percent of ASP. Some commenters suggested that the basis of payment policy remain consistent with how Medicare Part B pays other provider settings, for example, Physician Fee Schedule and the hospital outpatient PPS.

Response: Again, we believe that ASP+0 is sufficient because the ESRD PPS provides on a per treatment basis payment for administrative activities, including packaging and handling of drugs and staff costs. This payment along with the TDAPA is a reasonable basis for payment because we believe it mitigates the financial risk to the ESRD facilities. We appreciate the comments on the Medicare payment adjustments for the hospital outpatient setting and physician offices. MedPAC, which agreed with us, noted that the TDAPA is in addition to the ESRD PPS base rate, which already includes payment for the cost of storage and administration of renal dialysis services, therefore if the intent of the 6 percent is to address storage and administration costs, additional payment is not necessary. The ESRD PPS per treatment payment amount is paid for every dialysis treatment regardless of the items and services furnished. We will monitor the efficacy of payment for the ESRD PPS under TDAPA.

Comment: We received two comments on the proposal that in the event ASP is unavailable for a drug, WAC+0 would be used, and in the event both ASP and WAC are unavailable, the manufacturer's invoice would be used as the basis for the TDAPA payment. The commenters did not support WAC+0, and one commenter recommended that we base the payment in this circumstance on WAC+6. The other commenter suggested that, for instances in which ASP is not available, CMS should base payment on WAC+3 to be consistent with the hospital outpatient department. Both commenters supported basing the TDAPA on the manufacturer's invoice in the event ASP and WAC are not available.

Response: We appreciate the comments on our proposal for situations when ASP is unavailable. However, we believe that this is the same rationale that we discuss above. We believe that the administrative costs of packaging, handling, and staff are included in the ESRD PPS base rate and therefore the TDAPA is a reasonable basis for payment because we believe it mitigates the financial risk to the ESRD facilities. With regard to the consistency with other payment systems, we believe that they have different administrative circumstances. We appreciate that the commenters supported use of the manufacturer's invoice in the event ASP and WAC are not available.

Comment: Two commenters expressed concern that while the preamble of the proposed rule stated that the proposed drug designation changes would not apply to the use of ASP+6 percent for calcimimetics, the regulatory text is not clear. Commenters supported the statement in the preamble that CMS has not changed the TDAPA policy for calcimimetics with the new drug designation policy and strongly supports maintaining the policy as it is today. However the commenter is concerned that this intent be reflected in the regulatory text as well.

Response: We appreciate the feedback on the ambiguity of the regulatory text. We are finalizing a revision to the drug designation process regulations to reflect that for calcimimetics, the basis of payment will be based on pricing methodologies under section 1847A of

the Social Security Act (which includes ASP+6). We are maintaining the current policy for calcimimetics because these drugs are the only ones that qualify for the TDAPA at this time and are currently receiving the adjustment, and the basis of payment was established when they were launched. We note that any new injectable or intravenous product that is eligible for TDAPA until January 1, 2020 would be paid under the current policy, which is a TDAPA based on pricing methodologies under 1847A of the Act (which include ASP+6). As of January 1, 2020, all new renal dialysis drugs and biological products, regardless of functional category status, will be paid the TDAPA based on ASP+0.

Final Rule Action: After considering the public comments, we are finalizing the policy as proposed with two revisions. Specifically, we are finalizing the revision of § 413.234(c) under the authority of section 1881(b)(14)(D)(iv) of the Act, to reflect that we base the TDAPA payments on ASP+0 instead of the pricing methodologies available under section 1847A of the Act (which includes ASP+6), effective January 1, 2020. Since there are times when ASP is not available, we are finalizing that the TDAPA payment is based on WAC+0 and, when WAC is not available, the TDAPA payment is based on the drug manufacturer's invoice, effective January 1, 2020. We are also finalizing a revision to the proposed § 413.234(c) to reflect that the basis of payment for TDAPA for calcimimetics continues to be based on the pricing methodologies available under section 1847A of the Act (which includes ASP+6).

h. Drug Designation Process for Composite Rate Drugs and Biological Products

In the CY 2016 ESRD PPS final rule, we did not discuss composite rate drugs and biological products explicitly in context of the drug designation process. Composite rate services are discussed in the CY 2011 ESRD PPS final rule (75 FR 49036, 49078 through 49079) and are identified as renal dialysis services in § 413.171 and under section 1847(b)(14)(B) of the Act. Prior to the implementation of the ESRD PPS, certain drugs used in furnishing outpatient maintenance dialysis treatments were considered composite rate drugs and not billed separately. Composite rate drug and biological product policies are discussed in Pub. 100–02, chapter 11, section 20.3.F (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c11.pdf*). This manual lists the drugs and fluids considered in the composite rate as heparin, antiarrythmics, protamine, local anesthetics, apresoline, dopamine, insulin, lidocaine, mannitol, saline, pressors, heparin antidotes, benadryl, hydralazine, lanoxin, solu-cortef, glucose, antihypertensives, antihistamines, dextrose, inderal, levophed, and verapamil. Drugs that are used as a substitute for any of these items, or are used to accomplish the same effect, are also covered under the ESRD PPS.

We used the composite rate payments made under Part B in 2007 for dialysis in computing the ESRD PPS base rate. These are identified on Table 19 of the CY 2011 ESRD PPS final rule (75 FR 49075) as ''Composite Rate Services''. In addition, under § 413.237, composite rate drugs and biological products are not permitted to be considered for an outlier payment. The outlier policy is discussed in section II.B.3.c of this final rule.

Composite rate drugs and biological products were also grouped into functional categories during the drug categorization for the CY 2011 ESRD PPS final rule (75 FR 49044 through 49053). For example, heparin is a composite rate drug and falls within the Access Management category. However, these functional categories exclude certain composite rate items given that certain drugs and biological products formerly paid for under the composite rate were those that were routinely given during the time of the patient's dialysis and not always specifically for the treatment of their ESRD. For example, an antihypertensive composite rate drug that falls within the Cardiac Management category, which is not an ESRD PPS functional category, is not considered to be furnished for the treatment of ESRD and therefore, is not included under the ESRD PPS.

In light of our proposal to expand the drug designation process and the TDAPA, we also proposed, under the authority of section 1881(b)(14)(D)(iv) of the Act, that it extend to composite rate drugs and biological products that are furnished for the treatment of ESRD. Specifically, we proposed that beginning January 1, 2019, if a new renal dialysis drug or biological product as defined in the proposed revision at § 413.234(a) is considered to be a composite rate drug or biological product and falls within an ESRD PPS functional category, it would be eligible for the TDAPA. We noted that composite rate drugs and biological products that are not considered to be furnished for the treatment of ESRD, and therefore, are not included in the ESRD PPS, would not be eligible for the TDAPA, for example, antihypertensives. We stated in the proposed rule that we believed the same unique consideration for innovation and cost exists for drugs that are considered composite rate drugs. That is, the ESRD PPS base rate dollars allocated for these types of drugs may not directly address the costs associated with drugs in this category when they are newly launched and are finding their place in the market. Accordingly, we proposed that the expanded drug designation process and the TDAPA policy we proposed in section II.B.1.f of this final rule, including the proposed changes to § 413.234, would be applicable to composite rate drugs, with one exception. Under our proposal, new composite rate drugs would not be subject to outlier payments following the period that the TDAPA applies, since we did not propose to change the current outlier policy under § 413.237, which does not apply to composite rate drugs. We did, however, solicit comments on whether we should consider applying our outlier policy to composite rate drugs in the future (see section II.B.3.c of this final rule).

We solicited comment on the proposal to recognize composite rate drugs and biological products in the same manner as drugs that were formerly separately paid under Part B when furnished for the treatment of ESRD for purposes of the proposed revisions to the drug designation process and eligibility for the TDAPA.

The comments and our responses to the comments on our proposal to extend the TDAPA expansion proposals to composite rate drugs and biological products that are furnished for the treatment of ESRD are set forth below.

Comment: MedPAC commented that we should not proceed with our proposal to apply the TDAPA policy to new renal dialysis drugs that would be considered composite rate drugs for the same reasons that MedPAC believes we should not proceed with our proposal to apply the TDAPA to new renal dialysis drugs that would fall into an existing functional category.

Some commenters referred to the inclusion of composite rate drugs in their overall comments regarding the TDAPA expansion and supported their inclusion in the drug designation process.

Response: We appreciate MedPAC's feedback on our proposal to apply the TDAPA to composite rate drugs. As we stated in section B.1.f of this final rule, we believe that allowing all new renal dialysis drugs and biological products to be eligible for TDAPA will provide an

ability for a new drug to compete with other similar drugs in the market which could mean lower prices for all drugs. We believe that new renal dialysis composite rate drugs could benefit from this policy as well. Additionally, we continue to believe that the same unique consideration for innovation and cost exists for drugs that are considered composite rate drugs. That is, the ESRD PPS base rate dollars allocated for these types of drugs may not directly address the costs associated with drugs in this category when they are newly launched and are finding their place in the market. We will continue to monitor the use of the TDAPA, carefully evaluate the new renal dialysis drugs and biological products that qualify, and address any concerns through future refinements to the TDAPA policy.

Final Rule Action: After the consideration of public comments, we are finalizing our policy to extend the TDAPA to composite rate drugs and biological products that are furnished for the treatment of ESRD. Specifically, beginning January 1, 2020, if a new renal dialysis drug or biological product as defined in the proposed revision at § 413.234(a) is considered to be a composite rate drug or biological product and falls within an ESRD PPS functional category, it would be eligible for the TDAPA. We note that composite rate drugs and biological products will not be eligible for an outlier payment after the TDAPA period.

2. Low-Volume Payment Adjustment (LVPA) Revision

a. Background

As required by section 1881(b)(14)(D)(iii) of the Act, the ESRD PPS includes a payment adjustment that reflects the extent to which costs incurred by low-volume facilities in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. We have established a LVPA factor of 23.9 percent for ESRD facilities that meet the definition of a low-volume facility. Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation—(1) Furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year; and (2) Has not opened, closed, or received a new provider number due to a change in ownership in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year. Under § 413.232(c), for purposes of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question.

For purposes of determining eligibility for the LVPA, ''treatments'' mean total hemodialysis (HD) equivalent treatments (Medicare and non-Medicare as well as ESRD and non-ESRD). For peritoneal dialysis (PD) patients, 1 week of PD is considered equivalent to 3 HD treatments. As noted, we base eligibility on the 3 years preceding the payment year and those years are based on cost reporting periods. Specifically, under § 413.232(g), the ESRD facility's cost reports for the periods ending in the 3 years preceding the payment year must report costs for 12-consecutive months (76 FR 70237).

In order to receive the LVPA under the ESRD PPS, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets all of the requirements specified in § 413.232 and qualifies as a low-volume ESRD facility. Section 413.232(e) imposes a yearly November 1 deadline for attestation submissions. This timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236). Further information regarding the administration of the LVPA is provided in the Medicare Benefit Policy Manual, CMS Pub. 100–02, Chapter 11, section 60.B.1.

b. Revisions to the LVPA Requirements and Regulations

As we discussed in the CY 2019 ESRD PPS proposed rule, we have heard from stakeholders that low-volume facilities rely on the low-volume adjustment and loss of the adjustment could result in beneficiary access issues. Specifically, stakeholders expressed concern that the eligibility criteria in the LVPA regulations are very explicit and leave little room for flexibility in certain circumstances. For example, in the CY 2017 ESRD PPS final rule (81 FR 77863), a commenter suggested refinements to the definition of a low-volume facility to address the rare change of ownership (CHOW) instance wherein the new owner accepts the Medicare agreement but the ownership change results in a new provider number because of a facility's type reclassification. The commenter explained that in this example, due to the issuance of a new Medicare provider billing number or provider transaction access number (PTAN) when the facility's type is reclassified, this facility would be deemed ineligible for the LVPA since our policy requires that new Medicare provider billing numbers qualify for the LVPA, which takes 3 years. We have also discovered that facilities that change their fiscal year without going through a CHOW become ineligible for the adjustment. Finally, stakeholders have recommended that the strict enforcement of the attestation deadline without exception should be reevaluated since missing the deadline results in the facility losing the LVPA and its payments are significantly reduced. Thus, in order to be responsive to stakeholders and increase flexibility with regard to eligibility for the LVPA, we proposed to make changes to the LVPA regulation at § 413.232.

The first proposed revision concerned the assignment of a PTAN when a facility undergoes a CHOW as described in 42 CFR 489.18. Under § 413.232(b)(2) and (g)(2), a facility is ineligible for the LVPA for 3 years if it goes through a CHOW that results in a new PTAN. In response to a comment we received during the CY 2011 ESRD PPS rulemaking (75 FR 49123), we explained that we believe that a 3-year waiting period serves as a safeguard against facilities establishing new facilities that are purposefully small. We also explained that we structured our analysis of the ESRD PPS by looking across data for 3 years as we believed that the 3-year timeframe provided us with a sufficient span of time to view consistency in business operations.

However, as we noted above and in the CY 2019 ESRD PPS proposed rule, we have heard from stakeholders that this policy unfairly affects facilities that undergo a CHOW that results in a change in facility type (for example, the facility type changes from hospital-based to freestanding). Under this scenario, as discussed in the Medicare State Operations Manual, Pub. 100–07, Chapter 3, Section 3210.4C (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c03.pdf*) and the Medicare Program Integrity Manual, Pub. 100–08, Chapter 15, Section 15.7.7.1 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c15.pdf*), CMS requires the issuance of a new CMS Certification Number (CCN) and provider agreement, which may lead to the issuance of a new PTAN, even if the

new owner has accepted assignment of the existing Medicare provider agreement, that is, the new owner accepts the previous owner's assets and liabilities.

As we stated in the CY 2019 ESRD PPS proposed rule, we agree with the stakeholders that the language in the regulation regarding PTAN status could restrict LVPA eligibility to an otherwise qualified ESRD facility from receiving the adjustment for 3 years, until the new PTAN qualifies for the adjustment. We recognize that there are technicalities regarding the assignment of a PTAN that could cause substantive impacts with eligibility for the LVPA that were not contemplated at the time the regulation was established. We noted that the intent of the LVPA has always been that if an ESRD facility undergoes a CHOW wherein the new owner accepts assignment of the existing Medicare provider agreement, the facility should continue to be eligible for the LVPA since this indicates a consistency in business operations.

We proposed to expand the definition of a low-volume facility in § 413.232(b)(2) to include CHOWs where the new owner accepts assignment of the existing Medicare provider agreement and a new PTAN is issued due to a change in facility type. We noted that this proposal does not extend to CHOWs where a new PTAN is issued for any other reason. We solicited comment on the proposal to revise the language at § 413.232(b)(2) to reflect that ESRD facilities can meet the definition of a low-volume facility when they have a CHOW that results in a new PTAN due to a change in facility type but accepts assignment of the existing Medicare provider agreement. We also proposed to amend § 413.232(g)(2), which governs the determination of LVPA eligibility, to recognize the proposed expansion of the low-volume facility definition to allow for PTAN changes when the facility type changes as a result of CHOW. We solicited comment on this proposal.

We also proposed to allow for an extraordinary circumstance exception to the November 1 attestation deadline under § 413.232(e). As we explained in the CY 2019 ESRD PPS proposed rule, we agree with the stakeholders that there could be unforeseeable factors that contribute to a delay in the submission of the attestation, and we would not want to prevent an otherwise qualified ESRD facility from receiving the adjustment. For example, while a failure to timely submit the attestation because of poor communication between a facility and its respective MAC, or because a facility forgets to send the attestation to the MAC, would not constitute extraordinary circumstances; a natural disaster could, because such an event is unforeseeable and extraordinary, which may understandably delay the timely submission of the attestation. We noted that we expect extraordinary exceptions to be rare and the determination of acceptability would be made on a case-by-case basis. We stated that we have heard from stakeholders that they have lost eligibility for the LVPA due to extraordinary circumstances, such as natural disasters, that prevented them from submitting their attestation by the deadline. In those types of instances, we believe an exception to the attestation deadline could be warranted. Therefore, we proposed to add a clause in § 413.232(e) to recognize an exception to the filing deadline for extraordinary circumstances. In order to request an extraordinary circumstance exception, we also proposed that the facility would need to submit a narrative explaining the rationale for the exception to their MAC. We stated that we would evaluate and review the narrative to determine if an exception is justified, and such a determination would be final, with no appeal. We solicited comment on the proposal to revise the language at § 413.232(e) to reflect that CMS would allow an exception to the attestation deadline of November 1 for extraordinary circumstances, if determined appropriate.

In addition, we proposed to allow ESRD facilities that change their fiscal year-end for cost reporting purposes outside of a CHOW to qualify for the LVPA if they otherwise meet the LVPA eligibility criteria. Under § 413.24(f)(3), facilities are able to change their cost reporting period when they request a change in writing from their MAC and meet specific criteria for approval. However, the current LVPA regulation at § 413.232(g)(2)(ii) does not technically address requirements for changing cost reporting periods except as a result of a CHOW, which has prohibited facilities from receiving the LVPA if they make a business decision to adjust their cost reporting period, which could interfere with the normal course of business. We stated in the CY 2019 ESRD PPS proposed rule that we recognize there are business decisions an ESRD facility could make with regard to cost reporting periods that could substantively impact eligibility for the LVPA that we did not contemplate at the time the regulation was adopted. Specifically, there could be reasons why a cost report does not span 12-consecutive months. We noted that we did not intend for an ESRD facility to lose its LVPA eligibility simply because the facility made a decision to change its cost reporting period. The requirement that cost reports span 12-consecutive months was to bring a measure of consistent business operations.

We proposed to add a new paragraph (3) to § 413.232(g) to provide direction for MACs in verifying the number of treatments when a change in a cost reporting period is approved. When this occurs, we proposed that MACs would combine the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period or combine the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorate the data to equal a full 12-consecutive month period. We stated that this proposal would not impact or change requirements for reporting, as established by the MACs, or those set forth in § 413.24(f)(3). We solicited comment on the proposal to add § 413.232(g)(3) to change the information and cost report timeframes MACs would review to determine LVPA eligibility. We noted that this provision would apply to ESRD facilities that change their cost reporting year for purposes outside of a CHOW to qualify for the LVPA, provided they otherwise meet the LVPA eligibility criteria for the purposes of allowing the ESRD facilities to continue to receive the adjustment.

Finally, we proposed two additional changes to correct and further clarify the LVPA regulation. The first would correct a cross-reference in § 413.232(b) by changing ''paragraph (h)'' to ''paragraph (g)''. We explained that this error is the result of prior changes we made to the regulation when we deleted other paragraphs, but did not update the reference accordingly. The second proposed revision would clarify that the reference to miles in § 413.232(c)(2) is to road miles. We noted that CMS recognizes the current designation of miles under the regulation may not be specific enough and could cause confusion, and we have issued guidance in the Medicare Benefit Policy Manual (Pub. L. 100–02), Chapter 11, Section 60, addressing road miles. Accordingly, we proposed clarifying edits to § 413.232(c)(2).

We did not receive comments regarding the two technical corrections to the regulations text for the LVPA or the proposed extraordinary circumstances exception; therefore, we are finalizing these revisions as proposed.

The comments and our responses to the comments on our other proposed

revisions to the LVPA requirements and regulations are set forth below.

Comment: Several commenters supported the proposed revisions to the LVPA regulations. A large dialysis organization (LDO), a health plan, a dialysis organization and a dialysis provider organization expressed support for CMS' proposals to allow ESRD facilities to continue to receive LVPAs when there are changes that do not affect the business operations of the facility. Specifically, they stated that they support and appreciate CMS' proposed policies to allow facilities to retain low-volume facility status when a new owner accepts assignment of the existing Medicare provider agreement and when a facility changes its fiscal year-end for cost reporting purposes.

A patient advocacy organization commented that as CMS is proposing changes to the LVPA, CMS should consider removing the rural payment adjuster and instead include tiers for the LVPA to ensure it applies the most dollars to facilities that are serving a critical patient need and likely operating at a loss. The organization remains concerned that facilities in isolated areas serving predominately Medicare and Medicaid beneficiaries would be the first to be targeted for closure even with a rural payment adjuster. The organization pointed to the March 2018 MedPAC report that distinguished rural facilities adjacent to an urban area from rural non-adjacent facilities and stated that CMS should implement a tiered approach to the LVPA and ensure those facilities not adjacent to an urban area are receiving a higher adjuster.

Response: We appreciate the stakeholders' support for the LVPA proposals. With regard to the implementation of tiered LVPA adjustment, this comment is out of scope for this rule because we did not propose any changes to the structure of the LVPA adjustment or the rural adjustment, however, we will consider this recommendation for future refinements to those policies. Additionally, we are undertaking a new research effort and plan to engage with stakeholders further on this issue.

Final Rule Action: After considering the comments, we are finalizing the revisions to the LVPA regulations as proposed, with one technical edit. We are finalizing the revision to § 413.232(b)(2) to expand the definition of a low-volume facility to include CHOWs where the new owner accepts assignment of the existing Medicare provider agreement and a new PTAN is issued due to a change in facility type. This definition does not extend to CHOWs where a new PTAN is issued for any other reason. We are also finalizing the amendment of § 413.232(g)(2) to recognize the expansion of the low-volume facility definition and allow for PTAN changes when the facility type changes as a result of a CHOW.

In addition, we are finalizing the revisions to § 413.232(e) to include an exception to the attestation deadline of November 1st for extraordinary circumstances. In order to request an extraordinary circumstance exception, the facility will need to submit a narrative explaining the rationale for the exception to its MAC. The MAC will evaluate the narrative to determine if an exception is justified, and such a determination will be final, with no appeal.

Additionally, we are finalizing the addition of paragraph (3) to § 413.232(g) to provide direction for MACs in verifying the number of treatments when a change in a cost reporting period is approved. MACs should combine the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period or combine the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorate the data to equal a full 12-consecutive month period. This policy does not impact or change any other requirements for cost reporting, as established by the MACs, or those set forth in § 413.24(f)(3). This policy applies to ESRD facilities that change their cost reporting year for purposes outside of a CHOW to qualify for the LVPA, provided they otherwise meet the LVPA eligibility criteria for the purposes of allowing the ESRD facility to continue to receive the adjustment. We are making one technical change to refer to an ESRD facility that has changed ''its'' cost reporting period.

Finally, we are finalizing two technical corrections to the LVPA regulations. We are finalizing the revision to § 413.232(b) to reflect the correct cross-reference by changing ''paragraph (h)'' to ''paragraph (g)'' and the revision to § 413.232(c)(2) to reflect road miles.

3. Final CY 2019 ESRD PPS Update

a. ESRD Bundled (ESRDB) Market Basket and Labor-Related Share

i. Rebasing of the ESRDB Market Basket

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket increase factor and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. The statute also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services used to furnish renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRD Bundled (ESRDB) input price index (75 FR 49151 through 49162) and subsequently revised and rebased the ESRDB input price index in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). Effective for CY 2019, we proposed to rebase the ESRDB market basket to a base year of CY 2016.

Although ''market basket'' technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term ''ESRDB market basket,'' as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

The index is constructed in three steps. First, a base period is selected and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy''. In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price index levels) for all cost categories yields the

composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services purchased to provide ESRD services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, an ESRD facility hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the ESRD facility, but would not be factored into the price change measured by a fixed-weight ESRD market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect changes between base periods in the mix of goods and services that ESRD facilities purchase to furnish ESRD treatment.

We proposed to use CY 2016 as the base year for the rebased ESRDB market basket cost weights. The cost weights for the ESRDB market basket are based on the cost report data for independent ESRD facilities. We refer to the market basket as a CY market basket because the base period for all price proxies and weights are set to CY 2016 (that is, the average index level for CY 2016 is equal to 100). The major source data for the ESRDB market basket is the 2016 Medicare cost reports (MCRs) (Form CMS–265–11), supplemented with 2012 data from the United States (U.S.) Census Bureau's Services Annual Survey (SAS) inflated to 2016 levels. The 2012 SAS data is the most recent year of detailed expense data published by the Census Bureau for North American International Classification System (NAICS) Code 621492: Kidney Dialysis Centers. We also proposed to use May 2016 Bureau of Labor Statistics (BLS) Occupational Employment Statistics data to estimate the weights for the Wages and Salaries and Employee Benefits occupational blends. We provide more detail on our methodology below.

The terms ''rebasing'' and ''revising,'' while often used interchangeably, actually denote different activities. The term ''rebasing'' means moving the base year for the structure of costs of an input price index (that is, in the CY 2018 proposed rule (83 FR 34318), we proposed to move the base year cost structure from CY 2012 to CY 2016) without making any other major changes to the methodology. The term ''revising'' means changing data sources, cost categories, and/or price proxies used in the input price index. For CY 2019, we proposed to rebase the ESRDB market basket to reflect the 2016 cost structure of ESRD facilities. For CY 2019, we did not propose to revise the index; that is, we did not propose to make any changes to the cost categories or price proxies used in the index.

We selected CY 2016 as the new base year because 2016 is the most recent year for which relatively complete MCR data are available. In developing the market basket, we reviewed ESRD expenditure data from ESRD MCRs (CMS Form 265–11) for 2016 for each freestanding ESRD facility that reported expenses and payments. The 2016 MCRs are those ESRD facilities whose cost reporting period began on or after October 1, 2015 and before October 1, 2016. Of the 2016 MCRs, approximately 88 percent of freestanding ESRD facilities had a begin date on January 1, 2016, approximately 6 percent had a begin date prior to January 1, 2016, and approximately 6 percent had a begin date after January 1, 2016. Using this methodology allowed our sample to include ESRDs with varying cost report years including, but not limited to, the federal fiscal or CY.

We proposed to maintain our policy of using data from freestanding ESRD facilities (which account for over 90 percent of total ESRD facilities) because freestanding ESRD data reflect the actual cost structure faced by the ESRD facility itself. In contrast, expense data for a hospital-based ESRD reflect the allocation of overhead from the entire institution.

We developed cost category weights for the 2016-based ESRDB market basket in two stages. First, we derived base year cost weights for nine major categories (Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Lab Services, Housekeeping and Operations, Administrative and General, Capital-Related Building and Fixtures, and Capital-Related Machinery) from the ESRD MCRs. Second, we proposed to divide the Administrative and General cost category into further detail using 2012 U.S. Census Bureau Services Annual Survey (SAS) data for the industry Kidney Dialysis Centers NAICS 621492 inflated to 2016 levels. We apply the estimated 2016 distributions from the SAS data to the 2016 Administrative and General cost weight to yield the more detailed 2016 cost weights in the market basket. This is similar to the methodology we used to break the Administrative and General cost weight into more detail for the 2012-based ESRDB market basket (79 FR 40217 through 40221). The only difference is that for this rebasing, because SAS data is not available after 2012, we inflated the 2012 expense levels to 2016 dollars using appropriate price proxies and applied this expense distribution to the Administrative and General cost weight for 2016.

We proposed to include a total of 20 detailed cost categories for the 2016-based ESRDB market basket, which is the same number of cost categories as the 2012-based ESRDB market basket. We proposed to continue to assume that 87 percent of Professional Fees and 46 percent of capital costs are labor-related costs and would be included in the labor-related share.

The comments and our response to the comments on our proposal to rebase the ESRDB market basket are set forth below.

Comment: Several commenters supported the rebasing of the ESRDB market basket to a 2016 base year.

Response: We appreciate the commenters' support.

A more thorough discussion of the market basket is provided below.

a. Cost Category Weights

Using Worksheets A and B from the 2016 MCRs, we first computed cost shares for nine major expenditure categories: Wages and Salaries, Employee Benefits, Pharmaceuticals, Supplies, Lab Services, Housekeeping and Operations, Administrative and General, Capital-Related Building and Equipment, and Capital-Related Machinery. Edits were applied to include only cost reports that had total costs greater than zero. Total costs as reported on the MCR include those costs reimbursable under the ESRD bundled payment system. For example, we excluded expenses related to vaccine costs from total expenditures since these are not reimbursable under the ESRD bundled payment.

In order to reduce potential distortions from outliers in the calculation of the individual cost weights for the major expenditure categories, values less than the 5th percentile or greater than the 95th percentile were excluded from the major cost weight computations. The data set, after removing cost reports with total costs equal to or less than zero and excluding outliers, included

information from approximately 5,700 independent ESRD facilities' cost reports from an available pool of 6,410 cost reports.

Table 2 presents the final 2016-based ESRDB market basket and 2012-based ESRDB market basket major cost weights as derived directly from the MCR data.

TABLE 2—2016-BASED ESRDB MARKET BASKET MAJOR COST WEIGHTS DERIVED FROM THE MEDICARE COST REPORT DATA

Cost category	2016-Based ESRDB market basket (%)	2012-Based ESRDB market basket (%)
Wages and Salaries	32.6	31.8
Employee Benefits	7.0	6.6
Pharmaceuticals	12.4	16.5
Supplies	10.4	10.1
Lab Services	2.2	1.5
Housekeeping and Operations	3.9	3.8
Administrative and General	18.4	17.4
Capital-related Building and Fixed Equipment	9.2	8.4
Capital-related Machinery	3.8	3.9

Note: Totals may not sum to 100.0 percent due to rounding.

We proposed to disaggregate certain major cost categories developed from the MCRs into more detail to more accurately reflect ESRD facility costs. Those categories include: Benefits, Professional fees, Telephone, Utilities, and All Other Goods and Services. We describe below how the initially computed categories and weights from the cost reports were calculated to yield the 2016 ESRDB market basket expenditure categories and weights.

Wages and Salaries

The Wages and Salaries cost weight is comprised of direct patient care wages and salaries and non-direct patient care wages and salaries. Direct patient care wages and salaries for 2016 were derived from Worksheet B, column 5, lines 8 through 17 of the MCR. Non-direct patient care wages and salaries includes all other wages and salaries costs for non-health workers and physicians, which we derive using the following steps:

Step 1: To capture the salary costs associated with non-direct patient care cost centers, we calculated salary percentages for non-direct patient care from Worksheet A of the MCR. The estimated percentages were calculated as the ratio of salary costs (Worksheet A, columns 1 and 2) to total costs (Worksheet A, column 4). The salary percentages were calculated for seven distinct cost centers: 'Operations and Maintenance' combined with 'Machinery & Rental & Maintenance' (line 3 and 6), Housekeeping (line 4), Employee Health and Wellness (EH&W) Benefits for Direct Patient Care (line 8), Supplies (line 9), Laboratory (line 10), Administrative & General (line 11), and Pharmaceuticals (line 12).

Step 2: We then multiplied the salary percentages computed in step 1 by the total costs for each corresponding reimbursable costs center totals as reported on Worksheet B. The Worksheet B totals were based on the sum of reimbursable costs reported on lines 8 through 17. For example, the salary percentage for Supplies (as measured by line 9 on Worksheet A) was applied to the total expenses for the Supplies cost center (the sum of costs reported on Worksheet B, column 7, lines 8 through 17). This provided us with an estimate of Non-Direct Patient Care Wages and Salaries.

Step 3: The estimated wages and salaries for each of the cost centers on Worksheet B derived in step 2 were subsequently summed and added to the direct patient care wages and salaries costs.

Step 4: The estimated non-direct patient care wages and salaries (see step 2) were then subtracted from their respective cost categories to avoid double-counting their values in the total costs.

Using this methodology, we derive a Wages and Salaries cost weight of 32.6 percent, reflecting an estimated direct patient care wages and salaries cost weight of 25.1 percent and non-direct patient care wages and salaries cost weight of 7.5 percent, as seen in Table 3.

The final adjustment made to this category is to include Contract Labor costs. These costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disentangled using the MCRs. To avoid double counting of these expenses, we proposed to remove the estimated cost weight for the contract labor costs from the Administrative and General category (where we believe the majority of the contract labor costs would be reported) to the Wages and Salaries category. We proposed to use data from the SAS (2012 data inflated to 2016), which reported 2.3 percent of total expenses were spent on contract labor costs. We allocated 80 percent of that contract labor cost weight to Wages and Salaries. At the same time, we subtracted that same amount from Administrative and General, where the majority of contract labor expenses would likely be reported on the MCR. The 80 percent figure that was used was determined by taking salaries as a percentage of total compensation (excluding contract labor) from the 2016 MCR data. This is the same method that was used to allocate contract labor costs to the Wages and Salaries cost category for the 2012-based ESRDB market basket.

The resulting cost weight for Wages and Salaries increases to 34.5 percent when contract labor wages are added. The calculation of the Wages and Salaries cost weight for the 2016-based ESRDB market basket is shown in Table 3 along with the similar calculation for the 2012-based ESRDB market basket.

TABLE 3—2016 AND 2012 ESRD WAGES AND SALARIES COST WEIGHT DETERMINATION

Components	2016 Cost weight (percent)	2012 Cost weight (percent)	Source
Wages and Salaries Direct Patient Care	25.1	23.2	MCR
Wages and Salaries Non-direct Patient Care	7.5	8.6	MCR
Contract Labor (Wages)	1.9	1.8	80% of SAS Contract Labor weight
Total Wages and Salaries	34.5	33.7	

Employee Benefits

The Employee Benefits cost weight was derived from the MCR data for direct patient care and supplemented with data from the SAS (2012 data inflated to 2016) to account for non-direct patient care Employee Benefits. The MCR data only reflects Employee Benefit costs associated with health and wellness; that is, it does not reflect retirement benefits.

In order to reflect the benefits related to non-direct patient care for employee health and wellness, we estimated the impact on the benefit weight using SAS. Unlike the MCR, data from the SAS benefits share includes expenses related to the retirement and pension benefits. In order to be consistent with the cost report definitions we do not want to include the costs associated with retirement and pension benefits in the cost share weights. These costs are relatively small compared to the costs for the health-related benefits, accounting for only 2.7 percent of the total benefits costs as reported on the SAS. Incorporating the SAS data produced an Employee Benefits (both direct patient care and non-direct patient care) weight that was 1.6 percentage points higher (8.6 vs. 7.0) than the Employee Benefits weight for direct patient care calculated directly from the MCR. To avoid double-counting and to ensure all of the market basket weights still totaled 100 percent, we removed this additional 1.6 percentage points for Non-Direct Patient Care Employee Benefits from the Administrative and General cost category (where we believe the majority of the contract labor costs would be reported).

The final adjustment made to this category is to include contract labor benefit costs. Once again, these costs appear on the MCR; however, they are embedded in the Other Costs from the trial balance reported on Worksheet A, Column 3 and cannot be disentangled using the MCR data. Identical to our methodology above for allocating Contract Labor Costs to Wages and Benefits, we applied 20 percent of total Contract Labor Costs, as estimated using the SAS, to the Benefits cost weight calculated from the cost reports. The 20 percent figure was determined by taking benefits as a percentage of total compensation (excluding contract labor) from the 2016 MCR data. The resulting cost weight for Employee Benefits increases to 9.1 percent when contract labor benefits are added. This is the same method that was used to allocate contract labor costs to the Benefits cost category for the 2012-based ESRDB market basket.

The Table 4 compares the 2012-based Benefits cost share derivation as detailed in the CY 2015 ESRD PPS proposed rule (79 FR 40218) to the 2016-based Benefits cost share derivation.

TABLE 4—2016 AND 2012 ESRD EMPLOYEE BENEFITS COST WEIGHT DETERMINATION

Components	2016 Cost weight (percent)	2012 Cost weight (percent)	Source
Employee Benefits Direct Patient Care	7.0	6.6	MCR
Employee Benefits Non-direct Patient Care	1.6	1.8	SAS
Contract Labor (Benefits)	0.5	0.5	20% of SAS Contract Labor weight
Total Employee Benefits	9.1	8.8	

Pharmaceuticals

The 2016-based ESRDB market basket includes expenditures for all drugs, including formerly separately billable drugs and ESRD-related drugs that were covered under Medicare Part D before the ESRD PPS was implemented. We calculated a Pharmaceutical cost weight from the following cost centers on Worksheet B, the sum of lines 8 through 17, for the following columns: 11 ''Drugs Included in Composite Rate''; 12 ''Erythropoiesis stimulating agents (ESAs)''; 13 ''ESRD-Related Drugs''. We also added the drug expenses reported on line 5 column 10 ''Non-ESRD related drugs''. The Non-ESRD related drugs would include drugs and biologicals administered during dialysis for non-ESRD related conditions as well as oral-only drugs. Since these are costs to the facility for providing ESRD treatment to the patient, we proposed to continue to include them in the Pharmaceutical cost weight. Section 1842(o)(1)(A)(iv) of the Act requires that influenza, pneumococcal, and hepatitis B vaccines described in paragraph (A) or (B) of section 1861(s)(10) of the Act be paid based on 95 percent of average wholesale price (AWP) of the drug. Since these vaccines are not reimbursable under the ESRD PPS, we exclude them from the 2016-based ESRDB market basket.

Finally, to avoid double-counting, the weight for the Pharmaceuticals category was reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with the applicable pharmaceutical cost centers referenced above. This resulted in an ESRDB market basket weight for Pharmaceuticals of 12.4 percent. ESA expenditures accounted for 10.0 percentage points of the Pharmaceuticals cost weight, and All Other Drugs accounted for the remaining 2.4 percentage points.

The Pharmaceutical cost weight decreased 4.1 percentage point from the 2012-based ESRDB market basket to the 2016-based ESRDB market basket (16.5

percent to 12.4 percent). Most providers experienced a decrease in their Pharmaceutical cost weight since 2012. One provider in particular, a major dialysis provider, experienced a significant pharmaceutical cost weight decline in 2016. This provider's decline had an effect on the overall Pharmaceutical cost weight in the 2016-based ESRDB market basket. We wish to note that the provider's decline in the pharmaceutical cost weight was found across the board in all states where the provider has facilities. Given this, we proposed to include this provider's decline in our market basket results treating it as a 'real' change in relative pharmaceutical costs. We did not propose to use an alternative methodology, such as averaging cost weights from multiple years, which we proposed for Lab Services as stated below.

Supplies

We calculated the Supplies cost weight using the costs reported in the Supplies cost center (Worksheet B, line 5 and the sum of lines 8 through 17, column 7) of the MCR. To avoid double-counting, the Supplies costs were reduced to exclude the estimated share of Non-Direct patient care Wages and Salaries associated with this cost center. The resulting 2016-based ESRDB market basket weight for Supplies is 10.4 percent, about the same as the weight for the 2012-based ESRDB market basket.

Lab Services

We calculated the Lab Services cost weight using the costs reported in the Laboratory cost center (Worksheet B, line 5 and the sum of line 8 through 17, column 8) of the MCR. To avoid double-counting, the Lab Services costs were reduced to exclude the estimated share of Non-Direct Patient Care Wages and Salaries associated with this cost center. The 2016-based ESRDB market basket weight for Lab Services is estimated at 2.2 percent.

The 2016 Lab Services expenses reported for a main chain provider were significantly lower than those reported in the 3 years prior (2013 through 2015) and lower than the 2016 Lab Services weight for all other providers. We believe the lower costs were based on a correction to the way that this chain is billing for these services, an assumption that is supported by the findings of a January 2016 Health and Human Services Office of the Inspector General (OIG) Report [2]. Because the recent reported costs from this chain reflect these unique circumstances, we proposed to take a 2-year average of Lab Services costs for 2015 and 2016 for this chain in order to smooth out the year-to-year volatility. This approach results in a Lab cost weight for this chain that is higher than it was in 2012, which is then added to the 2016 Lab Services costs for all other providers, where the cost weight was similar in 2012 and 2016. As a result, the overall Lab Services cost weight increased 0.7 percentage points (1.5 vs 2.2 percent) from the 2012-based ESRDB market basket to the 2016-based ESRDB market basket.

Housekeeping and Operations

We calculated the Housekeeping and Operations cost weight using the costs reported on Worksheet A, lines 3 and 4, column 8, of the MCR. To avoid double-counting, the weight for the Housekeeping and Operations category was reduced to exclude the estimated share of Non-Direct Patient Care Waged and Salaries associated with this cost center. These costs were divided by total costs to derive a 2016-based ESRDB market basket weight for Housekeeping and Operations of 3.9 percent.

Capital

We developed a market basket weight for the Capital category using data from Worksheet B of the MCRs. Capital-related costs include depreciation and lease expenses for buildings, fixtures and movable equipment, property taxes, insurance costs, the costs of capital improvements, and maintenance expense for buildings, fixtures, and machinery. Because Housekeeping and Operations and Maintenance costs are included in the Worksheet B cost center for Capital-Related costs (Worksheet B, column 2), we excluded the costs for these two categories and developed a separate expenditure category for Housekeeping and Operations, as detailed above. Similar to the methodology used for other market basket cost categories with a salaries component, we computed a share for non-direct patient care Wages and Salaries and Benefits associated with the Capital-related cost centers. We used Worksheet B to develop two capital-related cost categories: (1) Buildings and Fixtures (Worksheet B, the sum of lines 8 through 17, column 2 less housekeeping and operations as derived from expenses reported on Worksheet A (see above)), and (2) Machinery (Worksheet B, the sum of lines 8 through 17, column 4). We reasoned this delineation was particularly important given the critical role played by dialysis machines. Likewise, because price changes associated with Buildings and Equipment could move differently than those associated with Machinery, we continue to believe that two capital-related cost categories are appropriate. The resulting 2016-based ESRDB market basket weights for Capital-related Buildings and Fixtures and Capital-related Machinery are 9.2 percent and 3.8 percent, respectively.

Administrative and General

We computed the proportion of total Administrative and General expenditures using the Administrative and General cost center data from Worksheet B, the sum of lines 8 through 17, (column 9) of the MCRs. Additionally, we removed contract labor from this cost category and apportioned these costs to the Wages and Salaries and Employee Benefits cost weights. Similar to other expenditure category adjustments, we then reduced the computed weight to exclude Wages and Salaries and Benefits associated with the Administrative and General cost center for Non-direct Patient Care as estimated from the SAS data. The resulting Administrative and General cost weight is 14.5 percent.

We further disaggregated the Administrative and General cost weight to derive detailed cost weights for Electricity, Natural Gas, Water and Sewerage, Telephone, Professional Fees, and All Other Goods and Services. These detailed cost weights are derived by inflating the detailed 2012 SAS data forward to 2016 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 SAS data. We repeated this practice for each year to 2016. We then calculated the cost shares that each cost category represents of the 2012 data inflated to 2016. These resulting 2016 cost shares were applied to the Administrative and General cost weight derived from the MCR (net of contract labor and additional benefits) to obtain the detailed cost weights for the 2016-based ESRDB market basket. This method is similar to the method used for the 2012-based ESRDB market basket.

Table 5 lists all of the cost categories and cost weights in the 2016-based ESRDB market basket compared to the 2012-based ESRDB market basket.

[2] Review of Medicare Payments for Laboratory Tests Billed with an AY Modifier by Total Renal Laboratories, Inc.; *https://oig.hht.gov/oas/reports/region1/11400505.pdf.*

TABLE 5—COMPARISON OF THE 2016-BASED AND THE 2012-BASED ESRDB MARKET BASKET COST CATEGORIES AND WEIGHTS

2016 Cost category	2016 Cost weights (percent)	2012 Cost weights (percent)
Total	100.0	100.0
Compensation	43.6	42.5
Wages and Salaries	34.5	33.7
Employee Benefits	9.1	8.8
Utilities	2.0	1.8
Electricity	1.1	1.0
Natural Gas	0.1	0.1
Water and Sewerage	0.8	0.8
Medical Materials and Supplies	24.9	28.1
Pharmaceuticals	12.4	16.5
ESAs	10.0	12.9
Other Drugs (except ESAs)	2.4	3.6
Supplies	10.4	10.1
Lab Services	2.2	1.5
All Other Goods and Services	16.4	15.3
Telephone & Internet Services	0.5	0.5
Housekeeping and Operations	3.9	3.8
Professional Fees	0.7	0.6
All Other Goods and Services	11.3	10.4
Capital Costs	13.0	12.2
Capital Related-Building and Fixtures	9.2	8.4
Capital Related-Machinery	3.8	3.9

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detail may not add to the total due to rounding.

The comments and our response to the comments on the proposed cost category weights are set forth below.

Comment: One commenter had a question related to the methodology for estimating the cost weight for the pharmaceuticals and lab services in the proposed ESRDB market basket rebasing. The commenter noted that, per the proposed rule, the pharmaceuticals and lab services cost categories are influenced significantly by one LDO. The commenter questioned the rationale of CMS's proposal to smooth the change in the lab services cost weight while, at the same time, not proposing to smooth the change in the pharmaceutical cost weight. The commenter stated that this difference in treatment seems inconsistent and recommended that CMS consider using a similar ''smoothing'' approach for both the pharmaceuticals cost weight and the lab services cost weight. The commenter further stated that, CMS has used phase-ins and smoothing methods when there were significant changes in the past.

Response: We did not propose to use a ''smoothing'' or averaging approach for the proposed 2016-based pharmaceutical cost share weight because the decline in pharmaceutical costs, relative to the other cost categories, were based on a steady pattern of falling pharmaceutical expense shares from 2012 to 2016 for all ESRD providers. In the CY 2019 ESRD PPS proposed rule (83 FR 34321), we noted that one provider experienced a relatively larger drop in its pharmaceutical cost weight relative to other providers. This LDO would have renegotiated its agreement on the prices for ESA's in 2016 since the agreement between the LDO and a major drug manufacturer ended in 2015. This renegotiation should have contributed to the large drop in the LDO's pharmaceutical cost weight.

On the other hand, the rationale for using a 2-year average to determine the 2016 cost share weight for lab services was based on the documented instance of an LDO provider overbilling for lab services. The resulting low weight reported in 2016 was not reflective of normal business operations but was instead indicative of a correction to laboratory expenses. Therefore, reported laboratory expenses for 2013, 2014, and 2015 were higher than they should have been and laboratory expenses for 2016 were lower than they should have been since the LDO was required to reimburse Medicare for the prior overbilling. Given these unique circumstances, we proposed to average the lab cost weights for 2015 and 2016 for this chain. We did not average the lab cost weight for any other providers. This particular situation is documented in detail in the January 2016 Health and Human Services Office of the Inspector General (OIG) Report and was referenced in the proposed rule (83 FR 34322).

We did provide a rationale for the difference in the way we are estimating both the pharmaceuticals and lab services cost weight in the proposed rule, where we noted the OIG report and our analysis and research of the pharmaceutical cost weight trends. Thus, we disagree with the commenter that we should use a phase in or smoothing method for the pharmaceutical cost share weight for the 2016-based ESRDB market basket, as we believe the 2016 pharmaceutical cost weight reflects the pharmaceutical expenses experienced by providers in 2016. In contrast, we believe the lab services cost weight was being influenced by a reporting issue for one provider and did not reflect industry trends for 2016; therefore, averaging reported expenses for this provider produces a cost weight for 2016 that more appropriately reflects these industry trends.

After consideration of public comments, we are finalizing the 2016-based ESRDB market basket cost categories and weights as proposed without change.

b. Price Proxies for the 2016-Based ESRDB Market Basket

After developing the cost weights for the 2016-based ESRDB market basket, we select the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. We based

the price proxies on Bureau of Labor Statistics (BLS) data and group them into one of the following BLS categories:

(1) *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

(2) *Producer Price Indexes.* Producer Price Indexes (PPIs) measure price changes for goods sold in other than retail markets. PPIs are used when the purchases of goods or services are made at the wholesale level.

(3) *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure change in the prices of final goods and services bought by consumers. CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the wholesale level, or if no appropriate PPIs were available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

Reliability. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)

Timeliness. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

Availability. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this helps to ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

Relevance. Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 7 lists all price proxies for the 2016-based ESRDB market basket. We note that we proposed to use the same proxies as those used in the 2012-based ESRDB market basket. Below is a detailed explanation of the price proxies used for each cost category weight.

Wages and Salaries

We proposed to continue using a blend of ECIs to proxy the Wages and Salaries cost weight in the 2016-based ESRDB market basket, and to continue using four occupational categories and associated ECIs based on full-time equivalents (FTE) data from ESRD MCRs and ECIs from BLS. We calculated occupation weights for the blended Wages and Salaries price proxy using 2016 FTE data from the MCR data and associated 2016 Average Mean Wage data from the Bureau of Labor Statistics' Occupational Employment Statistics. This is similar to the methodology used in the 2012-based ESRDB market basket to derive these occupational wages and salaries categories.

Health Related Wages and Salaries

We proposed to continue using the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code #CIU1026220000000I) as the price proxy for health-related occupations. Of the two health-related ECIs that we considered (''Hospitals'' and ''Health Care and Social Assistance''), the wage distribution within the Hospital NAICS sector (622) is more closely related to the wage distribution of ESRD facilities than it is to the wage distribution of the Health Care and Social Assistance NAICS sector (62).

The Wages and Salaries—Health Related subcategory weight within the Wages and Salaries cost category accounts for 79.9 percent of total Wages and Salaries in 2016. The ESRD Medicare Cost Report FTE categories used to define the Wages and Salaries—Health Related subcategory include ''Physicians,'' ''Registered Nurses,'' ''Licensed Practical Nurses,'' ''Nurses' Aides,'' ''Technicians,'' and ''Dieticians''.

Management Wages and Salaries

We proposed to continue using the ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU2020000110000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of management personnel at ESRD facilities.

The Wages and Salaries—Management subcategory weight within the Wages and Salaries cost category is 6.7 percent in 2016. The ESRD Medicare Cost Report FTE category used to define the Wages and Salaries—Management subcategory is ''Management.''

Administrative Wages and Salaries

We proposed to continue using the ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support (BLS series code #CIU2020000220000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of administrative support personnel at ESRD facilities.

The Wages and Salaries—Administrative subcategory weight within the Wages and Salaries cost category is 7.7 percent in 2016. The ESRD MCR FTE category used to define the Wages and Salaries—Administrative subcategory is ''Administrative''.

Services Wages and Salaries

We proposed using the ECI for Wages and Salaries for Private Industry Workers in Service Occupations (BLS series code #CIU2020000300000I). We believe this ECI is the most appropriate price proxy to measure the wages and salaries price growth of all other non-health related, non-management, and non-administrative service support personnel at ESRD facilities.

The Services subcategory weight within the Wages and Salaries cost category is 5.7 percent in 2016. The ESRD Medicare Cost Report FTE categories used to define the Wages and Salaries—Services subcategory are ''Social Workers'' and ''Other.''

Table 6 lists the four ECI series and the corresponding weights used to construct the ECI blend for Wages and Salaries compared to the 2012-based weights for the subcategories. We believe this ECI blend is the most appropriate price proxy to measure the

growth of wages and salaries faced by ESRD facilities.

TABLE 6—ECI BLEND FOR WAGES AND SALARIES IN THE 2016-BASED AND 2012-BASED ESRDB MARKET BASKETS

Cost category	ECI series	2016 Weight (%)	2012 Weight (%)
Health Related Wages and Salaries	ECI for Wages and Salaries for All Civilian Workers in Hospitals	79.9	79.0
Management Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial.	6.7	8.0
Administrative Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support.	7.7	7.0
Services Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Service Occupations.	5.7	6.0

Employee Benefits

We proposed to continue using an ECI blend for Employee Benefits in the 2016-based ESRDB market basket where the components match those of the Wage and Salaries ECI blend. The occupation weights for the blended Benefits price proxy are the same as those for the wages and salaries price proxy blend as shown in Table 5. BLS does not publish ECI for Benefits price proxies for each Wage and Salary ECI; however, where these series are not published, they can be derived by using the ECI for Total Compensation and the relative importance of wages and salaries with total compensation as published by BLS for each detailed ECI occupational index.

Health Related Benefits

We proposed to continue using the ECI for Benefits for All Civilian Workers in Hospitals to measure price growth of this subcategory. This is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code #CIU10162200000000I) and the relative importance of Wages and Salaries within Total Compensation as published by BLS.

Management Benefits

We proposed to continue using the ECI for Benefits for Private Industry Workers in Management, Business, and Financial to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Management, Business, and Financial (BLS series code #CIU20100001100000I) and the relative importance of wages and salaries within total compensation.

Administrative Benefits

We proposed to continue using the ECI for Benefits for Private Industry Workers in Office and Administrative Support to measure price growth of this subcategory. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code #CIU20100002200000I) and the relative importance of Wages and Salaries within Total Compensation.

Services Benefits

We proposed to continue using the ECI for Total Benefits for Private Industry Workers in Service Occupations (BLS series code #CIU20300003000000I) to measure price growth of this subcategory.

We believe the benefits ECI blend continues to be the most appropriate price proxy to measure the growth of benefits prices faced by ESRD facilities. Table 7 lists the four ECI series and the corresponding weights used to construct the benefits ECI blend.

TABLE 7—ECI BLEND FOR BENEFITS IN THE 2016-BASED AND 2012-BASED ESRDB MARKET BASKETS

Cost category	ECI series	2016 Weight (%)	2012 Weight (%)
Health Related Benefits	ECI for Benefits for All Civilian Workers in Hospitals	79.9	79.0
Management Benefits	ECI for Benefits for Private Industry Workers in Management, Business, and Financial.	6.7	8.0
Administrative Benefits	ECI for Benefits for Private Industry Workers in Office and Administrative Support.	7.7	7.0
Services Benefits	ECI for Benefits for Private Industry Workers in Service Occupations	5.7	6.0

Electricity

We proposed to continue using the PPI Commodity for Commercial Electric Power (BLS series code #WPU0542) to measure the price growth of this cost category.

Natural Gas

We proposed to continue using the PPI Commodity for Commercial Natural Gas (BLS series code #WPU0552) to measure the price growth of this cost category.

Water and Sewerage

We proposed to continue using the CPI U.S. city average for Water and Sewerage Maintenance (BLS series code #CUUR0000SEHG01) to measure the price growth of this cost category.

Pharmaceuticals

We proposed to continue using the PPI Commodity for Biological Products, Excluding Diagnostic, for Human Use (which we will abbreviate as PPI–BPHU) (BLS series code #WPU063719) as the price proxy for the ESA drugs in the market basket. We proposed to continue using the PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations (which we will abbreviate as PPI–VNHP) (BLS series code #WPU063807) for all other drugs included in the bundle other than ESAs.

The PPI–BPHU measures the price change of prescription biologics, and ESAs would be captured within this index, if they are included in the PPI sample. Since the PPI relies on confidentiality with respect to the companies and drugs/biologicals included in the sample, we do not know if these drugs are indeed reflected in

this price index. However, we believe the PPI–BPHU is an appropriate proxy to use because although ESAs may be a small part of the fuller category of biological products, we can examine whether the price increases for the ESA drugs are similar to the drugs included in the PPI–BPHU. We did this by comparing the historical price changes in the PPI–BPHU and the ASP for ESAs and found the cumulative growth to be consistent over the past 4 years. We will continue to monitor the trends in the prices for ESA drugs as measured by other price data sources to ensure that the PPI–BPHU is still an appropriate price proxy.

Additionally, since the non-ESA drugs used in the treatment of ESRD are mainly vitamins and nutrients, we believe that the PPI–VNHP continues to be the best available proxy for these types of drugs as it reflects vitamins and nutrients. While this index does include over-the-counter drugs as well as prescription drugs, a comparison of trends in the prices for non-ESA drugs shows similar growth to the proposed PPI–VNHP.

Supplies

We proposed to continue using the PPI Commodity for Surgical and Medical Instruments (BLS series code #WPU1562) to measure the price growth of this cost category.

Lab Services

We proposed to continue using the PPI Industry for Medical Laboratories (BLS series code #PCU621511621511) to measure the price growth of this cost category.

Telephone Service

We proposed to continue using the CPI U.S. city average for Telephone Services (BLS series code #CUUR0000SEED) to measure the price growth of this cost category.

Housekeeping and Operations

In the proposed rule, we stated that we would continue using the PPI Commodity for Cleaning and Building Maintenance Services (BLS series code #WPU49) to measure the price growth of this cost category (83 FR 34325). This series name and series code from the proposed rule were incorrect. The series that we use to proxy the Housekeeping and Operations cost category is the PPI Industry for Janitorial Services (BLS series code #PCU561720561720). This is the same price proxy that was used in the 2012-based ESRDB market basket and is the same price proxy that we proposed to use in the 2016-based ESRDB market basket. Therefore, we have a technical correction to the price proxy for Housekeeping and Operations. Specifically, we will continue using the PPI Industry for Janitorial Services for this cost category, we incorrectly listed the series name as the PPI Commodity for Cleaning and Building Maintenance Services. This was not a proposed change to the price proxy for this category. We further note that the growth in these two indexes are essentially the same with an average growth rate of 1.4 percent over the 2010 through 2017 time period.

Professional Fees

We proposed to continue using the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code #CIU2010000120000I) to measure the price growth of this cost category.

All Other Goods and Services

We proposed to continue using the PPI Commodity for Final demand—Finished Goods Less Foods and Energy (BLS series code #WPUFD4131) to measure the price growth of this cost category.

Capital-Related Building and Equipment

We proposed to continue using the PPI Industry for Lessors of Nonresidential Buildings (BLS series code #PCU531120531120) to measure the price growth of this cost category.

Capital-Related Machinery

We proposed to continue using the PPI Commodity for Electrical Machinery and Equipment (BLS series code #WPU117) to measure the price growth of this cost category.

Table 8 shows all the price proxies and cost weights for the 2016-based ESRDB Market Basket.

TABLE 8—PRICE PROXIES AND ASSOCIATED COST WEIGHTS FOR THE 2016-BASED ESRDB MARKET BASKET

Cost category	Price proxy	2016 Cost weight
Total ESRDB Market Basket		100.0
Compensation		43.6
Wages and Salaries		34.5
Health-related Wages and Salaries	ECI for Wages and Salaries for All Civilian Workers in Hospitals	27.6
Management Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Management, Business, and Financial.	2.3
Administrative Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Office and Administrative Support.	2.7
Services Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Service Occupations.	2.0
Employee Benefits		9.1
Health-related Benefits	ECI for Total Benefits for All Civilian workers in Hospitals	7.3
Management Benefits	ECI for Total Benefits for Private Industry workers in Management, Business, and Financial.	0.6
Administrative Benefits	ECI for Total Benefits for Private Industry workers in Office and Administrative Support.	0.7
Services Benefits	ECI for Total Benefits for Private Industry workers in Service Occupations.	0.5
Utilities		2.0
Electricity	PPI Commodity for Commercial Electric Power	1.1
Natural Gas	PPI Commodity for Commercial Natural Gas	0.1
Water and Sewerage	CPI–U for Water and Sewerage Maintenance	0.8
Medical Materials and Supplies		24.9
Pharmaceuticals		12.4
ESAs	PPI Commodity for Biological Products, Excluding Diagnostics, for Human Use.	10.0

TABLE 8—PRICE PROXIES AND ASSOCIATED COST WEIGHTS FOR THE 2016-BASED ESRDB MARKET BASKET—Continued

Cost category	Price proxy	2016 Cost weight
Other Drugs	PPI Commodity for Vitamin, Nutrient, and Hematinic Preparations	2.4
Supplies	PPI Commodity for Surgical and Medical Instruments	10.4
Lab Services	PPI Industry for Medical Laboratories	2.2
All Other Goods and Services		16.4
Telephone Service	CPI–U for Telephone Services	0.5
Housekeeping and Operations	PPI—Industry—Janitorial services	3.9
Professional Fees	ECI for Total Compensation for Private Industry Workers in Professional and Related.	0.7
All Other Goods and Services	PPI for Final demand—Finished Goods less Foods and Energy	11.3
Capital Costs		13.0
Capital Related Building and Equipment	PPI Industry for Lessors of Nonresidential Buildings	9.2
Capital Related Machinery	PPI Commodity for Electrical Machinery and Equipment	3.8

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.

The comments and our responses to the comments on our proposed price proxies are set forth below.

Comment: Several commenters recommended that CMS identify a more suitable price proxy to update non-ESA drugs. The commenters stated that they believe that the current proxy (PPI Commodity data for Vitamin, nutrient, and hematinic preparations) does not appropriately capture the price of drugs that fall within the non-ESA cost category. Specifically, the commenters stated that Vitamin D analogs in this category, such as Doxercalciferol and Paricalcitol, are distinct from over-the-counter vitamins. They further assert that the non-ESA drugs in the bundle are unique chemical entities, Food and Drug Administration (FDA)-approved, and available by prescription only.

These commenters suggested the use of the BLS series PPI Commodity data for Chemical and allied products—Drugs and Pharmaceuticals, seasonally adjusted (series ID WPS063) because it is based on prescription drugs and would include fewer over-the-counter drugs.

Some commenters also noted that while the non-ESA drugs represent a small portion of overall cost of providing dialysis services currently, the proposed expansion of the transitional drug add-on payment adjustment (TDAPA) for all new renal dialysis drugs will likely result in a shift in the type and use of drugs (that is, the drug mix) that is included within the ESRD PPS bundled payment and introduce new oral products that deserve an accurate price proxy for updating.

Response: We finalized the use of a blended price proxy for the pharmaceutical cost category in the CY 2015 ESRD final rule (79 FR 66135). We proxied the ESA drugs in the 2012-based ESRDB market basket by the PPI for biological products, human use (PPI BPHU) and the non-ESA drugs in the market basket by the PPI for Vitamin, Nutrient, and Hematinic preparations (PPI VNHP).

We continue to believe that the PPI VNHP is the most technically appropriate price proxy for non-ESA drugs in the ESRDB market basket for several reasons. The non-ESA drugs included in the bundled per treatment amount are comprised primarily of vitamins and nutrients. While the PPI VNHP index does include over-the-counter drugs, it also includes prescription-required vitamins and nutrients. The commenters' suggested index—the PPI for Drugs and Pharmaceuticals—mostly reflects drugs that are not reimbursable under the ESRD PPS. Furthermore, prescription-required vitamins and nutrients (such as non-ESA drugs included in the ESRD bundled payment) would represent a small proportion of drugs represented in this index, making it less representative of the non-ESA drug prices. Furthermore, analysis of the ASP data over the period 2012 through 2017 found the prices of the non-ESA drugs in the ESRD PPS bundle declined by 27.4 percent compared to the PPI VNHP which grew by 13.0 percent and the PPI for Drugs and Pharmaceuticals which increased by 34.5 percent.

The non-ESA drugs represent 2.4 percent of total costs in the 2016-based ESRDB market basket or 19 percent of all ESRD drug expenses for 2016. In comparison, non-ESA drugs represented 3.6 percent of total costs in the 2012-based ESRDB market basket, or 22 percent of all drug costs. This indicates that from 2012 to 2016, the relative costs (reflecting both price and quantity) faced by ESRD facilities for non-ESA drugs has grown slower than other ESRD costs included in the PPS ESRD bundle.

Lastly, we disagree with the commenters' rationale that we should switch to an alternative price index in anticipation of potential shifts in the mix of drugs within the ESRD PPS bundled payment amount as a result of the proposed TDAPA provisions. Any impact that would result from the proposed TDAPA expansion are unknown at this time. We will continue to monitor the impact that these changes have on the relative cost share weights in the ESRDB market basket, over time, as reported on the MCR data. When appropriate we will rebase the ESRDB market basket to reflect observed shifts in cost weights.

For the reasons stated above, we continue to believe it is technically appropriate to proxy the price change for non-ESA related drugs included in the ESRD PPS bundled payment by the PPI VNHP. Therefore, we are finalizing the PPI VNHP as the price proxy for non-ESA drugs in the 2016-based ESRDB market basket.

After consideration of public comments, we are finalizing the price proxies of the 2016-based ESRDB market basket as proposed—noting the error in the CY 2019 ESRD PPS proposed rule for the Housekeeping and Operations cost category.

ii. CY 2019 ESRDB Market Basket Update, Adjusted for Multifactor Productivity

Under section 1881(b)(14)(F) of the Act, beginning in CY 2012, ESRD PPS payment amounts shall be annually increased by an ESRD market basket percentage increase factor reduced by the productivity adjustment. We proposed to use the 2016-based ESRDB market basket to compute the CY 2019 ESRDB market basket increase factor

and labor-related share. Consistent with historical practice, we estimate the ESRDB market basket update based on IHS Global Inc.'s (IGI's) forecast using the most recently available data. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets.

a. Market Basket Update

After consideration of public comments, we are finalizing the proposed 2016-based ESRDB market basket without modification. A comparison of the yearly changes from CY 2014 to CY 2021 for the 2012-based ESRDB market basket and the final 2016-based ESRDB market basket is shown in Table 9.

TABLE 9—COMPARISON OF THE 2012-BASED ESRDB MARKET BASKET AND THE FINAL 2016-BASED ESRDB MARKET BASKET, PERCENT CHANGE, 2014–2021

	ESRDB Market basket, 2012-based	ESRDB Market basket, 2016-based	Difference (2016-based less 2012-based)
Historical data:			
CY 2014	1.6	1.5	−0.1
CY 2015	2.2	2.0	−0.2
CY 2016	2.0	1.9	−0.1
CY 2017	1.3	1.4	0.1
Average CYs 2014–2017	1.8	1.7	−0.1
Forecast:			
CY 2018	1.7	1.7	0.0
CY 2019	2.2	2.1	−0.1
CY 2020	2.4	2.4	0.0
CY 2021	2.5	2.4	−0.1
Average CYs 2018–2021	2.2	2.2	0.0

Source: IHS Global Inc. 3rd Quarter 2018 forecast with historical data through 2nd Quarter 2018.

Table 9 shows that the forecasted rate of growth for CY 2019 for the 2016-based ESRDB market basket is 2.1 percent, which is 0.1 percentage point lower than the rate of growth as estimated using the 2012-based ESRDB market basket. The lower update is mainly due to a lower relative pharmaceuticals (particularly ESAs) cost weight in the 2016-based ESRD market basket compared to the 2012-based ESRDB market basket,

The growth rates in Table 9 are based on IHS Global Inc.'s (IGI) 3rd quarter 2018 forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets. We noted in the proposed rule that if more recent data were subsequently available (for example, a more recent estimate of the market basket), we would use such data to determine the market basket increases in the final rule. In the proposed rule the forecasted rate of growth for CY 2019, based on IGI's 1st quarter 2018 forecast, for the 2016-based ESRDB market basket was 2.2 percent (83 FR 34326).

b. Multifactor Productivity (MFP)

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRD market basket percentage increase factor shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The multifactor productivity (MFP) is derived by subtracting the contribution of labor and capital input growth from output growth. The detailed methodology for deriving the MFP projection was finalized in the CY 2012 ESRD PPS final rule (76 FR 70232 through 70235). The most up-to-date MFP projection methodology is available on the CMS website at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.* We did not propose any changes to the methodology for the projection of the MFP adjustment.

Based on IGI's 3rd quarter 2018 forecast with history through the 2nd quarter of 2018, the projected MFP adjustment (the 10-year moving average of MFP for the period ending December 31, 2019) for CY 2019 is 0.8 percent.

We noted in the proposed rule that if more recent data were subsequently available (for example, a more recent estimate of the MFP adjustment), we would use such data to determine the MFP adjustment in the final rule. For comparison purposes, the proposed MFP adjustment for CY 2019 was 0.7 percent (83 FR 34327), and was based on IGI's 1st quarter 2018 forecast.

The comments and our responses to the comments on the proposed MFP adjustment for CY 2019 are set forth below.

Comment: Many commenters expressed their objection to the MFP adjustment to the ESRD PPS bundled payment update. Several commenters requested that CMS support development and adoption of a dialysis facility-specific productivity adjustment that: (1) Better reflects factors that affect opportunities for productivity gains over which dialysis providers have little, if any, control; and (2) account for the statutory reductions to the ESRD PPS already in place to account for expected gains in efficiency.

The commenters provided several reasons why they believe that a MFP adjustment is not appropriate to apply to ESRD care which includes: overall rising labor costs, dialysis facilities compliance with staffing minimums to assure quality of care, the mix of contracted and staffed employment, increased labor costs due to wage pressures, and additional administrative costs to comply with quality incentive program (QIP) reporting requirements.

One commenter noted that 55 percent of facilities have negative margins (as calculated by the Moran Company). The commenter also stated that MedPAC estimated ESRD margins at 0.5 percent. The commenter stated that these low margins challenge the idea that productivity can be improved year over year. One commenter further stated that the industry's ability to remain viable is directly tied to the unique private-public partnership that supports the Medicare ESRD program.

The commenters noted that current law requires CMS to apply an MFP adjustment. Regardless, they agree with the views of the Medicare Board of Trustees, per the 2018 Trustees Report, that unrealistic productivity gain targets could negatively impact beneficiaries' access to care and quality of service. The commenters encouraged CMS to work with the kidney care community to find a more appropriate adjustment and potentially encourage Congress to eliminate the MFP adjustment for ESRD facilities in the future.

Response: Section 1881(b)(14)(F)(i) of the Act requires the application of the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the ESRD PPS market basket update for 2012 and subsequent years. We will continue to monitor the impact of the payment updates, including the effects of the MFP adjustment, on ESRD provider margins as well as beneficiary access to care as reported by MedPAC. However, as mentioned, any changes to the productivity adjustment would require a change to current law.

In the March 2018 Report to Congress [3], MedPAC found that outpatient dialysis payments are adequate, noting positive indicators for beneficiaries' access to care, the supply and capacity of providers, volume of services, quality of care, and access to capital.

While we understand that the kidney care community would like to find a more appropriate adjustment, such as an ESRD-specific MFP measure, we encourage commenters to discuss the feasibility of such measures with the Bureau of Labor Statistics, the agency that produces and publishes industry-level MFP. We would also refer commenters to the November 2006 article, ''*Hospital Multifactor Productivity: A Presentation and Analysis of Two Methodologies*'', published in the Health Care Financing Review [4] that discusses challenges that exist in measuring health care specific multifactor productivity.

Finally, we understand that labor costs may be rising due to the tighter labor market and additional administrative costs resulting from QIP reporting requirements; however, we would remind commenters that these increased compensation pressures are taken into account within the annual market basket update. Increasing relative wage costs are reflected in a higher Wages and Salaries cost weight of 34.5 percent in the 2016-based ESRDB market basket compared to the 2012-based ESRDB market basket wage cost weight of 33.7 percent. Also, expected compensation pressures are taken into account via the annual forecasts of the price proxies for wages used in the annual payment update. The CY 2019 payment update of 2.1 percent reflects compensation prices increasing faster than the majority of the non-compensation price proxies, which is evident with a Compensation relative importance of about 45 percent in CY 2019 compared to the 2016 base weight of 43.6 percent. The relative importance reflects the different rates of price change for cost categories between the base year (2016) and CY 2019.

c. Market Basket Update Adjusted for Multifactor Productivity (MFP)

As a result of these provisions, the CY 2019 ESRDB market basket increase is 1.3 percent. This market basket increase is calculated by starting with the 2016-based ESRDB market basket percentage increase factor of 2.1 percent for CY 2019, and reducing it by the MFP adjustment (the 10-year moving average of MFP for the period ending CY 2019) of 0.8 percentage point.

The CY 2019 ESRDB increase factor would be 0.1 percentage point higher if we used the 2012-based ESRDB market basket. That is, the CY 2019 ESRDB market basket increase factor is 1.4 percent using the 2012-based ESRDB market basket.

The comments and our response to the comments on the proposed CY 2019 market basket increase are set forth below.

Comment: Several commenters supported the proposed market basket update for CY 2019.

Response: We appreciate the commenters' support. The proposed 1.5 percent payment increase was based on IGI's 1st quarter 2018 forecast of the proposed 2016-based ESRDB market basket and the 10-year moving average of annual economy-wide private nonfarm business MFP. As noted in the proposed rule, if a more recent forecast of the market basket and MFP adjustment becomes available, we would use such data to determine the CY 2019 market basket update and MFP adjustment in the final rule. Based on IGI's more recent 3rd quarter 2018 forecast, we determined a payment increase of 1.3 percent for the final update percentage.

iii. Labor-Related Share for ESRD PPS

We define the labor-related share as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. The labor-related share is typically the sum of Wages and Salaries, Benefits, Professional Fees, Labor-related Services, and a portion of Capital from a given market basket.

We proposed to use the 2016-based ESRDB market basket cost weights to determine the labor-related share for ESRD facilities. Therefore, effective for CY 2019, we proposed a labor-related share of 52.3 percent, slightly higher than the current 50.673 percent that was based on the 2012-based ESRDB market basket, as shown in Table 10. We proposed to move the labor-related share to a one decimal level of precision rather than the three decimal level of precision used previously. CMS is migrating all payment system labor-related shares to a one decimal level of precision. These figures represent the sum of Wages and Salaries, Benefits, Housekeeping and Operations, 87 percent of the weight for Professional Fees (details discussed below), and 46 percent of the weight for Capital-related Building and Equipment expenses (details discussed below). We used the same methodology for the 2012-based ESRDB market basket.

TABLE 10—CY 2019 LABOR-RELATED SHARE AND CY 2018 LABOR-RELATED SHARE

Cost category	CY 2019 ESRD labor-related share	CY 2018 ESRD labor-related share
Wages and Salaries	34.5	33.650
Employee Benefits	9.1	8.847
Housekeeping and Operations	3.9	3.785

[3] *https://medpac.gov/docs/default-source/reports/mar18_medpac_ch6_sec.pdf?sfvrsn=0.*

[4] D Cylus, Jonathan & A Dickensheets, Bridget. (2006). Hospital Multifactor Productivity: A Presentation and Analysis of Two Methodologies. Health care financing review. 29. 49–64.

TABLE 10—CY 2019 LABOR-RELATED SHARE AND CY 2018 LABOR-RELATED SHARE—Continued

Cost category	CY 2019 ESRD labor-related share	CY 2018 ESRD labor-related share
Professional Fees (Labor-Related)	0.6	0.537
Capital Labor-Related	4.2	3.854
Total Labor-Related Share	52.3	50.673

The labor-related share for Professional Fees reflects the proportion of ESRD facilities' professional fees expenses that we believe vary with local labor market (87 percent). We conducted a survey of ESRD facilities in 2008 to better understand the proportion of contracted professional services that ESRD facilities typically purchase outside of their local labor market. These purchased professional services include functions such as accounting and auditing, management consulting, engineering, and legal services. Based on the survey results, we determined that, on average, 87 percent of professional services are purchased from local firms and 13 percent are purchased from businesses located outside of the ESRD's local labor market. Thus, we include 87 percent of the cost weight for Professional Fees in the labor-related share (87 percent is the same percentage as used in prior years).

The labor-related share for capital-related expenses reflects the proportion of ESRD facilities' capital-related expenses that we believe varies with local labor market wages (46 percent of ESRD facilities' Capital-related Building and Equipment expenses). Capital-related expenses are affected in some proportion by variations in local labor market costs (such as construction worker wages) that are reflected in the price of the capital asset. However, many other inputs that determine capital costs are not related to local labor market costs, such as interest rates. The 46-percent figure is based on regressions run for the inpatient hospital capital PPS in 1991 (56 FR 43375). We use a similar methodology to calculate capital-related expenses for the labor-related shares for rehabilitation facilities (70 FR 30233), psychiatric facilities, long-term care facilities, and skilled nursing facilities (66 FR 39585).

The comments and our response to the comments on the proposed labor-related share for CY 2019 are set forth below.

Comment: Several commenters supported the proposal to increase the labor-related share for CY 2019 to 52.3 percent.

Response: We appreciate the commenters' support of the proposed labor-related share of 52.3 percent. This increase in the ESRD labor-related share reflects the relative increase in labor-related costs compared to non-labor-related costs that ESRD facilities have experienced since 2012.

After consideration of public comments, CMS is finalizing the labor-related share of 52.3 percent, as proposed.

b. The CY 2019 ESRD PPS Wage Indices

i. Annual Update of the Wage Index

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. We use the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at *https://www.whitehouse.gov/omb/bulletins/.*

For CY 2019, we updated the wage indices to account for updated wage levels in areas in which ESRD facilities are located using our existing methodology. We use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the inpatient PPS. The ESRD PPS wage index values are calculated without regard to geographic reclassifications authorized under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. The final CY 2019 wage index values for urban areas are listed in Addendum A (Wage Indices for Urban Areas) and the final CY 2019 wage index values for rural areas are listed in Addendum B (Wage Indices for Rural Areas). Addenda A and B are located on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.html.*

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there is no hospital data. For a full discussion, we refer readers to the CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we compute the average wage index value of all urban areas within the state and use that value as the wage index. For rural areas with no hospital data, we compute the wage index using the average wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We apply the statewide urban average based on the average of all urban areas within the state to Hinesville-Fort Stewart, Georgia (78 FR 72173), and we apply the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172). A wage index floor value is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor.

In the CY 2011 ESRD PPS final rule (75 FR 49116 through 49117), we finalized a policy to reduce the wage index floor by 0.05 for each of the remaining years of the ESRD PPS transition, that is, until CY 2014. We applied a 0.05 reduction to the wage index floor for CYs 2012 and 2013, resulting in a wage index floor of 0.55 and 0.50, respectively (CY 2012 ESRD PPS final rule, 76 FR 70241). We continued to apply and reduce the wage index floor by 0.05 in CY 2013 (77 FR 67459 through 67461). Although we only intended to provide a wage index

floor during the 4-year transition in the CY 2014 ESRD PPS final rule (78 FR 72173), we decided to continue to apply the wage index floor and reduce it by 0.05 per year for CY 2014 and for CY 2015.

In the CY 2016 ESRD PPS final rule (80 FR 69006 through 69008), we decided to maintain a wage index floor of 0.40, rather than further reduce the floor by 0.05. We stated we needed more time to study the wage indices that are reported for Puerto Rico to assess the appropriateness of discontinuing the wage index floor (80 FR 69006).

In the CY 2017 ESRD PPS proposed rule (81 FR 42817), we presented the findings from analyses of ESRD facility cost report and claims data submitted by facilities located in Puerto Rico and mainland facilities. We solicited public comments on the wage index for CBSAs in Puerto Rico as part of our continuing effort to determine an appropriate policy. We did not propose to change the wage index floor for CBSAs in Puerto Rico, but we requested public comments in which stakeholders could provide useful input for consideration in future decision-making. Specifically, we solicited comment on the suggestions that were submitted in the CY 2016 ESRD PPS final rule (80 FR 69007). After considering the public comments we received regarding the wage index floor, we finalized a wage index floor of 0.40 in the CY 2017 ESRD PPS final rule (81 FR 77858).

In the CY 2018 ESRD PPS final rule (82 FR 50747), we finalized a policy to maintain the wage index floor of 0.40 for CY 2018 and subsequent years, because we believed it was appropriate and continuing to provide additional payment support to the lowest wage areas. It also obviated the need for an additional budget-neutrality adjustment that would reduce the ESRD PPS base rate, beyond the adjustment needed to reflect updated hospital wage data, in order to maintain budget neutrality for wage index updates.

ii. Wage Index Floor for CY 2019 and Subsequent Years

For CY 2019 and subsequent years, we proposed to increase the wage index floor to 0.50. As we explained in the CY 2019 ESRD PPS proposed rule, this wage floor increase would be responsive to stakeholder comments, safeguard access to care in areas at the lowest end of the current wage index distribution, and be supported by data, as discussed below, which supports a higher wage index floor. We noted that stakeholders, particularly those located in Puerto Rico, have described the adverse impact the low wage index floor value has on a facility, such as closure and the resulting impact on access to care. Also, natural disasters (for example, hurricanes, floods) common to this geographic area can cause significant infrastructure issues, create limited resources, and create conditions that may accelerate kidney failure in patients predisposed to chronic kidney disease, all of which have a significant impact on renal dialysis services. These negative effects of natural disasters on the local economy affect wages and salaries. For example, there is the potential of the outmigration of qualified staff that would cause a facility the need to change its hiring practices or increase the wages that it would otherwise pay had there not been a natural disaster.

We noted that in response to the CY 2018 ESRD PPS proposed rule, commenters described the economic and health care crisis in Puerto Rico and recommended that CMS use the United States (U.S.) Virgin Islands wage index for payment rate calculations in Puerto Rico as a proxy for CY 2018.

Commenters indicated that the primary issue is that Puerto Rico hospitals report comparatively lower wages that are not adjusted for occupational mix and, as indicated in the CY 2017 ESRD PPS proposed rule (81 FR 42817), in Puerto Rico, only registered nurses (RNs) can provide dialysis therapy in the outpatient setting. Commenters explained that this staffing variable artificially lowers the reportable index values even though the actual costs of dialysis service wages in Puerto Rico are much higher than the data CMS is relying upon. In addition, several commenters stated that non-labor costs, including utilities and shipping costs and the CY 2015 change in the labor-share based on the rebased and revised ESRDB market basket compound the issue even further. One organization stated that it did not believe maintaining the current wage index for Puerto Rico for CY 2018 would be enough to offset the poor economic conditions, high operational costs and epidemiologic burden of ESRD on the island.

Since we did not propose to change the wage index floor or otherwise change the wage indexes for Puerto Rico in the CY 2018 ESRD PPS proposed rule, we maintained the wage index floor of 0.40 for CY 2018. We noted that the current wage index floor and labor-related share have been in effect since CY 2015 and neither the floor nor the labor share has been reduced since then. We also explained that the wage index is solely intended to reflect differences in labor costs and not to account for non-labor cost differences, such as utilities or shipping costs (82 FR 50747).

With regard to staffing in Puerto Rico facilities, we noted that ESRD facilities there utilize RNs similarly to ESRD facilities on the mainland, that is, facilities utilize dialysis technicians and aides to provide dialysis services with oversight by an RN, and that hourly wages for RNs and dialysis support staff were approximately half of those salaries in mainland ESRD facilities. For those reasons, we stated that we did not agree that the hospital-reported data is unreliable, and we believed using that data is more appropriate than applying the wage index value for the Virgin Islands where salaries are considerably higher.

We explained in the CY 2019 ESRD PPS proposed rule that even though we did not propose a change in the wage index floor for CY 2018, we continued to analyze the cost of furnishing dialysis care in Puerto Rico, staffing in Puerto Rico ESRD facilities and hospital wage data. We stated that while we found the analyses to be inconclusive for the CY2018 ESRD PPS final rule (82 FR 50746), in light of the recent natural disasters that profoundly impacted delivery of ESRD care in Puerto Rico, we revisited the analyses and concluded that we should propose a new wage index floor. We conducted various analyses to test the reasonableness of the current wage index floor value of 0.40. The details of these analyses and our proposal for CY 2019 are provided below.

a. Analysis of Puerto Rico Cost Reports

We performed an analysis using cost reports and wage information specific to Puerto Rico from the BLS (*https://www.bls.gov/oes/2015/may/oes_pr.htm*).

- The analysis utilized data from cost reports for freestanding facilities and for hospital-based facilities in Puerto Rico for CYs 2013 through 2015. We noted that the available variables differ between these two sources. For freestanding facilities, data were obtained regarding treatment counts, costs, salaries, benefits, and FTEs by labor category. For hospital-based facilities, a more limited set of variables are available for treatment counts and FTEs.
- We annualized cost report data for each facility in order to create one cost report record per facility per calendar. If cost report forms were submitted at a non-calendar-year cycle, multiple cost report records were proportionated and combined in order to create an annualized cost report record.

• We calculated weighted means across all facilities for each variable. The means were weighted by treatment counts, where facilities with more treatment counts contributed more to the value of the overall mean.

Using this data, we calculated alternative wage indices for Puerto Rico that combined labor quantities (FTEs) from cost reports with BLS wage information to create two regular Laspeyres price indexes. The Laspeyres index can be thought of as a price index in which there are two prices for goods (prices for labor FTEs in Puerto Rico and the mainland U.S.), where the distribution of goods (labor share of FTEs) is held constant (across Puerto Rico and the U.S.). The first index used quantity weights from the overall U.S. use of labor inputs. The second index used quantity weights from the Puerto Rico use of labor inputs.

The alternative wage indices derived from the analysis indicated that Puerto Rico's wage index likely lies between 0.51 and 0.55. Both of these values are above the current wage index floor and suggested that the current 0.40 wage index floor may be too low.

b. Statistical Analysis of the Distribution of the Wage Index

We also performed a statistical outlier analysis to identify the upper and lower boundaries of the distribution of the current wage index values and remove outlier values at the edges of the distribution.

In the general sense, an outlier is an observation that lies an abnormal distance from other values in a population. In this case, the population of values is the various wage indices within the CY 2019 wage index. The lower and upper quartiles (the 25th and 75th percentiles) are also used. The lower quartile is Q1 and the upper quartile is Q3. The difference (Q3 − Q1) is called the interquartile range (IQR). The IQR is used in calculating the inner and outer fences of a data set. The inner fences are needed for identifying mild outlier values in the edges of the distribution of a data set. Any values in the data set that are outside of the inner fences are identified as an outlier. The standard multiplying value for identifying the inner fences is 1.5.

First, we identified the Q1 and Q3 quartiles of the CY 2018 wage index, which are as follows: Q1 = 0.8303 and Q3 = 0.9881. Next, we identified the IQR: IQR = 0.9881 − 0.8303 = 0.578. Finally, we identified the inner fence values as shown below.

Lower inner fence: Q1 − 1.5*IQR = 0.8303 − (1.5 × 0.1578) = 0.5936

Upper inner fence: Q3 + 1.5*IQR = .881 + (1.5 × 0.1578) = 1.2248

This statistical outlier analysis demonstrated that any wage index values less than 0.5936 are considered outlier values, and 0.5936 as the lower boundary also suggested that the current wage index floor could be appropriately reset at a higher level.

Based on these analyses, we proposed a wage index floor of 0.50. We noted that we believe this increase from the current 0.40 wage index floor value minimizes the impact to the ESRD PPS base rate while providing increased payment to areas that need it. We considered the various wage index floor values based on our analyses. We noted that while the statistical analysis supports our decision to propose a higher wage index floor, the cost report analysis is more definitive as it is based on reported wages using an alternative data source. As a result, we considered wage index floor values between 0.40 and 0.55 and proposed 0.50 in an effort to strike a balance between providing additional payments to affected areas while minimizing the impact on the base rate. We stated that we believe the proposed 25 percent increase from the current 0.40 value would help to address stakeholder requests for a higher wage index floor, would minimize patient access issues, and would have a lower impact to the base rate than if we proposed a higher wage index floor value.

We noted that the wage index floor directly affects the base rate and currently, only rural Puerto Rico and four urban CBSAs in Puerto Rico receive the wage index floor of 0.40. The next lowest wage index is in the Wheeling, West Virginia CBSA with a value of 0.6598. Under our proposal, all CBSAs in Puerto Rico would receive the wage index floor of 0.50. Though the proposed wage index value currently affects CBSAs in Puerto Rico, we noted that, consistent with our established policy, any CBSA that falls below the floor would be eligible to receive the floor. We solicited comment on the proposal to increase the wage index floor from 0.40 to 0.50 for CY 2019 and beyond.

iii. Application of the Wage Index Under the ESRD PPS

A facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In section II.B.3.b.iv of this final rule, we finalized the labor-related share of 52.3 percent, which is based on the final 2016-based ESRDB market basket. Thus, for CY 2019, the labor-related share to which a facility's wage index would be applied is 52.3 percent.

iv. New Urban Core-Based Statistical Area (CBSA)

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provide detailed information on the update to statistical areas since July 15, 2015, and are based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the U.S. Census Bureau population estimates for July 1, 2014 and July 1, 2015. In OMB Bulletin No. 17–01, OMB announced that one Micropolitan Statistical Area now qualifies as a Metropolitan Statistical Area. The new urban CBSA is as follows:

• Twin Falls, Idaho (CBSA 46300). This CBSA is comprised of the principal city of Twin Falls, Idaho in Jerome County, Idaho and Twin Falls County, Idaho.

The OMB bulletin is available on the OMB website at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*. In the CY 2019 ESRD PPS proposed rule (83 FR 34330) we noted that we did not have sufficient time to include this change in the computation of the proposed CY 2019 wage index, rate setting, and Addenda associated with this proposed rule and stated that this new CBSA may affect the budget neutrality factors and wage indexes, depending on the impact of the overall payments of the hospital located in this new CBSA. However, 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 CY 2019 wage index. We noted that 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 proposed wage index for CBSA 46300 was calculated using the average hourly wage data for one provider (provider 130002). Taking the estimated unadjusted average hourly wage of $35.833564813 of the new CBSA 46300 and dividing by the national average hourly wage of $42.990625267 resulted in the proposed estimated wage index of 0.8335 for CBSA 46300.

We noted that in the final rule, we would incorporate this change into the final CY 2019 ESRD PPS wage index, rate setting and Addenda. Thus, for CY 2019, we are using the OMB delineations that were adopted

beginning with CY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 13–01, 15–01, and 17–01.

The comments and our responses to the comments on our proposed revisions to the wage index floor are set forth below.

Comment: MedPAC commented that its standing position, as stated in its June 2007 report to the Congress, is that creating rural floors and implementing other changes (for example, exceptions and reclassifications) to a wage index system distorts area wage indexes. In addition, the Commission stated that the current ESRD PPS wage index is flawed in that it is based only on data from hospitals, rather than data for all of the health care providers in a given market. In place of using the hospital wage index for ESRD facilities, MedPAC recommended that CMS establish an ESRD PPS wage index for all ESRD facilities (not just those located in Puerto Rico) that: (1) Uses wage data representing all employers and industry-specific occupational weights; (2) is adjusted for geographic differences in the ratio of benefits to wages; (3) is adjusted at the county level and smooths large differences between counties; and (4) is implemented so that large changes in wage index values are phased in over a transition period.

MedPAC commented that this alternative approach to the wage index is based on wage data from BLS and the Census Bureau, and benefits data from provider cost reports submitted to CMS. The Commission noted that CMS's analysis of alternative wage indices (ranging between 0.510 and 0.550) for Puerto Rico also combined labor data from provider (ESRD facilities) cost reports with BLS wage information and recommended CMS provide additional documentation of its analysis to determine the two alternative wage indices for Puerto Rico.

Response: As described in the CY 2019 ESRD PPS proposed rule (83 FR 34328 through 34330), the analysis we conducted to test the reasonableness of the current wage index floor used wages from the BLS and full-time equivalents (FTEs) by occupation reported on the cost reports for independent facilities. Specifically, we calculated labor weights by occupation for Puerto Rico and the greater U.S. as the treatment-weighted average of the FTEs reported on independent facility cost reports. We did not include hospital-based cost report data because the occupations for which the FTEs were reported were not identical between independent and hospital-based cost reports (for example, hospital cost reports do not have FTEs for administrative and management staff associated with renal units). Although we used the wages from the BLS data, we did not use benefits data and therefore we did not adjust for geographic differences in the ratio of benefits to wages.

The values of 0.510 and 0.550 are the calculated 2015 wage index values based on the use of FTEs specific to Puerto Rico and the greater U.S., respectively. The 2015 wage index based on Puerto Rico FTEs is a standard Laspeyres price (wage) index that used quantity weights from the reported composition of FTEs in Puerto Rico, such that the wage index can be represented as the FTE-weighted sum of Puerto Rico wages by occupation divided by the FTE-weighted sum of U.S. wages by occupation. Note that the numerator and denominator in this formula use the same FTEs. Similarly, we constructed the 2015 wage index based on U.S. FTEs as a standard Laspeyres price index using quantity weights from the reported composition of FTEs in the U.S. The wage index value in each of these calculated indices exceeds the current wage floor, suggesting that the current wage index may not adequately capture the full cost of labor at dialysis facilities operating in Puerto Rico. Also, we did not calculate the wage index at the county level because the analysis was aimed at calculating a single wage index for all of Puerto Rico. We appreciate MedPAC's feedback on the current wage index and suggestions for establishing a new wage index for the ESRD PPS and will consider the Commission's recommendations for future rulemaking.

Comment: Several commenters, including a national dialysis provider organization, two LDOs, and an insurance company expressed support for the proposal to increase the wage index from 0.40 in 2018 to 0.50 in 2019, because they believe it will assist dialysis clinics in providing access to high-quality care particularly in rural areas where access challenges may be present.

Another insurance company urged CMS to take another look at the amount of the wage index increase. This commenter pointed out that in the proposed rule, CMS noted that its analysis indicates that the wage index in Puerto Rico likely lies between 0.51 and 0.55. The commenter urged the adoption of the 0.55 level as most accurately reflecting the post-hurricane wage environment, which includes provider migration and higher costs for capital and utilities.

A coalition of Puerto Rico stakeholders and a dialysis organization expressed support for CMS's position that the current wage index floor is too low and steps should be taken to increase it. While they appreciate any increase in ESRD fee for service (FFS) rates that move payment closer to a level where providers can cover costs, they stated CMS has an opportunity to further narrow the gap between FFS rates and costs in Puerto Rico so that ESRD providers are not wholly dependent on rates from Medicare Advantage plans to sustain operations. The dialysis organization stated that while an incremental increase would move the gauge toward better alignment with costs, the 0.50 falls far short, and would perpetuate a cycle of rate challenges for the healthcare stakeholders and high dialysis patient mortality and hospitalization rates.

The stakeholders recommended CMS evaluate increasing the floor to 0.70 to mitigate the distance of payments for dialysis services in critical areas relative to the range of wage index levels across the nation. They pointed out this amount is still lower than most jurisdictions, including the U.S. Virgin Islands, but could support a tangible and meaningful change in FFS payments considering the need for these services, as Puerto Rico goes through a crucial disaster recovery period. The stakeholders asserted that this wage index floor is necessary to reduce the flight of health care providers out of Puerto Rico, and this level of wage index floor would be related to actual wage indices in the states. The commenters stated that CMS should use its administrative authority to adjust payment formulas in Puerto Rico to address the endemic problems in the health care system: Provider migration due to low wages and reimbursement; poor infrastructure; higher costs for capital and utilities. The commenter estimated increasing the wage index floor to 0.70 could raise the Puerto Rico ESRD PPS rate to approximately $200 to $212 per episode, which would represent an approximate 18 percent increase over the 2018 rate.

At a minimum, they recommended CMS set the wage index floor at 0.5936, which was identified as the lower boundary of CMS's statistical outlier analysis. They also recommended CMS conduct a new survey on ESRD wages in Puerto Rico that distinguishes inpatient facility wages from outpatient facility wages, and recognizes the value of proposed increases on all the high cost health care factors faced by Puerto Rico in the wake of Hurricanes Irma and Maria. They pointed out the professional scope of practice for technicians is different between

inpatient and outpatient facilities in Puerto Rico. They noted that while such technicians are permitted to assist in ESRD care under the supervision of an RN in inpatient facilities, this is not the case in outpatient facilities where RNs must provide all the care per local scope of practice laws. Therefore, to get a fully accurate projection of wage costs for ESRD providers in Puerto Rico, they recommended CMS evaluate inpatient and outpatient facility data separately.

A dialysis provider also stated the recruitment of bilingual staff and the shortage of bilingual RN's is a huge challenge. They pointed out the databases and websites used by all facilities are all English based and facilities must hire additional staff to work around the language barriers, and the current methodology and payment policies do not capture this anomaly. Although they expressed support for the wage index floor increase from 0.40 to 0.50, they pointed out CMS's analysis shows that Puerto Rico's wage index ''likely lies between 0.51 and 0.55'', while additional analyses note that any wage index values less than 0.5936 are considered outlier values, with 0.5936 therefore as the lower wage index boundary. They expressed concern that CMS proposed a new floor of only 0.50 despite CMS's own analyses and recognition that the present methodology applied to Puerto Rico has created the only outlier in the U.S.

Response: As we stated in the CY 2019 ESRD PPS proposed rule, we continue to believe that a wage index floor of 0.50 strikes an appropriate balance between providing additional payments to areas that fall below the wage floor while minimizing the impact on the ESRD PPS base rate. The analyses were conducted to gauge the appropriateness of the current wage index floor and determine whether it is too low; we did not propose to use these analyses to determine the exact value for a new wage index floor. Instead, we considered these analyses along with the hospital wage data to determine an appropriate policy for a wage index floor. The purpose of the wage index adjustment is to recognize differences in ESRD facility resource use for wages specific to the geographic area in which facilities are located. While a wage index floor of 0.50 would continue to be the lowest wage index nationwide, we note that the areas subject to the floor continue to have the lowest wages compared to mainland facilities. We note that an increase to the wage index floor to 0.50 is a 25 percent increase over the current floor and will provide a higher wage index for all facilities in Puerto Rico where wage indexes, based on hospital reported data, range from .33 to .44. For these reasons, we believe a wage index floor of 0.50 is appropriate and will support labor costs in low wage areas.

With regard to concerns raised about the need to hire bilingual RNs, the need for bilingual staff occurs in both inpatient and outpatient settings and hospital cost reports should reflect those additional costs. We note that in every analysis we conducted, the average salary of RNs in Puerto Rico was approximately half that of mainland facilities and none of the analyses produced a 0.70 wage index value. We do not believe it is appropriate to raise the wage index floor to 0.70 in order to mitigate non-labor losses from the disaster. The wage index adjustment is intended to recognize geographic differences in wage levels in areas in which ESRD facilities are located. As such it would not be appropriate to utilize the wage index floor policy to address infrastructure, capital, and other non-labor related costs.

With regard to the use of RNs in Puerto Rico facilities, we have received conflicting information from Puerto Rico about the how local scope of practice for RNs and other staff impact ESRD facility costs. We are continuing to explore alternative methodologies for accounting for the labor-related costs of all Medicare providers and we may revisit the use of a wage index floor under the ESRD PPS in that context.

Final Rule Action: After considering the public comments we received regarding the wage index floor, we are finalizing an increase to the wage index floor from 0.40 to 0.50 for CY 2019 and subsequent years as proposed. Currently, all areas with wage index values that fall below the floor are located in Puerto Rico. However, the wage index floor value is applicable for any area that may fall below the floor. For CY 2019, the labor-related share to which a facility's wage index is applied is 52.3 percent, based on the finalized 2016-based ESRDB market basket which is discussed in section II.B.2 of this final rule.

c. Final CY 2019 Update to the Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care would be frailty, obesity, and comorbidities, such as cancer. The ESRD PPS recognizes high cost patients, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237. The policy provides that the following ESRD outlier items and services are included in the ESRD PPS bundle: (1) ESRD-related drugs and biologicals that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (2) ESRD-related laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (3) medical/surgical supplies, including syringes, used to administer ESRD-related drugs that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and (4) renal dialysis services drugs that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including ESRD-related oral-only drugs effective January 1, 2025.

In the CY 2011 ESRD PPS final rule (75 FR 49142), we stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as outlier services were originally specified in Attachment 3 of Change Request 7064, Transmittal 2033 issued August 20, 2010, rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which was issued to correct the subject on the Transmittal page and made no other changes.

Furthermore, we use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. We use this separate guidance to identify renal dialysis service drugs that were or would have been covered under Medicare Part D for outlier eligibility purposes and in order to provide unit prices for calculating imputed outlier services. In addition, we also identify through our monitoring efforts items and services that are either incorrectly being identified as eligible outlier services or any new items and services that may require an update to

the list of renal dialysis items and services that qualify as outlier services, which are made through administrative issuances.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its actual or imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted and described below) plus the fixed-dollar loss (FDL) amount. In accordance with § 413.237(c) of our regulations, facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and at § 413.220(b)(4), using 2007 data, we established the outlier percentage, which is used to reduce the per treatment base rate to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments, at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis to compute the payment adjustments.

For CY 2019, we proposed that the outlier services MAP amounts and FDL amounts would be derived from claims data from CY 2017. Because we believe that any adjustments made to the MAP amounts under the ESRD PPS should be based upon the most recent data year available in order to best predict any future outlier payments, we proposed the outlier thresholds for CY 2019 would be based on utilization of renal dialysis items and services furnished under the ESRD PPS in CY 2017. We stated in the CY 2019 ESRD PPS proposed rule that we recognize that the utilization of ESAs and other outlier services have continued to decline under the ESRD PPS, and that we have lowered the MAP amounts and FDL amounts every year under the ESRD PPS.

i. CY 2019 Update to the Outlier Services Medicare Allowable Payment (MAP) Amounts and Fixed Dollar Loss (FDL) Amounts

For this final rule, the outlier services MAP amounts and FDL amounts were updated using 2017 claims data. The impact of this update is shown in Table 11, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2018 with the updated final estimates for this rule. The estimates for the final CY 2019 outlier policy, which are included in Column II of Table 11, were inflation adjusted to reflect projected 2019 prices for outlier services.

TABLE 11—OUTLIER POLICY: IMPACT OF USING UPDATED DATA TO DEFINE THE OUTLIER POLICY

	Column I final outlier policy for CY 2018 (based on 2016 data, price inflated to 2018) *		Column II final outlier policy for CY 2019 (based on 2017 data, price inflated to 2019)	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$37.41	$44.27	$34.18	$40.18
Adjustments				
Standardization for outlier services	1.0177	0.9774	1.0503	0.9779
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	37.31	42.41	35.18	38.51
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	47.79	77.54	57.14	65.11
Patient-month-facilities qualifying for outlier payment	9.0%	7.4%	7.2%	8.2%

As demonstrated in Table 11, the estimated FDL amount per treatment that determines the CY 2019 outlier threshold amount for adults (Column II; $40.18) is lower than that used for the CY 2018 outlier policy (Column I; $44.27). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $42.41 to $38.51. For pediatric patients, there is an increase in the FDL amount from $47.79 to $57.14. There is a corresponding decrease in the adjusted average MAP for outlier services among pediatric patients, from $37.31 to $35.18.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2019 will be 8.2 percent for adult patients and 7.2 percent for pediatric patients, based on the 2017 claims data. The pediatric outlier MAP and FDL amounts continue to be lower for pediatric patients than adults due to the continued lower use of outlier services (primarily reflecting lower use of ESAs and other injectable drugs).

ii. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. For this final rule and based on the 2017 claims, outlier payments represented approximately 0.80 percent of total payments, slightly below the 1 percent target due to declines in the use of outlier services. Recalibration of the thresholds using 2017 data is expected to result in aggregate outlier payments close to the 1 percent target in CY 2019. We believe the update to the outlier MAP and FDL amounts for CY 2019 would increase payments for ESRD beneficiaries requiring higher resource utilization and move us closer to meeting our 1 percent outlier policy because we are using more current data for computing the MAP and FDL which is more in line with current outlier services utilization rates. We note that recalibration of the FDL amounts in this

final rule would result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments, but would increase payments to ESRD facilities for beneficiaries with renal dialysis items and services that are eligible for outlier payments, as well as co-insurance obligations for beneficiaries with renal dialysis services eligible for outlier payments.

The comments and our responses to the comments on our proposed updates to the outlier policy are set forth below.

Comment: Although we did not propose changes to the outlier target percentage or methodology for computing the MAP or FDL amounts, we received many comments regarding the difference between estimated outlier payments and the 1.0 percent outlier target.

An LDO and a patient advocacy organization pointed out that since its inception, the outlier policy has not consistently achieved parity in distributing dollars withheld to fund the pool. The commenters stated that although the undistributed outlier pool dollars may not represent a significant amount per treatment, their analyses estimate that since 2011, $5.48 per treatment has been removed from the ESRD PPS by outlier pool underpayments. They noted that the outlier pool's imperfect performance further supports their view that it is inappropriate to extend the outlier policy to new drugs and biologicals upon the expiration of the TDAPA. The patient advocacy organization stated that although the use of updated claims data has led to small improvements, the persistent gap indicates the need for additional efforts to achieve parity and end what the organization views as inappropriate reductions to ESRD PPS payments. The organization stated paying out any remaining outlier pool dollars to providers in a subsequent year should be a central part of those efforts.

A dialysis provider organization urged CMS to reconsider the 1 percent outlier policy and pointed out while an outlier adjustment is required under the statute, it does not specify a particular value. The organization stated a 0.5 percent outlier threshold would reduce the offset to the base payment and still provide for payment in the case of extraordinary costs. A national dialysis organization, as part of its comment on the outlier expansion comment solicitation, expressed concern that the outlier policy continues to underestimate the outlier payment actually paid out each year since 2011, and believes money has been inappropriately removed from the ESRD PPS overall funding that is not returned to the system. For example, the organization noted the change from 2017 to 2018 is only 0.78 to 0.80. Over time, the organization estimates that the amount has resulted in a loss of $67 million since 2015 and $231 million since 2011.

Response: We appreciate the suggestions provided. We continue to believe that 1.0 percent is an appropriate target for outlier payments and that the recalibrated thresholds will lead to increased payments that are closer to the 1.0 percent target. A 1.0 percent outlier target percentage is a modest amount in comparison to other Medicare prospective payment systems and helps ensure high cost patients receive the individualized services they need. We disagree that a .50 percent threshold is more appropriate since the outlier payments represent .80 percent of total payments, close to the 1.0 percent target. We will, however, take the commenters' views into consideration as we explore ways to enhance and update the outlier policy.

Final Rule Action: After considering the public comments, we are finalizing the updated outlier thresholds for CY 2019 displayed in Column II of Table 11 of this final rule and based on CY 2017 data.

iii. Solicitation on the Expansion of the Outlier Policy

Currently, former separately payable Part B drugs, laboratory services, and supplies are eligible for the outlier payment. In the interest of supporting innovation, ensuring appropriate payment for all drugs and biologicals, and as a complement to the TDAPA proposals, in the CY 2019 ESRD PPS proposed rule, we solicited comment on whether we should expand the outlier policy to include composite rate drugs and supplies (83 FR 34332). We noted that under the proposed expansion to the drug designation process, such expansion of the outlier policy could support appropriate payment for composite rate drugs once the TDAPA period has ended. Additionally, with regard to composite rate supplies, an expansion of the outlier policy could support use of new innovative devices or items that would otherwise be considered in the ESRD PPS bundled payment. We stated that if commenters believe such an approach is appropriate, we requested they provide input on how we would effectuate such a shift in policy. For example, the reporting of these services may be challenging since they have never been reported on ESRD claims previously. We specifically requested feedback about how such items might work under the existing ESRD PPS outlier framework or whether specific changes to the policy to accommodate such items are needed. We stated that we will consider all comments and address them by making proposals, if appropriate.

A summary of the comments we received and our response to the comments are set forth below.

Comments: A dialysis provider association supported the proposed expansion of the outlier policy to include drugs, biologicals, and supplies that currently fall into the ESRD PPS composite rate. The association strongly agreed with CMS that an expansion of the outlier policy would promote and incentivize the development of innovative new therapies and devices to treat the highly vulnerable ESRD adult and pediatric patient populations, and therefore urged CMS to propose such an expansion in future rulemaking. The association further suggested that CMS include a line in the claim for identification of supplies for outlier payment, explaining that having this information on the claim would both ease administrative burden and improve payment accuracy.

A dialysis provider organization commented that within the context of an expanded TDAPA policy, including formerly composite rate drugs within the outlier calculation in the future would be a positive step, even if a new drug added to the ESRD PPS bundled payment includes additional payment. The organization stated if a new drug is folded into an existing ESRD PPS functional category without additional payment, providing outlier eligibility to these drugs could be even more important. The organization also indicated that collecting the data necessary to implement such a policy may have merit and encouraged CMS to continue to seek stakeholder input in future rulemaking in the context of whatever final policy it establishes for an expanded TDAPA in this year's CY 2019 ESRD PPS final rule.

A health plan encouraged CMS to propose changes to the outlier policy that would take into account composite rate drugs and supplies because the health plan believes all costs of treating a patient should be included when determining outlier payments. The health plan pointed out that many patients who receive composite rate drugs and supplies have complex needs due to non-compliance or comorbid conditions and excluding composite rate drugs and supplies could discourage ESRD facilities from accepting higher acuity patients.

An LDO commented that it does not support the proposal to expand the outlier policy to include composite rate drugs and supplies and would prefer the outlier payment adjustment be removed from the ESRD PPS. The LDO expressed concern that money is being taken out of the system that is never returned to support patient care and expanding this policy will only make matters worse. The LDO understands the agency would require statutory authority to eliminate the outlier provision, however, it stated CMS does have discretion to reduce the size of the outlier pool and recommended CMS decrease the outlier percentage from 1 percent to 0.5 percent.

A national LDO and a national dialysis organization stated the outlier pool cannot provide adequate reimbursement for costly new drugs and biologicals in the ESRD PPS. In the national dialysis organization's view, outlier payments are not designed to pay for drugs. They are meant for patients with unusually high costs. The LDO noted that while the outlier pool had an early connection to beneficiaries who were high utilizers of certain high-cost drugs and biologicals in the ESRD PPS bundled payment, specifically ESAs, the outlier pool was never designed to provide comprehensive reimbursement for such products. Rather, the LDO stated, CMS incorporated funding for ESAs into the ESRD PPS base rate and the small number of individuals whose ESA utilization was a true outlier would then qualify for an outlier payment in addition to what was already built into the base rate for the average patient. Both commenters expressed that expanding the outlier pool would still not address the need for money to be added to the base rate.

The national dialysis organization does not support extending the outlier payment to new drugs or biologicals that CMS would classify as being within the existing ESRD PPS functional categories. The organization believes it would be inappropriate to do so because outlier payments are not designed to pay for drugs and biologicals used regularly.

MedPAC commented that an outlier policy should act as a stop-loss insurance for medically necessary care, and outlier payments are needed when the PPS's payment adjustments do not capture all of the factors affecting providers' costs of delivering care. For example, MedPAC stated, when higher costs arise due to the occurrence of random events, such as patients who suffer serious complications, then outlier payments would be appropriately triggered. Consequently, MedPAC noted in order to develop an effective outlier policy, CMS must first develop accurate patient- and facility-level payment adjustments.

Further, MedPAC indicated CMS should develop an outlier policy that accounts for variation in the cost of providing the full ESRD PPS payment bundle; the outlier policy should not apply solely to exceedingly high costs of ESRD drugs and supplies. MedPAC stated that this approach would be more patient-centric and would align the ESRD PPS outlier policy with the policies of other Medicare PPSs.

However, MedPAC cautioned if CMS elects to expand the outlier pool only for composite rate drugs and supplies, then the agency should explicitly define which supplies would be eligible for an outlier payment. In addition, MedPAC recommended that the agency should develop clinical criteria for the use of all drugs and supplies eligible for outlier payments to ensure their appropriate (medically necessary) use.

MedPAC noted that expanding the outlier policy may require the agency to impose additional reporting requirements on facilities in order to determine patient-level costs. Should the agency elect to expand the outlier policy, MedPAC recommended minimizing the administrative burden on providers and including a mechanism for validating the additional collected data.

Response: We appreciate the thoughtful responses from the commenters. We recognize that the commenters' concerns regarding the expansion of outlier eligibility to include composite rate drugs and supplies are inextricably linked to their views on the effectiveness of our broader outlier policy or other payment adjustments. We will take these views into account as we consider the outlier policy and payment adjustments for future rulemaking.

d. Final Impacts to the CY 2019 ESRD PPS Base Rate

i. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), we established the methodology for calculating the ESRD PPS per-treatment base rate, that is, ESRD PPS base rate, and the determination of the per-treatment payment amount, which are codified at § 413.220 and § 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, and transitional drug add-on payment adjustment.

ii. Annual Payment Rate Update for CY 2019

The ESRD PPS base rate for CY 2019 is $235.27. This update reflects several factors, described in more detail as follows:

- *Market Basket Increase:* Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by the ESRD market basket percentage increase factor. The latest CY 2019 projection for the final ESRDB market basket is 2.1 percent. In CY 2019, this amount must be reduced by the multifactor productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As discussed above, the final MFP adjustment for CY 2019 is 0.8 percent, thus yielding a final update to the base rate of 1.3 percent for CY 2019 ($2.1 - 0.8 = 1.3$). Therefore, the ESRD PPS base rate for CY 2019 before application of the wage index budget-neutrality adjustment factor would be $235.39 ($232.37 \times 1.013 = $235.39).
- *Wage Index Budget-Neutrality Adjustment Factor:* We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2019, we did not propose any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). The final CY 2019 wage index budget-neutrality adjustment factor is 0.999506, based on the updated wage index data. This application would yield a final CY 2019 ESRD PPS base rate of $235.27 ($235.39 \times 0.999506 = $235.27).

The comments and our responses to the comments on our proposals to update the ESRD PPS base rate for CY 2019 are set forth below.

Comment: A dialysis provider organization expressed appreciation for the proposed increase to the ESRD PPS base rate for CY 2019 but stated the increase is insufficient to cover the annual growth in costs for dialysis facilities necessary to offer life-sustaining, high-quality care to pediatric and adult ESRD patients. The organization noted that this is a concern for small and independent providers in rural and underserved areas, and can significantly impact whether a facility remains open. Therefore, the organization believes an appropriate increase in overall reimbursement is required.

A clinician association stated that while it appreciates the proposed increase to the ESRD PPS base rate, the association is concerned about other policies in the ESRD PPS and ESRD QIP that may result in reductions to the already limited resources used by nephrology nurses to provide high quality care to Medicare ESRD beneficiaries.

The association stated that since the implementation of the ESRD PPS, nephrology nurses have been required to balance the constant increases in demands for data collection and the time required to provide quality patient care to a population of individuals with complex care needs. The commenter explained nephrology nurses understand the increased administrative burden placed on dialysis facilities in meeting regulatory documentation requirements and are often the collectors and providers of this data at the unit level.

We received many comments, including from MedPAC, national kidney dialysis organizations, professional associations, patient advocacy organizations, LDOs, and a health plan, related to the current ESRD PPS patient and facility-level adjustments and the negative impact these adjustment factors have on the ESRD PPS base rate due to the standardization adjustment.

Response: We appreciate the support for the increase in the ESRD PPS base rate and the comments regarding the issues impacting ESRD facilities. We understand facilities in rural and underserved areas face unique challenges. We also recognize the administrative work done by the nephrology nurses. We note that in a PPS, the payment is for the average patient and the facility and patient adjusters attempt to mitigate any loss by those at the lower end of the payment spectrum.

As we stated in section II.B.3.d.i of this final rule, we established an ESRD PPS base rate that reflected the lowest per patient utilization data as required by statute. This amount is adjusted for patient specific case-mix adjustments, applicable facility adjustments, and geographic difference in area wage levels which are reflective of facility costs since cost data is used to derive the adjustment factors. The CY 2016 ESRD PPS final rule discusses the methodology for calculating the patient and facility-level adjustments (80 FR 68972 through 69004). In addition, the base rate is adjusted for any applicable outlier payment, training add-on payment, and the TDAPA to arrive at the per treatment payment amount. The ESRD PPS base rate is annually updated by the ESRDB market basket and adjusted for productivity and wage index budget neutrality. For these reasons, we believe that the CY 2019 ESRD PPS base rate is appropriate despite the challenges some facilities experience. We also continue to believe that the rural adjustment and LVPA provide payment for the challenges faced by those facilities that are eligible for the adjustment. We note that the ESRDB market basket for CYs 2015 through 2018 was reduced in accordance with section 217(b)(2) of PAMA and for CY 2019, ESRD facilities are getting the full ESRDB market basket update, which increases payment.

The comments on the current ESRD PPS patient and facility-level adjustments based on the regression analysis are out of scope for this final rule since we proposed changes to the administration of certain adjustments (that is, LVPA and comorbidities), but did not propose any changes related to the calculation of these adjustments. However, we will continue to consider these comments for future refinements to ESRD PPS policies. Additionally, we are undertaking a new research effort and plan to engage with stakeholders further on this issue.

Final Rule Action: We are finalizing a CY 2019 ESRD PPS base rate of $235.27.

C. Solicitation for Information on Transplant and Modality Requirements

When an individual is faced with failing kidneys, life-extending treatment is available. The most common treatment is dialysis, but the best treatment is receiving a kidney transplant from a living or deceased donor. Dialysis, either HD or PD, can sustain life by removing impurities and extra fluids but cannot do either job as consistently or efficiently as a functioning kidney. Dialysis also carries risks of its own, including anemia, bone disease, hypotension, hypertension, heart disease, muscle cramps, itching, fluid overload, nerve damage, depression, and infection. Timely transplantation, despite requiring a major surgery and ongoing medication, offers recipients a longer, higher quality of life, without the ongoing risks of dialysis. Unfortunately, the number of people waiting for healthy donor kidneys far exceeds the number of available organs. In 2015, the most recent year for which complete data is available, 18,805 kidney transplants were performed in the U.S., while over 80,000 individuals remained on waiting lists (*https://www.usrds.org/2017/view/v2_06.aspx*). That same year, there were 124,114 newly reported cases of ESRD and over 703,243 prevalent cases of ESRD (*https://www.usrds.org/2017/view/v2_01.aspx*).

In recognition of the superiority of transplantation but the need for dialysis, CMS has required for nearly 10 years that Medicare-certified dialysis facilities evaluate all patients for transplant suitability and make appropriate referrals to local transplant centers (73 FR 20370). Specifically, dialysis facilities must:

- Inform every patient about all treatment modalities, including transplantation (§ 494.70(a)(7)).
- Evaluate every patient for suitability for a transplantation referral (§ 494.80(b)(10)).
- Document any basis for non-referral in the patient's medical record (§ 494.80(b)(10)).
- Develop plans for pursuing transplantation for every patient who is a transplant referral candidate (§ 494.90(a)(7)(ii)).
- Track the results of each kidney transplant center referral (§ 494.90(c)(1)).
- Monitor the status of any facility patients who are on the transplant waitlist (§ 494.90(c)(2)).
- Communicate with the transplant center regarding patient transplant status at least annually, and when there is a change in transplant candidate status (§ 494.90(c)(3)).
- Educate patients, family members, or caregivers or both about transplantation, as established in a patient's plan of care (§ 494.90(d)).

Despite these requirements, the percentage of prevalent dialysis patients wait-listed for a kidney has recently declined (*https://www.usrds.org/2017/view/v2_06.aspx*, Figure 6.2), meaning that fewer people have the opportunity to be matched with a donor kidney. Some individuals do receive kidneys

directly from suitable friends or family members, but still must be placed on the waiting list. Organ Procurement and Transplantation Network (OPTN) policy requires that all transplant recipients, including recipients of organs from living donors, be registered and added to the OPTN waiting list. Until a dialysis patient is referred to a transplant center, he or she is not able to be placed on the waiting list, and is ineligible to receive a kidney. While dialysis facilities have no control over the total supply of kidneys made available for transplantation, transplantation education, referral, and waitlist tracking are appropriate and necessary services for them to furnish. Unfortunately, there are performance gaps and disparities between dialysis facilities in providing these services.[5] Therefore, as discussed in section IV.C.1.a. of section IV ''End-Stage Renal Disease Quality Incentive Program (ESRD QIP)'' of the CY 2019 ESRD PPS proposed rule (83 FR 34344), we proposed a reporting measure under the ESRD QIP that would track the percentage of patients at each dialysis facility who are on the kidney or kidney-pancreas transplant waiting list. We also solicited input on other ways to increase kidney transplant referrals and improve the tracking process for patients on the waitlist:

- Are there ways to ensure facilities are meeting the Conditions for Coverage (CfC) requirements, in addition to the survey process?
- Are the current dialysis facility CfC requirements addressing transplantation support services adequately, or should additional requirements be considered?

With regard to other treatment for failed kidneys, HD performed in an outpatient dialysis center is most common, followed by HD performed at home, and PD (almost always performed at home). Just as we are concerned about disparities in access to transplantation, we are also concerned about disparities in access to dialysis modality options. Although ESRD disproportionately affects racial and ethnic minority patients, minority individuals are far less likely to be treated with home dialysis than white patients.[6] Home dialysis modalities necessitate a higher level of self-care than in-center care, and are not appropriate for or desired by every dialysis patient. We are concerned, however that not all dialysis patients are aware of, or given the opportunity to learn about, home modalities or their benefits—primarily greater independence and flexibility. Individuals performing home dialysis treatments are able to schedule their treatments at times most convenient for them, allowing them to coordinate with family and work schedules, and eliminate the need for thrice weekly transportation to and from a dialysis facility. The transportation savings are especially valuable to rural individuals, who might have to travel hours each week for regular treatments in a facility.

We take this opportunity to remind dialysis facilities of their responsibilities regarding modality education and options. Some dialysis facilities do not support home modalities, but all facilities are required to make appropriate referrals if a patient elects to pursue home treatments. Specifically, dialysis facilities must:

- Inform every patient about all treatment modalities, including transplantation, home dialysis modalities (home HD, intermittent PD, continuous ambulatory PD, continuous cycling PD), and in-facility HD (§ 494.70(a)(7)).
- Ensure all patients are provided access to resource information for dialysis modalities not offered by the facility, including information about alternative scheduling options for working patients (§ 494.70(a)(7)).
- Assess every patient's abilities, interests, preferences, and goals, including the desired level of participation in the dialysis care process; the preferred modality (hemodialysis or peritoneal dialysis), and setting, (for example, home dialysis), and the patient's expectations for care outcomes (§ 494.80(a)(9)).
- Identify a plan for every patient's home dialysis or explain why the patient is not a candidate for home dialysis (§ 494.90(a)(7)(i)).
- Provide education and training, as applicable, to patients and family members or caregivers or both, in aspects of the dialysis experience, dialysis management, infection prevention and personal care, home dialysis and self-care, quality of life, rehabilitation, transplantation, and the benefits and risks of various vascular access types (§ 494.90(d)).

Persons with failed kidneys often begin dialysis with no prior exposure to nephrology care or knowledge of treatment options. The practitioners and professionals who care for them are best suited to provide the necessary information to support informed, shared decision-making. Patient education is not a one-time incident, but an ongoing aspect of all health care services and settings. We welcomed your suggestions on ways to ensure that dialysis facilities are meeting these obligations, and to ensure equal access to dialysis modalities.

In the proposed rule we reviewed the importance of treatment modality options and education for individuals with failed kidneys, including transplantation and home dialysis, and the related CfC standards that dialysis facilities must meet. We requested suggestions on other ways to increase kidney transplant referrals and improve the tracking process for patients on the waitlist. We also asked for input on ways to better ensure that dialysis facilities are meeting these obligations, and to ensure equal access to dialysis modalities. We received extensive comments on these issues from approximately 20 stakeholders. While we will not respond to these comments here, we will take them into consideration during future policy development. We thank the commenters for their input.

D. Miscellaneous Comments

We received many comments from beneficiaries, physicians, professional organizations, renal organizations, and manufacturers related to issues not specifically addressed in the CY 2019 ESRD PPS proposed rule. These comments are discussed below.

Comment: A device manufacturer and device manufacturer association asked CMS to establish a transitional add-on payment adjustment for new FDA-approved medical devices. They commented on the lack of FDA approved or authorized new devices for use in a dialysis facility, highlighting the need to promote dialysis device innovation for use by dialysis clinics. The commenters indicated they believe the same rationale CMS used to propose broadening the TDAPA eligibility also would apply to new medical devices. Specifically, the commenters noted the statute provides CMS with ''discretionary authority'' to adopt payment adjustments determined

[5] R. E. Patzer, L. Plantinga, J. Krisher, S.O. Pastan, ''Dialysis facility and network factors associated with low kidney transplantation rates among U.S. dialysis facilities,'' American Journal of Transplantation, 2014 Jul; 14(7):1562–72; and Sudeshna Paul, Laura C. Plantinga, Stephen O. Pastan, Jennifer C. Gander, Sumit Mohan, and Rachel E. Patzer, ''Standardized Transplantation Referral Ratio to Assess Performance of Transplant Referral among Dialysis Facilities,'' Clinical Journal of the American Society of Nephrology, January 2018.

[6] Mehrotra, R., Soohoo, M., Rivara, M.B., Himmelfarb, J., Cheung, A.K., Arah, O.A., Nissenson, A.R., Ravel, V., Streja, E., Kuttykrishnan, S., Katz, R., Molnar, M., Kalantar-Zadeh, K., ''*Racial and Ethnic Disparities in Use of and Outcomes with Home Dialysis in the United States*,'' Journal of the American Society of Nephrology December 10, 2015.

appropriate by the Secretary, and precedent supports CMS' authority to use non-budget neutral additions to the base rate for adjustments under specific circumstances. The commenters asserted CMS could finalize this adjustment in the CY 2019 ESRD PPS final rule. A professional association urged CMS and other relevant policymakers to prioritize the development of a clear pathway to add new devices to the ESRD PPS bundled payment. They believe new money must be made available to appropriately reflect the cost of new devices added to the ESRD PPS bundled payment.

A national dialysis organization and an LDO asked CMS to clarify how it incentivizes the development of new dialysis devices. The organization asked CMS to describe how such a device would be included in the ESRD PPS bundle, and suggested the initial application of a pass-through payment which would be evaluated later, based on the data. This evaluation would determine if the device should be included in the ESRD PPS base rate and whether or not additional funds should be added to the bundle. The organization offered to engage with CMS to develop a more detailed policy, but in the short-term, asked CMS to indicate in the final rule that it will provide such a pathway and work with stakeholders in future rulemakings to further define it.

An LDO requested CMS plan appropriately for innovative devices or other new innovative products. However, as the unfolding of the drug designation process has demonstrated the complexity of the process, the commenter noted the process should be both thoughtful and collaborative. The commenter asked CMS to work with the kidney community to consider if and how new devices or other new innovative products delivering high clinical value, can be delivered to beneficiaries, whether through the ESRD PPS or through other payment systems.

A home dialysis patient group also expressed concern regarding the absence of a pathway or guidance for adding new devices to the ESRD PPS bundled payment or for reimbursement, stating that it left investors and industry wary of investing in the development of new devices for patients.

Response: We appreciate the commenters' thoughts regarding payment for new and innovative devices, either via a TDAPA for medical devices or a pass-through payment for medical devices. We also appreciate the commenter's comments regarding the complexity of such an adjustment as well as the concerns related to a lack of pathway for new devices. We did not include any proposals regarding these topics in the CY 2019 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

Comment: MedPAC strongly encouraged CMS to accelerate completion of the ESRD facility cost report audits and release its final results. MedPAC has repeatedly discussed the importance of auditing the cost reports dialysis facilities submit to CMS to ensure the data are accurate. MedPAC made the following points: First, inaccurate cost report data could affect the ESRD PPS's payment adjustment factors and ESRD market basket index, which are derived from this data source. Second, accurate accounting of costs is essential for assessing facilities' financial performance under Medicare. The Medicare margin is calculated from this data source, and policymakers consider the margin (and other factors) when assessing the adequacy of Medicare's payments for dialysis services. If costs are overstated, then the Medicare margin is understated. Third, it has been more than 15 years since cost reports were audited, and in 2011, the outpatient dialysis payment system underwent a significant change, which might have affected how facilities report their costs. Fourth, historically, facilities' cost reports have included costs Medicare does not allow.

Response: We appreciate MedPAC's thoughts and suggestions on our cost reports and audits. The audit process is complete and the audit staff are reviewing the findings. We did not include any proposals regarding these topics in the CY 2019 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

Comment: An LDO stated excluding the 50-cent network fee from dialysis facilities' cost reports remains problematic, explaining that failure to account for the fee understated facilities' costs by more than $20 million in 2017 and inhibits informed policymaking. The commenter noted that in response to a prior recommendation on this issue, CMS suggested it does not have the statutory authority to include the network fee on cost reports. However, this commenter stated the Omnibus Budget Reconciliation Act of 1986 (OBRA 86), which established the network fee, does not address its inclusion or exclusion. The House Report accompanying OBRA 86 elaborates on Congressional intent with respect to the network fee, but it too does not address the fee's inclusion or exclusion. The organization urged CMS to reexamine its interpretation of the statute, which they believe affords CMS the necessary authority to add the network fee as a revenue reduction on Worksheet D effective with CY 2019 dialysis facility cost reports. A national LDO organization made a similar comment.

Response: We appreciate the feedback regarding the 50-cent network fee and its inclusion in the cost reports. We did not include any proposals regarding these topics in the CY 2019 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

Comment: An LDO stated several years have elapsed since CMS eliminated the medical director fee limitation, but the ESRD Medicare Claims Processing Manual instructions, despite being updated in November 2016, do not reflect this policy change. Some Medicare contractors incorrectly continue to require dialysis facilities to submit detailed physician logs and apply the fee. The organization urged CMS to resolve this small, administrative matter to ensure the even application of its long-standing decision to eliminate the medical director fee limitation.

Response: The ESRD Medicare Claims Processing Manual (Pub 100–02 Section 40.6) was updated via Change Request 10541 (transmittal 4010) effective June 26, 2018.

Comment: An LDO stated the claim submission requirement to report the amount of an oral equivalent used by an ESRD patient, not the amount dispensed, presents significant challenges for dialysis facilities. The organization noted that changes in a patient's condition may require a different course of treatment that calls for a lower or higher dose than initially recommended. Other common circumstances, such as a patient's relocation, necessitating the delivery of services at a different, geographically closer facility, further complicate compliance with the reporting requirement. The organization recommended CMS modify the current requirement and permit dialysis facilities to report the dispensed amount of an oral drug. The organization suggested the following revised requirement: CMS should permit dialysis facilities to claim products dispensed in good faith, even if discarded, because of death, change in prescription, transfer to another facility, hospitalization, or transplant. CMS also should cover any replacement medication should the beneficiary lose it.

Response: We appreciate the commenter's feedback on the reporting of oral equivalent drugs. We did not include any proposals regarding these topics in the CY 2019 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

Comment: We received comments on home dialysis from several different commenters, including patient advocacy groups, national kidney organizations, a national LDO organization, dialysis provider associations, dialysis equipment manufacturers, and a large number of beneficiaries. These commenters called for modifications or rescission of the Medicare Administrative Contractor proposed Local Coverage Determinations, in order to remove uncertainty in reimbursement for more frequent dialysis for home dialysis patients. They urged CMS to ensure all MACs abide by the requirements included in the Medicare Program Integrity Manual in implementing policies regarding payment for more frequent dialysis. They expressed strong support for efforts to increase access to home dialysis for patients for whom it is medically appropriate. Additionally, they encouraged CMS to eliminate ambiguity in past rulemaking regarding CMS' payment policy for medically justified more frequent hemodialysis sessions, to provide clear and correct information for the MAC's understanding and for providers who may be inadvertently discouraged from informing patients of all suitable treatment options.

Response: We appreciate the commenters' thoughts on home dialysis. We did not include any proposals regarding these topics in the CY 2019 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

Comment: We received many other comments that we consider outside the scope of the CY 2019 ESRD PPS proposed rule, including the following suggestions: Incorporation of the CFC requirement to document why a patient is not a candidate for home dialysis on the UB-04 claims; modification of the kidney dialysis education program so it may be practically implemented and more broadly utilized; and reinforcement of providers' responsibility to inform Skilled Nursing Facility (SNF) dialysis patients of their option to perform home dialysis in a SNF, and a reminder to providers to appropriately code their home dialysis patients residing in SNFs to allow for better population surveillance.

Response: We appreciate receiving these comments regarding issues affecting ESRD facilities and beneficiaries. However, we did not include any proposals regarding these topics in the CY 2019 ESRD PPS proposed rule, and therefore we consider these suggestions to be beyond the scope of this rule.

III. CY 2019 Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

A. Background

The Trade Preferences Extension Act of 2015 (TPEA), Public Law 114–27, was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with acute kidney injury (AKI). Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new paragraph (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies in order to implement subsection (r) of section 1834 of the Act and the amendments to section 1881(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872, and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on CY 2019 Payment for Renal Dialysis Services Furnished to Individuals With AKI

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS'' (83 FR 34304 through 34415), hereinafter referred to as the ''CY 2019 ESRD PPS proposed rule'', was published in the **Federal Register** on July 19, 2018, with a comment period that ended on September 10, 2018. In that proposed rule, we proposed to update the AKI dialysis payment rate. We received approximately 7 public comments on our proposal, including comments from ESRD facilities; national renal groups, nephrologists and patient organizations; patients and care partners; manufacturers; health care systems; and nurses.

In this final rule, we provide a summary of the proposed provisions, a summary of the public comments received and our responses to them, and the policies we are finalizing for CY 2019 payment for renal dialysis services furnished to individuals with AKI.

C. Annual Payment Rate Update for CY 2019

1. CY 2019 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including market basket adjustments, wage adjustments and any other discretionary adjustments, for such year. We note that ESRD facilities have the ability to bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis.

As discussed in section II.B.3.d of the CY 2019 ESRD PPS proposed rule (83 FR 34332 through 34333), the CY 2019 proposed ESRD PPS base rate was $235.82, which reflected the proposed ESRD bundled market basket and multifactor productivity adjustment. Therefore, we proposed a CY 2019 per treatment payment rate of $235.82 for renal dialysis services furnished by ESRD facilities to individuals with AKI.

This payment rate is further adjusted by the wage index as discussed below.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRD bundled market basket and multifactor productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS and discussed in section II.B.3.f of the CY 2019 ESRD PPS proposed rule (83 FR 34332). The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. We proposed a CY 2019 AKI dialysis payment rate of $235.82, adjusted by the ESRD facility's wage index.

The comments and our responses to the comments on the AKI payment proposal are set forth below.

Comment: A national dialysis organization expressed appreciation that CMS announced the AKI payment rate as part of the CY 2019 ESRD PPS proposed rule and provided the kidney care community with the opportunity to provide comments on the recommendations.

A dialysis provider association urged CMS to increase payments for AKI treatments to be consistent with its analysis of preliminary 2017 cost report data showing that average costs for an AKI treatment are nearly $50 (about 19 percent) higher than average costs for in-center hemodialysis patients. In the analysis, 1,524 of a total of 5,255 freestanding facilities reported AKI treatments. The association explained that the nearly $50 higher per treatment costs for AKI versus in-center maintenance dialysis were driven by the higher direct patient care staffing needs for AKI patients (4.0 staff hours per treatment) compared to maintenance dialysis (2.5 staff hours per treatment). Additionally, laboratory costs ($4.93 vs. $3.91) and administrative and general services costs ($80.06 vs. $65.48) were higher for AKI treatments than for in-center maintenance hemodialysis treatments.

Given that the facility costs vastly exceed payment rates for AKI treatments on average, the association urged CMS to increase the AKI payment rate and make appropriate payment adjustments for case-mix, comorbidities, and others (described below) to more accurately account for the costs that facilities bear when treating AKI patients. The association stated that it believes with more accurate and adequate reimbursement it is likely more dialysis facilities will be able to extend dialysis treatment access to AKI patients in a generally lower cost setting than the outpatient hospital setting, where many AKI patients currently receive treatment.

The association also requested that CMS establish payment adjusters beyond the wage index in order to ensure that facilities have sufficient resources to provide high-quality care to AKI patients, including the following:

- Low-volume adjustment: The association noted that facilities with low treatment volumes face similar cost challenges in providing dialysis to AKI and ESRD patients. The relatively high fixed costs in operating a dialysis clinic are more difficult to offset in facilities with low treatment volume. Therefore, the association urged CMS to apply a low-volume adjustment to AKI treatments for patients in low-volume facilities.
- Pediatric adjustment: The association stated that similar to pediatric patients with ESRD, pediatric patients with AKI experience costly treatment challenges that are unique and distinct from the adult AKI patient population. As such, the association urged CMS to adopt a pediatric adjustment to the AKI payment rate for facilities treating pediatric AKI patients.
- A rural adjustment factor: The association noted that this should be added to the AKI payment rate to account for the additional treatment costs incurred by rural facilities. The association also asked CMS to review the CBSA methodology used for purposes of the rural adjustment, which prevents units that reside within a county that is rural from receiving the adjustment if the CBSA in which they reside is deemed urban.

Response: We appreciate the support from commenters with regard to our CY 2019 per treatment base rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. We also appreciate the feedback on the costs associated with an AKI treatment as compared to an ESRD treatment. We note that the Independent Renal Dialysis Facility Cost Report (Form CMS–265–11) was revised in February 2018 for AKI renal dialysis services furnished on and after January 1, 2017 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R4PR242.pdf*). We will use the data reported on this form to review the efficacy of the AKI payment rate and determine the appropriate steps toward further developing the AKI payment rate.

We also appreciate the commenters' feedback on the application of the LVPA, pediatric, and rural adjustments to AKI dialysis treatments. In the CY 2017 ESRD PPS final rule (81 FR 77868), we discussed not applying the case-mix adjusters to the payment for AKI treatments because those adjusters were developed based on ESRD treatments, and we continue to believe this is the most appropriate policy at this time. As we continue to monitor data, we will review the efficacy of the AKI payment rate to determine if modification is required.

We also received comments related to monitoring programs, data collection, budget neutrality, inclusion of AKI in the ESRD QIP, questions related to a patient's transition from AKI to ESRD and eligibility for transplant, home dialysis for AKI patients, and other operational concerns. We did not include any proposals on these topics in the proposed rule, and therefore we believe these comments are out of scope for this rulemaking. However, we will consider these comments for future refinements to AKI payment policies.

Final Rule Action: We are finalizing the AKI payment rate as proposed, that is, based on the finalized ESRD PPS base rate. Specifically, the final CY 2019 ESRD PPS base rate is $235.27. Accordingly, we are finalizing a CY 2019 payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI as $235.27.

IV. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the End-Stage Renal Disease Quality Incentive Program's (ESRD QIP's) background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the calendar year (CY) 2018 ESRD Prospective Payment System (PPS) final rule (82 FR 50756 through 50757).

B. Summary of the Proposed Provisions, Public Comments, Responses to Comments, and Newly Finalized Policies for the End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS'' (83 FR 34304 through 34415), hereinafter referred to as the ''CY 2019 ESRD PPS proposed rule'', was published in the **Federal Register** on July 19, 2018, with a comment period that ended on September 10, 2018. In that proposed rule, we proposed updates to the ESRD QIP, including for PY 2021 through PY 2024. We received approximately 36 public comments on our proposal, including comments from large dialysis organizations, renal dialysis facilities, national renal groups, nephrologists, patient organizations, patients and care partners, health care systems; nurses, and other stakeholders.

In this final rule, we provide a summary of each proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing for the ESRD QIP.

We received numerous general comments on the ESRD QIP.

Comment: Commenters provided feedback on adding new measures to the QIP. Commenters' suggestions for new measures included a standardized mortality measure, outcome measures that can replace existing process measures, a measure of shared decision-making, two process measure for evaluating the share of patients receiving dialysis modality education (one measure focusing on education within 90 days of initiating dialysis and a second measure focusing on annual education). Another commenter recommended that CMS allow providers to test upcoming changes or software updates to CROWNWeb and the ESRD QIP system.

Response: We appreciate these comments and thank the commenters for their feedback. We will consider these comments for future rulemaking.

1. Improving Patient Outcomes and Reducing Burden Through the Meaningful Measures Initiative

Regulatory reform and reducing regulatory burden are high priorities for the Centers for Medicare & Medicaid Services (CMS). 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.[7] This initiative is one component of our agency-wide Patients Over Paperwork Initiative,[8] 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 will foster operational efficiencies and will reduce costs, including collection and reporting burden, while producing quality measurement that is more focused on meaningful outcomes.

The Meaningful Measures Initiative 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 discussed in the CY 2019 ESRD PPS proposed rule that we had identified 19 Meaningful Measures areas and mapped them to six overarching quality priorities as shown in Table 12.

TABLE 12—QUALITY PRIORITY ASSOCIATED WITH MEANINGFUL 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.

[7] Meaningful Measures webpage: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.html.*

[8] 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. Available at *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html.*

TABLE 12—QUALITY PRIORITY ASSOCIATED WITH MEANINGFUL 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 stated our belief 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 also stated that 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 as well as promoting operational efficiencies.

The comments and responses to the Meaningful Measure Initiative are set forth below.

Comment: Many commenters were pleased with our launch of the Meaningful Measures Initiative. One commenter expressed support for our aim to focus the Program on the highest priority areas for quality measurement and quality improvement. The commenter recommended that we differentiate between the ESRD QIP, a pay-for-performance or value-based purchasing (VBP) program, and Dialysis Facility Compare (DFC), a public reporting site. The commenter suggested that the relationship between these two programs is confusing and called on CMS to separate the programs clearly by using different measures in each program, using star ratings based on the ESRD QIP payment penalties, and improving the DFC website's functionality. Another commenter urged CMS to be cognizant of the unfunded regulatory burden on dialysis facilities to track and monitor QIP measures and recommended aligning measures in QIP with those in Dialysis Facility Reports (DFR), DFC, and Core Survey, suggesting that facility burden is significant, and using a single website such as the ESRD Quality Reporting System (EQRS) to track and report data for all programs. Another commenter appreciated our interest in focusing the Program on measures that improve quality care, drive improved patient health outcomes, and reduce administrative burdens on providers, but was concerned with the overlap between the ESRD QIP, the Five Star Program, and DFC. The commenter recommended that we streamline the ESRD QIP and reduce the Program's administrative burden and promote transparency.

Response: We appreciate and thank the commenters for their feedback and support of the Meaningful Measures Initiative, and we will consider this feedback in future rulemaking as we continue to examine our programs for opportunities to improve operational efficiencies and clinical efficacy. As part of the Meaningful Measures Initiative and our desire to reduce provider burden, we are working to align requirements across CMS quality programs where possible and we will consider ways to align the requirements for QIP, DFR, DFC, the Five Star Program, and Core Survey in future years.

In addition, we would like to clarify that the ESRD QIP and the Five Star Program have different objectives. The purpose of the ESRD QIP is to assign a payment penalty to facilities that do not meet national performance standards on quality measures. The purpose of Five Star Program is to provide patients with an easy way to assess quality of care, so they can make health care decisions or learn about their current dialysis facility. Analysis has shown that using the payment reduction categories developed for the QIP as a basis for assigning Star Ratings would result in over 80 percent of facilities receiving four or five stars. This would render the Five Star Program inadequate for being able to determine the differences between facilities and allowing patients to make informed choices about their health care. The ESRD QIP is designed to reduce Medicare payments to penalize facilities that do not meet national performance standards on quality measures. Because the national performance standards are set at the median performance level from a previous time period and national performance on quality measures has typically been stable or improving over time, the majority of facilities have historically tended to meet or exceed those standards in the aggregate and have not received receive a payment reduction. We believe, however, that a 5-star rating should indicate excellence. Awarding the highest star rating to facilities based solely on where their performance for a program year falls relative to the minimum total performance score used in the ESRD QIP would not allow patients to discern the difference between facilities and would not appropriately distinguish those facilities that are providing excellent care.

Comment: One commenter agreed that our VBP programs should assess those core issues that are most critical to providing high-quality care and restated its long support for a smaller QIP measure set. Another commenter appreciated our development of the Meaningful Measures objectives and quality priorities and expressed its agreement with the application of those priorities to the QIP. The commenter also appreciated the Initiative's call for alignment across programs, noting that dialysis patients see multiple health care providers and are frequently hospitalized. A third commenter was supportive of our goal to align the QIP more closely with the Meaningful Measures Initiative, and also stated its support for our efforts to account for social risk factors in the ESRD QIP. Another commenter expressed support for CMS's evaluation of each QIP measure in the context of improving outcomes and reducing burden.

Response: We thank the commenters for their support.

Comment: A commenter supported our work on the Meaningful Measures Initiative and suggested that the catheter >90 days measure is the most meaningful measure in the ESRQ QIP measure set because long-term catheter use is associated with poorer clinical outcomes.

Response: We thank the commenter for its support and feedback. We believe that all of the measures included in the QIP are meaningful.

Comment: A commenter supported our prioritization of regulatory reform and burden reduction, including through Meaningful Measures. The commenter supported the use of fewer, more meaningful measures in QIP and other programs and appreciated CMS's efforts to incorporate these concepts in its proposed policies.

Response: We thank the commenter for its support.

Comment: One commenter explained that development of a patient-reported outcome measure for dialysis is one of its priorities and suggested that it would be a worthwhile investment for CMS to explore the topic further.

Response: We thank the commenter for this suggestion and agree that patient reported outcomes are important to examining quality of care. We will consider the feasibility of developing such a measure along with our other quality measure development priorities.

Comment: One commenter explained that it did not believe that measures of Transfusion Ratios, Mortality, Hospitalizations/Readmissions, Pain Management, or Transplant Access are appropriate for the QIP because the outcomes assessed by measures on those topics are largely not within the control of facilities. However, the commenter acknowledged that the Meaningful Measures Initiative emphasizes the inclusion of measures covering significant outcomes, and that the avoidance of hospitalizations and mortality are significant outcomes. The commenter also acknowledged that including measures of hospitalizations and mortality is consistent with the Meaningful Measures Initiative, despite facilities' lack of control over those outcomes.

Response: We thank the commenter for this feedback. However, we continue to believe that shared responsibility for patients' health is an important feature of the ESRD QIP's quality measure set, and we therefore do not agree that these measures are inappropriate for the Program. We note that we have previously adopted measures that incorporate shared responsibility for patients' health across care settings, including the Standardized Hospitalization Ratio (SHR) and Standardized Readmission Ratio (SRR) measures. Though dialysis facilities may not have total control over patients' hospitalizations or readmissions, we have adopted those measures to highlight the shared responsibility that providers and suppliers have for ensuring that their patients remain healthy, which is an important clinical goal. We are continuing to build on this belief by adopting a measure of transplant waitlisting (discussed in more detail in section IV.C.1.a. of this final rule), which focuses on the responsibility shared by dialysis facilities and transplant centers for patient education about transplant options and maintaining patients' health status so that they are suitable for waitlisting. We view our efforts to improve health care quality through the adoption of cross-cutting quality measures as necessary to ensure that providers of all types have strong incentives to ensure their patients' continued health.

As we noted with respect to the SRR measures in the CY 2015 ESRD PPS final rule (79 FR 66177), while the specific causes of readmissions are multifactorial, our analyses supported the view that the dialysis facility exerts an influence on readmissions roughly equivalent to that exerted by the discharging acute care hospital. We continue to believe that the care coordination required for numerous ESRD QIP measures requires interaction between multiple care providers, and that quality measures spanning those providers' care will necessarily incorporate shared responsibility for improved clinical outcomes.

Comment: One commenter asked that we focus the QIP's measure set on dialysis adequacy, safety/bloodstream infections (BSIs), depression management, medication management, in-center hemodialysis consumer assessment of healthcare providers and systems (ICH CAHPS), and patient-reported outcomes, and suggested that we reduce the Program's measure set to ensure that facilities focus on those clinical topics.

Response: We thank the commenter for this feedback. We proposed to reduce the ESRD QIP's measure set specifically to ensure that facilities focus on the most relevant clinical topics. However, we do not believe that the subset of topics identified by the commenter represents the fullest possible picture of care quality in dialysis facilities.

We appreciate commenters' feedback on the Meaningful Measures Initiative and its application to the ESRD QIP.

2. Accounting for Social Risk Factors in the ESRD QIP

In the fiscal year (FY) 2018 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital Prospective Payment System (LTCH PPS) final rule (82 FR 38237 through 38239), 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 the Department of Health and Human Services, 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 CMS VBP programs.[10] As we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38237), ASPE's report to Congress found that, in the context of VBP programs, dual eligibility was the most powerful predictor of poor health care outcomes among those social risk factors that they examined and tested. In addition, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38237), 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 IPPS/LTCH PPS and CY 2018 ESRD PPS proposed rules for our quality reporting and VBP programs, we solicited feedback on which social

[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.*

risk factors provide the most valuable information to stakeholders and the methodology for illuminating differences in outcomes rates among patient groups within a hospital or 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 that could be used to stratify or risk adjust the measures (beyond dual eligibility); considering the full range of differences in patient backgrounds that might affect outcomes; exploring risk adjustment approaches; and offering 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 VBP programs, commenters also cautioned 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 VBP program measure selection, domain weighting, performance scoring, and payment methodology must account for social risk.

As a next step, CMS is 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 VBP 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.

The comments on social risk factors in the ESRD QIP, as well as our responses to those comments, are set forth below.

Comment: Some commenters appreciated our exploration of social risk factor adjustments and reiterated their support for evaluating social risk factors' impact on measuring dialysis facility performance. Commenters suggested that stratifying performance reporting for each dialysis facility by social risk factors known to influence measure performance may help illuminate outcomes disparities in dialysis facilities. Commenters also recommended that we provide support through quality improvement activities to facilities with lower quality performance and high proportions of patients with social risk factors, potentially through the ESRD Networks. However, commenters recommended against adopting any social risk factor adjustment due to the risk of masking poor performance and because they believe that risk adjustment may discourage additional improvement efforts.

Response: We thank the commenters for their support and will take their recommendations on stratifying performance under advisement. We agree with the commenters' recommendation about providing support to dialysis facilities through quality improvement activities, such as promoting best practices for performance on ESRD QIP quality measures, and we will continue to do so to the greatest extent feasible. We also share the commenters' concern about masking poor performance rates via social risk factors adjustment and will continue to consider our options on this topic.

Comment: One commenter recommended assessing four measures for sociodemographic status (SDS) risk factors regardless of whether they are expressed as a rate or ratio: SRR, standardized transfusion ratio (STrR), standardized mortality ratio, and SHR. The commenter stated that evidence shows that patient-level SDS factors affect performance on these measures in other settings.

Response: We thank the commenter for these specific suggestions and will continue to consider our options on this topic.

Comment: One commenter suggested assessing whether a patient's insurance status at the start of his or her dialysis treatment should be applied to the arteriovenous fistula (AV fistula) clinical measure and the catheter > 90 days clinical measure. The commenter noted that patients who are uninsured when their dialysis treatment begins may have had trouble obtaining appropriate pre-dialysis care from a nephrologist. The commenter further noted that while the QIP makes some allowances for the care that dialysis patients initially receive, additional review of insurance status is appropriate.

Response: We thank the commenter for this suggestion and will consider it as we continue to examine this issue.

Comment: One commenter was concerned about the possibility that facilities may be discouraged from accepting patients with social risk factors if measures are not risk-adjusted to account for such factors. The commenter was also concerned that facilities could be discouraged from opening or maintaining service in areas where patients with social risk factors reside and suggested that we consider a reward-based incentive for facilities that improve outcomes in populations with social risk factors.

Response: We thank the commenter for this feedback and will consider whether any of its suggestions are feasible and within the scope of our statutory authority as we further examine whether social risk factors should be accounted for in the ESRD QIP. We do not agree that incorporating social risk factors into the Program will discourage facilities from accepting patients who have those factors. We are committed to ensuring that the interests of consumers are put first and we expect providers to do the same. We encourage the commenter to contact the U.S. Department of Health and Human Services, Office for Civil Rights to submit a formal complaint if it believes that dialysis patients are being discriminated against.

Comment: A commenter requested that we consider additional social risk factors for pediatric patients, including race, ethnicity, insurance status, and other socioeconomic factors, as well as school attendance, academic performance, and peer interactions. The commenter also suggested that we consider additional factors for parents and other primary caregivers, including employment status, financial burden of a chronically ill dependent child, and levels of fatigue and caregiver burn-out. The commenter also noted that pediatric patients may face disparities in access to care when they are displaced by natural disasters.

Response: We thank the commenter for these suggestions and will take them into account as we continue analyzing

whether social risk factors should be accounted for in the ESRD QIP.

Comment: A commenter suggested studying the following SDS factors to determine whether and to what extent they affect patient outcomes: income (for example, dual eligibility/low-income subsidy), race and ethnicity, insurance status at dialysis initiation, and geographic area of residence. The commenter offered to work with CMS to identify additional SDS factors that affect patient outcomes. The commenter also suggested that CMS use its dual eligibility/low-income subsidy data and geographic area of residence data as additional data points for social risk factors adjustment. The commenter also recommended using patient self-reporting to collect data for race/ethnicity. Another commenter suggested that we consider developing a temporary risk-adjustment policy based on our experience with risk adjustment for dual-eligible patients in the Medicare Advantage Program.

Response: We thank the commenters for these suggestions and will take them into account as we continue to examine this issue. We also note that we will continue to welcome input from all stakeholders on this important topic.

Comment: A commenter expressed support for our efforts to assess and account for social risk factors in the QIP through adjusters and other mechanisms. The commenter agreed that providers and suppliers should be assessed fairly, without masking potential disparities or creating disincentives to care for more medically complex patients.

Response: We thank the commenter for its feedback.

Comment: A commenter supported the elimination of health disparities and noted that health disparities are particularly pronounced in the kidney patient population, where African Americans are four times as likely and Latino Americans are twice as likely to have kidney disease. The commenter encouraged CMS to revisit the commenter's recommendations related to improving health equity that were submitted in response to the CY 2018 ESRD PPS proposed rule.

Response: We thank the commenter for its suggestions and recommendations submitted in response to the CY 2018 ESRD PPS proposed rule, to which we responded in the CY 2018 ESRD PPS final rule (82 FR 50759). In that final rule, we stated that we intend to consider all suggestions as we continue to assess each measure and the overall Program. We will continue to take these suggestions into account as we continue to examine health disparities and health equity.

Comment: A commenter suggested not applying SDS factors to three measures: the Kt/V Dialysis Adequacy Comprehensive clinical measure, the Hypercalcemia clinical measure, and the New Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure. The commenter believed that no evidence shows that SDS factors affect performance on these measures. Another commenter suggested not adjusting the NHSN BSI in Hemodialysis Patients clinical measure for SDS factors. Another commenter suggested not adjusting the QIP's reporting measures for SDS factors. The commenter stated that the purpose of reporting measures is to assess whether the facility has reported the required data, rather than assessing patient outcomes.

Another commenter acknowledged the importance of trying to account for social risk factors through risk adjustment in the Program but expressed concern that those adjustments could have unintended consequences on the quality of care received in dialysis facilities. The commenter recommended that CMS ensure that patients continue receiving the highest standards of care and acknowledge the challenges associated with capturing data for Program measures under the current systems.

Response: We thank the commenters for these suggestions and will take them into account as we continue analyzing the social risk factors topic.

Comment: A commenter suggested that we review and make publicly available the data needed to determine the effect of SDS factors on the ICH CAHPS Survey clinical measure. The commenter believed that the effect of SDS factors on the survey's response rate is unknown. Another commenter was uncertain about the effects of SDS adjustment on the ICH CAHPS Survey and requested that we study the issue further.

Response: We thank the commenters for this feedback. Education is included as a case mix adjuster for the ICH CAHPS Survey. We are currently examining the effects of other social risk factors on ICH CAHPS Survey responses and will provide as much information as possible to the public as these results are finalized.

Comment: A commenter offered to assist CMS in assessing the effects of SDS factors, such as geography, biological factors, and demographic factors, on transplantation measures. The commenter believed that factors such as regional differences may affect transplantation access and eligibility, and therefore may affect waitlist placement.

Response: We always welcome feedback from all stakeholders on these and other issues related to the ESRD QIP.

Comment: A commenter recommended that we continue studying ESRD QIP measures for appropriate social risk factors adjustment. The commenter specifically suggested that we consider such adjustments for the SRR, STrR, and SHR measures, as well as the vascular access type (VAT) measures (for insurance status at time of dialysis initiation). However, the commenter recommended against adjustment for the Kt/V Dialysis, Hypercalcemia, and NHSN BSI clinical measures, and the reporting measures. The commenter also requested that we study the effects of SDS factors on measures of transplantation.

Response: We thank the commenter for this feedback and will take it into account as we continue to examine this issue.

Comment: One commenter questioned the ASPE report's conclusion that dual-eligible status is the strongest predictor of disparate clinical outcomes, noting that many patients with dual Medicare and Medicaid coverage have access to social services that patients without Medicaid coverage do not. The commenter suggested that CMS evaluate additional data points on social risk factors such as mental health status and income ranges.

Response: We thank the commenter for this feedback and acknowledge that there are other critical social risk factors that should be considered. However, as noted in the ASPE report, our analyses are limited to the social risk factors available in Medicare claims data. We will continue to examine other social determinants of health as additional social risk factor data are made available.

3. Updated Regulation Text for the ESRD QIP

In the CY 2019 ESRD PPS proposed rule (83 FR 34336), we proposed to codify a number of previously adopted requirements for the ESRD QIP in our regulations by revising § 413.177 and adopting a new § 413.178. We stated that codification of these requirements would make it easier for the public to locate these requirements, and that proposed § 413.178 would codify the following:

- Definitions of key terms used in the ESRD QIP;

- Rules for determining the applicability of the ESRD QIP to facilities, including new facilities;
- Measure selection;
- Rules governing performance scoring, including how we calculate the total performance score;
- Our process for making ESRD QIP performance information available to the public; and
- The limitation on administrative and judicial review.

We also stated that revised § 413.177(a) would codify that an ESRD facility that does not earn enough points under the ESRD QIP to meet or exceed the minimum total performance score established for a payment year would receive up to a 2 percent reduction to its otherwise applicable payment amount under the ESRD PPS for renal dialysis services furnished during that payment year.

We invited public comments on the proposed regulation text.

The comments and our responses to our regulation text proposals are set forth below.

Comment: One commenter suggested including a reference in the performance standards definition to the 50th percentile of national performance during the baseline period for the performance year, similar to its inclusion in the attainment threshold and benchmark definitions.

Response: We thank the commenter for the suggestion. However, we disagree with the commenter's suggestion to include a reference in the performance standards definition to the 50th percentile of national performance during the baseline period for the performance year. As initially defined in the PY 2012 ESRD QIP final rule (76 FR 629 through 631), the performance standards term applies more broadly to levels of achievement and improvement and is not a specific reference to the 50th percentile of national performance.

Comment: One commenter suggested that CMS revise the clinical and reporting measure definitions proposed to be codified at § 413.178(a)(4) and (a)(13), respectively, and reclassify the QIP's measures using terms more widely used in the community—structural, process, outcomes, access, and efficiency—in future rulemaking. The commenter expressed concern that the proposed definitions could be manipulated and suggested defining outcome measures as clinical measures and structural measures as reporting measures. The commenter also suggested clarifying in the scoring section that paragraphs (d)(1)(i) through (iii) describe the scoring for clinical measures and that paragraph (d)(1)(iv) describes the scoring for reporting measures.

Response: We disagree with the commenter's suggestion to reclassify the Program's measures because the Program's current measure classification—reporting and clinical—represents the way in which the Program measures are scored and are Program specific. The commenters suggested classification system—structural, process, outcome, access, and efficiency—describe individual measure goals in terms of quality assessment.

We also disagree with the commenter's suggestion to add clarifying language to the scoring section to differentiate between scoring for clinical measures and reporting measures; each paragraph in § 413.178(d)(1) specifies whether the scoring methodology described in that paragraph applies to clinical measures or reporting measures.

Comment: A commenter expressed concern that that the proposed language to be codified at § 413.178(c) deviates from the statutory text at 42 U.S.C. 1395rr(h)(2). The commenter also expressed concern that CMS has not referenced the patient satisfaction provision in the language proposed to be codified. The commenter also expressed concern that CMS has not proposed to codify the requirement that the QIP use measures that are NQF-endorsed unless the exception applies. The commenter suggested that the regulatory text state that if NQF has reviewed but not endorsed a measure, then the exception does not apply.

Response: We thank the commenter for this feedback. We have revised the regulation text in § 413.178(c)(3) to reflect the statutory requirement to include a patient satisfaction measure to the extent feasible. However, we disagree that the regulatory text should state that if the NQF has reviewed but not endorsed a measure, then the exception that allows us to adopt a measure that has not been endorsed by the NQF should not apply. Section 1881(h)(2)(B) of the Act does not limit us to using only NQF-endorsed measures in the Program. Rather, that section allows us, in the case of a specified area or medical topic determined appropriate for which a feasible and practical measure has not been endorsed, to specify a measure that is not so endorsed as long as we give due consideration to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We do not believe it would be in the best interest of the Program to limit our ability to adopt measures that are not NQF-endorsed if, for example, they address significant clinical topics (as outlined by the priorities we described under the Meaningful Measures Initiative in section IV.B.1 of this final rule), or if they otherwise present significant opportunities for care quality improvement in dialysis facilities.

Comment: A commenter raised concerns that the proposed regulatory text that would be codified at § 413.178(d) does not reflect current scoring policies. The commenter suggested removing 0 as an achievement score option at paragraph (d)(i), noting that the FY 2019 Program details show that a facility with a measure performance below the achievement threshold receive an achievement score of 0 points, a facility with a measure performance that falls within the range receives an achievement score of 1 to 9 points, and a facility with a measure performance at or above the benchmark receives an achievement score of 10 points. The commenter also suggested clarifying at paragraph (d)(ii) that 0 points is provided as an option for scoring achievement for facilities whose performance falls below their comparison rate. The commenter also raised concerns that the references in paragraph (d)(iv) are very general and that the Program details recommend including reporting measure requirements in the rule. The commenter suggested that the regulatory text refer the reader to the location of the specific requirements if the Program details cross-reference remains.

Response: We thank the commenter for this feedback. However, we would like to clarify that the proposed regulation text at § 413.178(d)(1)(i) states that we will award between 1 and 9 points for achievement to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds the achievement threshold but is less than the benchmark. Facilities whose performance on a measure does not meet or exceed the achievement threshold for that measure will not be awarded between 1 and 9 points; they will instead be awarded 0 points for that measure, because their performance does not fall within the specified range.

We would also like to clarify that the language that we proposed at § 413.178(d)(1)(ii) is intended to capture situations where a facility's performance on a measure does not improve from the comparison period. By stating that we will award between 0 and 9 points for improvement, we believe we have appropriately captured that possibility.

Comment: A commenter expressed concern about the regulatory text

proposing to codify the recent changes to the performance score certificate (proposed § 413.178(e)(3)). The commenter raised concerns about including only the total performance score (TPS) on the revised performance score certificate (PSC). The commenter stated that the DFC website—where detailed information is available—needs improvement, that many patients may not have internet access, and past inclusion of more detailed information on the PSC has created an expectation among patients that they can view detailed information on the PSC. The commenter suggested that the PSC is difficult to read because QIP does not use a parsimonious set of measures.

Response: We thank the commenter for this feedback. We finalized changes to the PSC in the CY 2018 ESRD PPS final rule (82 FR 50759 through 50760), and we did not address this topic in the CY 2019 ESRD PPS proposed rule. However, we will take this feedback into consideration in future years.

Final Rule Action: After consideration of the public comments we received, we are finalizing our proposed regulation text with revisions to more clearly reflect previously finalized ESRD QIP policies. Specifically, we are revising the regulation text at § 413.178(c) to more clearly incorporate the requirement at section 1881(h)(2)(A) of the Act that the ESRD QIP measure set include, to the extent feasible, a measure (or measures) of patient satisfaction. We are also revising our proposed regulations text to include two new additional paragraphs at § 413.178(d)(1)(ii) and (d)(1)(iv) to clarify that we will award zero points for achievement on a clinical measure to each facility whose performance falls below the achievement threshold for that measure, and that we will award zero points for improvement on a clinical measure to each facility whose performance falls below the improvement threshold for that measure. We are renumbering the provisions in the proposed paragraph (d)(1) to accommodate these new paragraphs.

Update to Requirements Beginning with the PY 2021 ESRD QIP

1. Updates to the PY 2021 Measure Set

In the CY 2019 ESRD PPS proposed rule (83 FR 34336–34340), we proposed to refine and update the criteria for removing measures from the ESRD QIP measure set, and for consistency with the terminology we are adopting for other CMS quality reporting and VBP programs, stated that we would now refer to these criteria as factors. We also proposed to remove four of the reporting measures that we previously finalized for the PY 2021 ESRD QIP measure set. Table 13 summarizes the proposed revisions to the PY 2021 ESRD QIP measure set, and we discuss the measure removal proposals in section IV.B.1.c of this final rule.

TABLE 13—PROPOSED REVISIONS TO THE PREVIOUSLY FINALIZED PY 2021 ESRD QIP MEASURE SET

NQF #	Measure title and description	Measure continuing in PY 2021
0258	ICH CAHPS Survey Administration, a clinical measure ..... Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple testing tools.	Yes.
2496	Standardized Readmission Ratio (SRR), a clinical measure ..... Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.	Yes.
2979	Standardized Transfusion Ratio (STrR), a clinical measure ..... Risk-adjusted TrR for all adult Medicare dialysis patients ..... Number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.	Yes.
N/A	A measure of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume (Kt/V) Dialysis Adequacy Comprehensive, a clinical measure. Percentage of all patient months for patients whose delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.	Yes.
2977	Hemodialysis Vascular Access: Standardized Fistula Rate clinical measure ..... Measures the use of an AV fistula as the sole means of vascular access as of the last hemodialysis treatment session of the month.	Yes.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure ..... Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.	Yes.
1454	Hypercalcemia, a clinical measure ..... Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.	Yes.
1463*	Standardized Hospitalization Ratio (SHR), a clinical measure ..... Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.	Yes.
0255	Serum Phosphorus, a reporting measure. Percentage of all adult (≥18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum of plasma phosphorus measured at least once within month.	Proposed for Removal.
N/A	Anemia Management Reporting, a reporting measure. Number of months for which facility reports erythropoiesis-stimulating agent (ESA) dosage (as applicable) and hemoglobin/hematocrit for each Medicare patient, at least once per month.	Proposed for Removal.
Based on NQF #0420.	Pain Assessment and Follow-Up, a reporting measure. Facility reports in CROWNWeb one of six conditions for each qualifying patient once before August 1 of the performance period and once before February 1 of the year following the performance period.	Proposed for Removal.
Based on NQF #0418.	Clinical Depression Screening and Follow-Up, a reporting measure ..... Facility reports in CROWNWeb one of six conditions for each qualifying patient treated during performance period.	Yes.

TABLE 13—PROPOSED REVISIONS TO THE PREVIOUSLY FINALIZED PY 2021 ESRD QIP MEASURE SET—Continued

NQF #	Measure title and description	Measure continuing in PY 2021
Based on NQF #0431.	National Healthcare Safety Network (NHSN) Healthcare Personnel Influenza Vaccination, a reporting measure. Facility submits Healthcare Personnel Influenza Vaccination Summary Report to the Centers for Disease Control and Prevention's (CDC's) NHSN system, according to the specifications of the Healthcare, Personnel Safety Component Protocol by May 15 of the performance period.	Proposed for Removal.
N/A	Ultrafiltration Rate, a reporting measure ..... Number of months for which a facility reports elements required for ultrafiltration rates for each qualifying patient.	Yes.
Based on NQF #1460.	NHSN Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure ..... The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.	Yes.
N/A	NHSN Dialysis Event reporting measure ..... Number of months for which facility reports NHSN Dialysis Event data to CDC	Yes.

Comment: Numerous commenters provided feedback on various aspects of measures that are continuing in PY 2021. These comments included recommendations to keep or remove continuing measures from the Program, recommendations to modify continuing measures (for example, by revising their exclusions), and recommendations to reduce the provider burden associated with continuing measures (for example, by changing the administration of the ICH CAHPS Survey).

Response: We thank the commenters for their feedback. We note that these comments are not responsive to a proposal included in the CY 2019 ESRD PPS proposed rule, and therefore, are considered beyond the scope of the proposed rule. We refer readers to the CY 2018 ESRD PPS final rule (82 FR 50767 through 50769), the CY 2017 ESRD PPS final rule (81 FR 77898 through 77906), and the CY 2016 ESRD PPS final rule (80 FR 69052 through 69053) for public comments on measures that we have previously adopted for the ESRD QIP and our responses.

a. Refinement and Update to the Factors Used for ESRD QIP Measure Removal

Under our current policy, we consider an ESRD QIP measure for removal or replacement if: (1) Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made; (2) performance or improvement on a measure does not result in better or the intended patient outcomes; (3) a measure no longer aligns with current clinical guidelines or practice; (4) a more broadly applicable (across settings, populations, or conditions) measure for the topic becomes available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available; (6) a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available; or (7) collection or public reporting of a measure leads to negative or unintended consequences (77 FR 67475). In the CY 2015 ESRD PPS final rule, we adopted statistical criteria for determining whether a clinical measure is topped out, and adopted a policy under which we could retain an otherwise topped-out measure if we determined that its continued inclusion in the ESRD QIP measure set would address the unique needs of a specific subset of the ESRD population (79 FR 66174). In the CY 2013 ESRD PPS final rule (77 FR 67475), we finalized that we would generally remove an ESRD QIP measure using notice and comment rulemaking, unless we determined that the continued collection of data on the measure raised patient safety concerns. In that case, we stated that we would promptly remove the measure and publish the justification for the removal in the **Federal Register** during the next rulemaking cycle. In addition, we stated that we would immediately notify ESRD facilities and the public through the usual communication channels, including listening sessions, memos, email notification, and Web postings.

In order to align with terminology we are adopting for use across a number of quality reporting and pay for performance programs, we stated in the CY 2019 ESRD PPS proposed rule (83 FR 34338) that we would now refer to these criteria as ''factors'' rather than ''criteria.'' We also proposed to update these measure removal factors so that they are more closely aligned with the factors we have adopted or proposed to adopt for other quality reporting and pay for performance programs, as well as the priorities we have adopted as part of our Meaningful Measures Initiative. Specifically, we proposed to combine current Factors 4 and 5 (proposed new Factor 4), and we proposed to adjust the numbering of subsequent factors to account for this change. We also proposed to add a new factor for measures where it is not feasible to implement the measure specifications; we would refer to this new factor as Factor 7. The proposed Factors 1 through 7 are as follows:

- Factor 1. Measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made (for example, the measure is topped-out).
- Factor 2. Performance or improvement on a measure does not result in better or the intended patient outcomes.
- Factor 3. A measure no longer aligns with current clinical guidelines or practice.
- Factor 4. A more broadly applicable (across settings, populations, or conditions) measure for the topic or a measure that is more proximal in time to desired patient outcomes for the particular topic becomes available.
- Factor 5. A measure that is more strongly associated with desired patient outcomes for the particular topic becomes available.
- Factor 6. Collection or public reporting of a measure leads to negative or unintended consequences.
- Factor 7. It is not feasible to implement the measure specifications.

We stated that we believe these proposed updates would better ensure that we use a consistent approach across our quality reporting and VBP programs when considering measures for removal, and that they reflect the considerations we have long used when evaluating measures for removal from the ESRD QIP. However, even if one or more of the measure removal factors applies, we stated that we might 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 result in poor quality, or in the event that a given measure is statutorily required. Furthermore, consistent with other quality reporting programs, we proposed to apply these factors on a case-by-case basis.

We invited public comment on these proposals. The comments and our responses to those comments are set forth below.

Comment: A commenter supported measure removal factors 1 through 8. The commenter urged CMS to include stakeholders in decisions related to factor 8 removal.

Response: We thank the commenter for its support and note that we always welcome feedback from all stakeholders regarding our policies for the ESRD QIP. We also note that we would propose to remove any measures under Factor 8 through notice and comment rulemaking, thereby allowing opportunities for stakeholders to participate in decisions related to that factor.

Comment: A commenter expressed support for Factors 1, 2, 3, 6, 7, and 8 as well as the proposed list of costs that CMS would consider for Factor 8. The commenter suggested that Factors 4 and 5 be revised to state that ''become available'' means that the replacement has been tested for patients with ESRD and at the dialysis facility level.

Response: We thank the commenter for its support. Our intention is to adopt measures that have been tested for patients with ESRD and at the dialysis facility level. This policy is consistent with our policy to only adopt measures that are reliable and valid. We note that we can remove a measure without a replacement using other measure removal factors.

Comment: A commenter supported our adjustments to the measure removal factors. Two commenters encouraged us to consider adding an additional factor for measures that do not meet NQF's scientifically-accepted measure evaluation and testing criteria. One of those commenters noted that the QIP includes several measures that NQF has rejected and suggested that their inclusion is inconsistent with our statutory authority.

Response: We thank the commenter for its support. Although we acknowledge that there are some QIP measures that are not currently NQF-endorsed, we note that we have statutory discretion to include such measures in the QIP where there is no feasible or practical NQF-endorsed measure on a topic that we have determined appropriate as long as we give due consideration to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

Comment: A commenter stated general agreement with the proposed measure removal factors and expressed appreciation that they align with factors in other programs. The commenter also suggested that we continue to require CROWNWeb reporting of measures that have been removed from the ESRD QIP due to topped-out status for at least 3 years in order to monitor unintended changes in performance.

Response: We appreciate the commenter's feedback. We agree that we should strive to prevent unintended consequences related to the removal of a QIP measure, and we currently monitor for such consequences through our usual monitoring and evaluation activities.

Comment: A commenter supported our proposal to add additional measure removal factors to the ESRD QIP.

Response: We thank the commenter for this support.

Comment: A commenter expressed strong support for including the new measure removal factors and agreed that topped out measures should be removed. However, the commenter believed that the current definition of topped-out is too stringent and not patient centered. The commenter suggested revising CMS's mathematical definition to allow for a measure that is clinically topped out to remain in the QIP if the removal of that measure would discourage facilities from incorporating patient preference into their care decisions.

Response: We thank the commenter for its support. We also carry that in the CY 2015 ESRD PPS final rule, we adopted a policy under which we could retain an otherwise topped-out measure if we determined that its continued inclusion in the ESRD QIP measure set would address the unique needs of a specific subset of the ESRD population (79 FR 66174). We believe that this policy provides us sufficient flexibility to continue using a measure that might be topped-out according to our statistical criteria but otherwise addresses an important aspect of clinical quality for the ESRD population.

Comment: A commenter expressed concern with the proposal that would allow CMS to retain a measure even if the measure otherwise qualified for removal under one of the proposed measure removal factors. The commenter believed that the purpose of the measure removal factors is to provide predictability and consistency among programs, and that retaining a measure that satisfies one of the measure removal factors would undermine those goals.

Response: We understand the commenter's concern. However, we may have strong justification for continuing to use a measure that satisfies one of the measure removal factors and that this justification may outweigh removing the measure from QIP. We also note that unless a measure needed to be immediately removed for patient safety reasons, we intend to continue making measure removal decisions for the ESRD QIP through rulemaking, and we believe that this process provides sufficient predictability for facilities and consistency among our programs.

Comment: A commenter recommended that CMS utilize a consistent numbering sequence for the measure removal factors across all of its programs and that all of the measure removal factors be standardized. The commenter stated that ESRD QIP, Hospital VBP, Inpatient Quality Reporting, and PPS-Exempt Cancer Hospital Quality Reporting; and Inpatient Psychiatric Facilities Quality Reporting Programs have a removal factor (measure is not feasible to implement as specified) not included in the other programs. The commenter believed that inconsistent numbering and removal factors across programs may contribute to confusion and add to the burden of managing and reviewing rules.

Response: We thank the commenter for this feedback. Our proposals in the CY 2019 ESRD PPS proposed rule were intended to conceptually align our measure removal factors across our programs. While we have attempted to align the numbering and language of the measure removal factors across programs, we acknowledge that the ESRD QIP's measure removal factors have minor, non-substantive differences in language and numbering when compared to HIQR, HVBP, PCHQR, and IPFQR.

Final Rule Action: After considering public comments, we are finalizing the updates to the existing measure removal factors as proposed.

b. New Measure Removal Factor

In the CY 2019 ESRD QIP proposed rule (83 FR 34338 through 34339), we proposed to adopt an additional factor to consider when evaluating measures for removal from the ESRD QIP measure set: Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the Program.

As we discuss in the CY 2019 ESRD PPS proposed rule (83 FR 34338 through 34339), with respect to our new ''Meaningful Measures Initiative,'' we are engaging in efforts to ensure that the ESRD QIP 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) Provider, supplier and clinician information collection burden and related cost and burden associated with the submission/reporting of quality measures to CMS; (2) provider, supplier and clinician cost associated with complying with other quality programmatic requirements; (3) provider, supplier and clinician cost associated with participating in multiple quality programs, and tracking multiple similar or duplicative measures within or across those programs; (4) CMS cost associated with the Program oversight of the measure, including measure maintenance and public display; and (5) provider, supplier 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 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 needed 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.

We stated in the CY 2019 ESRD PPS proposed rule (83 FR 34338 through 34339) that when these costs outweigh the evidence supporting the continued use of a measure in the ESRD QIP, we believe it may be appropriate to remove the measure from the Program. Although we recognize that one of the main goals of the ESRD QIP is to improve beneficiary outcomes by incentivizing health care providers to focus on specific care issues and making public data related to those issues, we also recognize that those goals can have limited utility where, for example, the publicly reported data are of limited use because they cannot be easily interpreted by beneficiaries to influence their choice of providers. In these cases, we stated our belief that removing the measure from the ESRD QIP 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 stated that 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. We stated that our goal is to move the Program forward in the least burdensome manner possible, while maintaining an appropriately sized 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, ''the costs associated with a measure outweigh the benefit of its continued use in the Program,'' beginning with PY 2021.

Comment: A commenter urged us to consider that the benefits of a measure's continued use in the ESRD QIP may not be the same for the agency, providers, and patients when assessing whether a measure's costs outweigh the benefits of its continued use in the Program. The commenter stated that some facilities struggle to participate fully in the Program because the Program does not include pediatric-specific measures and pediatric dialysis patients are excluded from the calculation of most QIP measures. The commenter stated that facilities that furnish dialysis mainly to pediatric patients might benefit from the retention of measures that impose costs to other stakeholders because the retention of those measures would enlarge the overall number of measures that these facilities can report.

Response: We thank the commenter for this suggestion, and we agree. We intend to balance the costs with the benefits to a variety of stakeholders. These stakeholders include, but are not limited to, patients and their families or caregivers, providers, the healthcare research community, healthcare purchasers, and patient and family advocates. Because for each measure the relative benefits to each stakeholder may vary, we believe that the benefits to be evaluated for each measure are specific to the measure and the original rationale for including the measure in the Program.

We also understand that while a measure's use in the ESRD QIP may benefit many entities, the primary benefit is to patients and caregivers through incentivizing the provision of high quality care and through providing publicly reported data regarding the quality of care available. One key aspect of patient benefits is assessing the improved beneficiary health outcomes if a measure is retained in our measure set. We believe that these benefits are multifaceted and are illustrated through the domains of the Meaningful Measures Initiative. When the costs associated with a measure outweigh the evidence supporting the benefits to patients with the continued use of a measure in the ESRD QIP, we believe it may be appropriate to remove the measure from the Program.

Final Rule Action: After considering public comments, we are finalizing Measure Removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the Program, as proposed, for use in the ESRP QIP, beginning with PY 2021.

c. Removal of Four Reporting Measures

As we discussed in the CY 2019 ESRD PPS proposed rule (83 FR 34339), we have undertaken efforts to review the existing ESRD QIP measure set in the context of the Meaningful Measures Initiative. Based on that analysis and our evaluation of the Program's measures, we proposed to remove four measures previously adopted for the ESRD QIP, starting with PY 2021. We stated that if these proposals are finalized, facilities would no longer be required to report data specific to these measures beginning with January 1, 2019 dates of service. The four measures we proposed to remove from the ESRD QIP measure set are:

- Healthcare Personnel Influenza Vaccination.
- Pain Assessment and Follow-Up.
- Anemia Management.
- Serum Phosphorus.

Removal of the Healthcare Personnel Influenza Vaccination Reporting Measure From the ESRD QIP Measure Set

In the CY 2015 ESRD PPS final rule, we adopted the Healthcare Personnel Influenza Vaccination reporting measure in the ESRD QIP measure set beginning with PY 2018 because we recognize that influenza immunization is an important public health issue and that vaccinating healthcare personnel against influenza can help to protect healthcare personnel and their patients

(79 FR 66206 through 66208). We stated in the CY 2019 ESRD PPS proposed rule (83 FR 34339) that we continue to believe that the Healthcare Personnel Influenza Vaccination measure provides the benefit of protecting patients against influenza. However, we stated that our analysis of CY 2016 data indicates that ESRD facility performance on the measure was consistently high; 98 percent of ESRD facilities received the highest possible score on the measure (10 points) and the remaining 2 percent received no score on the measure because they did not report the required data. We stated that this finding indicates that influenza vaccination of healthcare personnel in ESRD facilities is a widespread practice and that there is little room for improvement on this measure. Accordingly, we proposed to remove this measure from the ESRD QIP measure set beginning with PY 2021 under Factor 1 (measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made).

Removal of the Pain Assessment and Follow-Up Reporting Measure From the ESRD QIP Measure Set

In the CY 2015 ESRD PPS final rule, we adopted the Pain Assessment and Follow-Up reporting measure beginning with PY 2018 (79 FR 66203 through 66206) because patients with ESRD frequently experience pain that has a debilitating impact on their daily lives, and research has shown a lack of effective pain management strategies in place in dialysis facilities. We stated in the CY 2019 ESRD PPS proposed rule (83 FR 34339) that we continue to believe that effective pain management is an important component of the care received by ESRD patients. However, our analysis of CY 2016 data indicates that with respect to that year, 90 percent of ESRD facilities received the highest possible score on the measure (10 points) and 1 percent of ESRD facilities received no score on the measure. We stated that this finding indicates that documentation of pain management using a standardized tool, as well as documentation of a follow-up plan where pain is present, are widespread practices in ESRD facilities and that there is little room for improvement on the measure. Accordingly, we proposed to remove this measure from the ESRD QIP measure set based on our proposed Factor 1 (measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made).

Removal of the Anemia Management Reporting Measure From the ESRD QIP Measure Set

In the CY 2013 ESRD PPS final rule, we adopted the Anemia Management reporting measure beginning with the PY 2015 ESRD QIP (77 FR 67491 through 67495) because we believe that it is important to monitor hemoglobin levels in patients to ensure that anemia is properly treated. Additionally, we stated that the measure's adoption fulfilled the statutory requirement at section 1881(h)(2)(A)(i) of the Act that the ESRD QIP include measures on anemia management that reflect labeling approved by the Food and Drug Administration (FDA) for such management. Additionally, in the CY 2015 ESRD PPS final rule (79 FR 66192 through 66197), we adopted the NQF-endorsed Standardized Transfusion Ratio (STrR) measure beginning with PY 2018 to ensure that patients with ESRD are not negatively affected by underutilization of ESAs, with the result that these patients have lower achieved hemoglobin levels and more frequently need red-blood-cell transfusions. We stated that there is a strong association between achieved hemoglobin levels and subsequent transfusion events, and that facilities have a direct role in determining achieved hemoglobin as a result of their anemia management practices (79 FR 66194). We also noted that the STrR measure meets the requirement at section 1881(h)(2)(A)(i) of the Act for the ESRD QIP to adopt measures of anemia management that reflect the labeling approved by the Food and Drug Administration for such management.

In the CY 2019 ESRD PPS proposed rule (83 FR 34339), we stated that our analysis of CY 2016 data indicates that ESRD facility performance on the Anemia Management reporting measure was consistently high; 96 percent of ESRD facilities received the highest possible score on the measure (10 points). This finding indicates that facility tracking of hemoglobin values and, as applicable, ESA dosages, is widely performed among ESRD facilities and that there is little room for improvement on the measure.

We therefore proposed to remove the Anemia Management reporting measure from the ESRD QIP measure set based on Factor 1 (measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made).

Removal of the Serum Phosphorus Reporting Measure From the ESRD QIP Measure Set

In the CY 2014 ESRD PPS final rule, we adopted the Hypercalcemia measure beginning with the PY 2016 ESRD QIP (78 FR 72200 through 72203) as a measure of bone mineral metabolism. Specifically, this measure assesses the number of patients with uncorrected serum calcium greater than 10.2 mg/dL for a 3-month rolling average. In the CY 2017 ESRD PPS final rule (81 FR 77876 through 77879), we finalized two modifications to the measure's technical specifications, as recommended during the measure maintenance process at the NQF, beginning with PY 2019. First, we added plasma as an acceptable substrate in addition to serum calcium. Second, we amended the denominator definition to include patients regardless of whether any serum calcium values were reported at the facility during the 3-month study period. These changes ensure that, beginning with PY 2019, the measure aligns with the NQF-endorsed measure.

In the CY 2017 ESRD PPS final rule, we adopted a second measure of bone mineral metabolism, beginning with PY 2020: the Serum Phosphorus reporting measure (81 FR 77911 through 77912). This measure evaluates the extent to which facilities monitor and report patient phosphorus levels.

In the CY 2019 ESRD PPS proposed rule (83 FR 34340), we stated that while we consider both the Hypercalcemia measure and the Serum Phosphorus measure to be measures of bone mineral metabolism, the two measures track different minerals. Hypercalcemia measures calcium levels and Serum Phosphorus measures phosphorus levels. Numerous studies have associated disorders of mineral metabolism with morbidity, including fractures, cardiovascular disease, and mortality. Overt symptoms of these abnormalities often manifest in only the most extreme states of calcium-phosphorus dysregulation (81 FR 77911).

As a result of the NQF's 2017 re-endorsement of the Hypercalcemia measure, as well as the Hypercalcemia measure's focus on clinical factors that are more directly under the facility's control, we stated in the CY 2019 ESRD PPS proposed rule that we now consider the Hypercalcemia measure to be a superior measure of bone mineral metabolism compared with Serum Phosphorus. In addition, of the two measures, the Hypercalcemia measure is more focused on outcomes; the Serum Phosphorus is a reporting measure

while the Hypercalcemia measure is a clinical measure. Finally, the Hypercalcemia measure is an outcome-based measure specific to the conditions treated with oral-only drugs, which is a statutory requirement for the ESRD QIP measure set. Based on the limited benefit provided to the Program by the Serum Phosphorus measure as well as its reporting burden, we proposed to remove the Serum Phosphorus reporting measure from the ESRD QIP measure set based on Factor 5 (that is, a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available).

We invited comments on these proposals. We also stated in the CY 2019 ESRD PPS proposed rule that we did not propose any changes to the PY 2021 performance period or performance standards, and we referred readers to the CY 2018 ESRD PPS final rule (82 FR 50778 through 50779) for a discussion of those policies.

Comment: One commenter supported our proposal to remove the HCP Influenza Vaccination, Pain Assessment and Follow-up, and Anemia Management Reporting measures.

Response: We thank the commenter for its support for removing the HCP Influenza Vaccination, Pain Assessment and Follow-up, and Anemia Management Reporting Measures.

Comment: Some commenters suggested keeping the Serum Phosphorus measure in the QIP and removing the Hypercalcemia measure. One commenter noted that the NQF has concluded that the hypercalcemia measure is topped out and that there is agreement among nephrologists that the Hypercalcemia measure is not the best measure to affect patient outcomes. Another commenter stated that physicians and nurses use the Serum Phosphorus measure in clinical decision-making and that the Serum Phosphorus measure meets PAMA requirements. Another commenter believed that Serum Phosphorus is the only measure that meets PAMA requirements for an NQF-endorsed quality measure of conditions treated with oral-only medications. Another commenter noted that the Hypercalcemia measure is topped out and that dialysis facilities may focus less on other, more important clinical topics to avoid QIP penalties. Another commenter disagreed with our assessment that the Hypercalcemia clinical measure is a better measure than the Serum Phosphorus reporting measure, particularly for the pediatric population. The commenter stated that it takes a significant amount of time and clinical effort to control phosphorus levels in pediatric patients and suggested that the Serum Phosphorus reporting measure is particularly meaningful for that population.

Another commenter recommended that CMS remove the Hypercalcemia measure instead of the Serum Phosphorus measure. The commenter also suggested that the statutory requirement to include a mineral metabolism measure in the ESRD QIP no longer applies to hypercalcemia drugs with the launch of the IV calcimimetic. In addition, the commenter suggested that the Hypercalcemia measure is not clinically useful, is topped out, and discourages the home dialysis modality due to its reliance on monthly labs that require the patient to visit the facility.

Response: As we described in the CY 2019 ESRD PPS proposed rule (83 FR 34340), in 2017, the NQF re-endorsed the Hypercalcemia measure and its focus on clinical factors that are more directly under the facility's control. We noted further that the Hypercalcemia clinical measure is more focused on outcomes, which we believe should be emphasized more heavily in the ESRD QIP than reporting measures. However, we will continue examining the effects of the ESRD QIP's measures on different patient populations, including pediatric patients.

We note, however, that we have not adopted an IV calcimimetic measure in the ESRD QIP, and we therefore, do not agree that its launch means that the statutory requirement that we include measures of mineral metabolism in the ESRD QIP no longer applies.

We would also like to clarify that we have not concluded that the Hypercalcemia measure is topped out, and we will continue to assess the ESRD QIP to ensure that dialysis patients are not discouraged from pursuing treatment via their preferred modalities.

Comment: Commenters supported our proposal to remove four reporting measures from the Program. One commenter noted that the proposal takes a much-needed step towards creating a smaller, more patient-centered measure set. Another commenter suggested that we consider adding health care personnel influenza vaccinations to Medicare's conditions for coverage for ESRD facilities. One commenter requested clarification as to whether facility reporting on the health care personnel influenza vaccination measure would be discontinued beginning October 1, 2018—the start of the PY 2021 period of performance.

Response: We thank the commenters for their feedback and support, and we will consider whether we should add health care personnel influenza vaccinations to our conditions for coverage in the future. We intend to continue monitoring outcomes associated with influenza in the dialysis patient population. We would like to clarify that facilities can discontinue data collection on the HCP influenza vaccination measure beginning with October 1, 2018 dates of service and will not be required to submit vaccination reports in May 2019 for PY 2021.

We would also like to clarify that the Healthcare Personnel Influenza Vaccination reporting measure is evaluated on the basis of facility reporting to the NHSN, not on healthcare personnel influenza vaccination rates, and that the consistently high facility performance on the measure indicates that facility reporting, not influenza vaccination rates of facility staff, is a widespread practice and that there is little room for improvement on this reporting measure.

Comment: Commenters expressed support for the proposed removal of the Pain Assessment and Follow-Up reporting measure. One commenter stated that performance on the measure is uniformly high, and another commenter agreed that if meaningful distinctions among facilities for a specific measure cannot be made, then that measure should be removed from QIP. Another commenter stated that these types of measures may contribute to the opioid epidemic and that the pain management measure was not designed for dialysis patients. Another commenter believed that the standardized pain measurement tool is expensive and burdensome for facility staff and data entry coordinators.

Response: We thank the commenters for their support.

Comment: One commenter did not have any objection to our proposal to remove the Serum Phosphorus and Pain Assessment measures from the Program. Another commenter expressed support for removing the Healthcare Personnel Influenza Vaccination reporting measure, stating that it does not align with current clinical practice. Other commenters supported our proposal to remove HCP Influenza Vaccination, Pain Assessment and Follow-Up, and Anemia Management reporting measures.

Response: We thank the commenters for their support of the measure removals. We note that the CDC and the Advisory Committee on Immunization Practices recommend annual seasonal influenza vaccination for all healthcare personnel, including those working in dialysis facilities. However, the ESRD QIP does not include a Healthcare

Personnel Influenza Vaccination clinical measure that would evaluate facility performance on the basis of the proportion of ESRD healthcare personnel who undergo vaccination. The Program's Healthcare Personnel Influenza Vaccination measure proposed for removal is a reporting measure that assesses facilities' reporting of healthcare personnel influenza vaccination data to the NHSN system. Since facility reporting on the measure is high and there is little room for improvement, we proposed to remove the measure from the Program.

Comment: Commenter supported the removal of the Healthcare Personnel Influenza Vaccination reporting measure, suggesting that the data suggests facility compliance with the measure is close to 100 percent and the measure is no longer necessary for inclusion in QIP.

Response: We thank the commenter for this feedback and support.

Comment: Commenter generally supported our proposal to remove four reporting measures from the Program but expressed concern about the removal of the influenza vaccination measure. The commenter believed that the measure helps ensure that a healthy workforce furnishes services to ESRD patients, and worried that the removal of the measure will result in fewer employees becoming vaccinated.

Response: We thank the commenter for this support. As we noted in the CY 2019 ESRD PPS proposed rule (83 FR 34339), 98 percent of ESRD facilities received the highest possible score on the influenza vaccination measure, indicating that almost all ESRD facilities were reporting influenza vaccination of healthcare personnel. CDC and the Advisory Committee on Immunization Practices (ACIP) recommends that all healthcare personnel (HCP) and persons in training for healthcare professions should be vaccinated annually against influenza, given that HCP vaccination has been associated with reduced work absenteeism and fewer deaths among elderly patients. We and CDC will continue monitoring the effects of the measure's removal and the distal outcomes associated with influenza in the dialysis patient population, and will work to ensure that ESRD facilities continue to maintain the healthiest possible workforce. CDC also encourages ESRD facilities to continue to report this measure as part of their quality improvement programs.

Comment: A commenter supported the removal of the Serum Phosphorus reporting measure. However, the same commenter raised concerns that removing this measure from QIP will not reduce facility burden, as it is still a required field in CROWNWeb and CMS would still collect phosphorus values for use in DFC/DFR reports.

Response: Our goal is to streamline the QIP and implement a parsimonious, effective quality measure set. To that end, we are removing the Serum Phosphorus measure from the QIP because we have determined that the Hypercalcemia measure is a better measure of bone mineral metabolism compared to the Serum Phosphorus measure and given NQF's recent re-endorsement of the Hypercalcemia measure. We continue to believe that this removal reduces the burden associated with the ESRD QIP. However, we will examine the other burdens associated with the measure that the commenter highlighted and will consider whether we should remove any of those requirements in service of reducing facilities' reporting burden further.

Comment: Commenter was generally supportive of reducing the size of the ESRD QIP measure set but expressed concern about the proposed removal of the HCP Influenza Vaccination reporting measure. The commenter agreed with our assessment that performance on the measure is likely high across the industry and acknowledged the comparatively high burden associated with the measure but noted that the measure is also required by CDC's NHSN, meaning that its removal from the QIP wouldn't relieve facilities of the responsibility to report on it. Commenter encouraged us to work with CDC to align reporting requirements. Another commenter stated that the HCP Influenza Vaccination reporting measure is still meaningful, and its reporting burden is not particularly burdensome.

Response: As noted above, our goal is to streamline the QIP and implement a parsimonious, effective quality measure set. We also note that the CDC continues to encourage vaccination reporting, and that the CDC and the Advisory Committee on Immunization Practices (ACIP) recommend that all healthcare personnel (HCP) be vaccinated annually against influenza.

Comment: A commenter was concerned that the dates of vaccine availability for the HCP Influenza Vaccination measure do not coincide with the measure's reporting dates. The commenter encouraged us to modify the measure to align with CDC's immunization guidelines. Another commenter recommended that we adjust the reporting dates for the HCP Influenza vaccination to allow administrations beginning October 1 or when the vaccine becomes available.

Response: We thank the commenter for their feedback. Since we are finalizing our proposal to remove the Healthcare Personnel Influenza Vaccination measure from QIP, facilities will not be required to collect vaccination data beginning October 1, 2018—which would have been the beginning of the PY 2021 period of performance for that measure.

Comment: Commenters were concerned about our proposal to remove the HCP Influenza Vaccination measure from the QIP. One commenter believed that the measure's removal will send the message that preventive health services such as immunizations are no longer a priority. That commenter noted that sustained influenza vaccination should be a top priority for workers treating ESRD patients since they are at high risk for infectious diseases and that the measure's removal would create greater inconsistency across CMS's quality programs. Another commenter believed that removing the measure may result in facilities no longer mandating that their personnel receive vaccinations.

One commenter opposed the measure's removal based on its belief that the measure supports patient outcomes. The commenter stated that high compliance should be expected because the measure was adopted recently. The commenter noted that healthcare personnel can unintentionally expose patients to seasonal influenza if they have not been vaccinated and that patients with ESRD and acute kidney injury are often at risk for influenza due to their complex underlying comorbidities. The commenter also stated that annual influenza vaccination of healthcare personnel has been shown to reduce flu-related morbidity and mortality among health care personnel and their patients and reduce work absenteeism. The commenter also believed that a vaccinated workforce creates a safe environment for patients, their families, and employees.

Response: We agree that influenza vaccination of healthcare personnel is an important public health measure to protect both the healthcare personnel and ESRD patients against flu-related morbidity and mortality and healthcare personnel absenteeism. As we have noted previously, CDC and the Advisory Committee on Immunization Practices recommend annual seasonal influenza vaccination for all healthcare personnel, including those working in dialysis centers. However, as described above, our goal is to streamline the QIP and implement a parsimonious, effective

quality measure set for dialysis facilities, and we continue to believe that the high reporting rate on the HCP Influenza Vaccination measure indicates that there is little room for facilities to improve reporting on the measure. However, we will continue to monitoring the issue to assess whether the measure's removal results in any negative unintended consequences.

Comment: A commenter encouraged us to continue requiring reporting of the Pain Assessment and Follow-up reporting measure, the Healthcare Personnel Influenza Vaccination reporting measure, and the Anemia Management reporting measure. The commenter also urged us to maintain the Serum Phosphorus measure in the QIP until a better measure of bone and mineral metabolism can be developed. The commenter believed that the Pain Assessment measure, in particular, is important to patients and that a high performance rate on the measure does not indicate absence of a gap in addressing pain in dialysis patients. Another commenter stated that data do not support a performance measure based on hemoglobin level at this time but suggested that anemia management is still important as a reporting measure. Another commenter stated that anemia measures are helpful and may improve clinical outcomes for people in earlier stages of chronic kidney disease (CKD). The commenter recommended that we continue collecting the data for both the hemoglobin level and whether the patient received anemia treatment prior to ESRD onset. That commenter also suggested that we allow more granular anemia reporting.

Response: As we noted in the CY 2019 ESRD PPS proposed rule (83 FR 34339 through 34340), the NQF recently re-endorsed the Hypercalcemia measure, and the Hypercalcemia measure focuses on clinical factors that are more directly under the facility's control. We therefore believe that the Hypercalcemia clinical measure is a better measure of bone mineral metabolism than the Serum Phosphorus reporting measure, and in the interest of maintaining a more parsimonious quality measure set under the ESRD QIP, as well as a quality measure set more focused on clinical outcomes, we proposed to remove Serum Phosphorus.

With respect to the Pain Assessment measure, while we understand the commenter's point that high performance rates on the measure may not indicate the absence of a gap in addressing pain in dialysis patients, we weighed high performance on the measure against the measure's reporting burden and clinical value when we proposed to remove it. We expect that dialysis facilities will continue working to ensure that their patients' pain is assessed as thoroughly as possible.

We continue to believe that Anemia Management measure should be removed from the QIP because it is a reporting measure, is topped out, and is not consistent with FDA guidelines on the use of Erythropoietic Stimulating Agents (ESAs), because any measure focused on a specific hemoglobin level or target encourages ESA use for reasons other than symptom relief, and that action is associated with adverse cardiovascular effects.

Comment: Commenter opposed the removal of the Anemia Management measure, suggesting that its removal would not reduce burden. Commenter stated that facilities are still required to report this information on Medicare claims on a monthly basis.

Response: We thank the commenter for this feedback. Our goal is to streamline the QIP and implement a parsimonious, effective quality measure set. To that end, we are removing the Anemia Management measure from the QIP because as previously noted, our analysis of CY 2016 data indicates that ESRD facility performance on the Anemia Management reporting measure was consistently high, indicating that facility tracking of hemoglobin values and, as applicable, ESA dosages, is widely performed among ESRD facilities and that there is little room for improvement on the measure. Given these findings, we believe that the measure's continued inclusion in QIP is no longer necessary. However, we agree that removing the Anemia Management reporting measure from QIP will not reduce facility burden as measured by the Program because facilities do not report the measure's data through CROWNWeb. We will examine the other burdens associated with the measure that the commenter highlighted and will consider whether we should remove any of those requirements in service of further reducing facilities' reporting burden.

Comment: Commenter cautioned that removing the Anemia Management measure may result in facilities' skimping on medications vital to anemia management, which is a critical aspect of dialysis care. The commenter believed that anemia management in general remains of critical importance as a quality indicator.

Response: We understand the commenter's concern. We undertake a robust monitoring and evaluation effort for the ESRD QIP, and we will work to ensure that dialysis facilities do not skimp on needed medications or otherwise reduce the quality of the care they provide due to quality measure removals. In addition, the STrR measure remains in QIP, and facilities are still required to report hemoglobin levels in CROWNWeb and claims.

Comment: Commenter stated its opposition to removing the Anemia Management measure, suggesting that its removal while continuing to rely on the STrR measure raises significant concerns because the STrR measure will not accurately reflect the quality of care at dialysis facilities. Commenter stated its belief that STrR has not been a valid measure of transfusions since the implementation of the ICD–10–CM/PCS coding system and encouraged us to maintain the Anemia Management measure until we can assess the STrR measure's validity independently.

Response: We thank the commenter for its feedback. As we discuss further in a subsequent section of this final rule, we are finalizing a lower weight for the STrR measure in response to concerns raised about the measure, but we decided to retain that measure in the QIP as a way to monitor quality for anemia management.

Comment: A commenter supported the creation of a new reporting-only measure for anemia management, based on the average of 3 months of data. The commenter suggested that this measure is especially appropriate for the pediatric population, contending that, within the pediatric population, data shows that morbidity and hospitalizations rise when hemoglobin is less than 10g/dL.

Response: We thank the commenter for this feedback. We are constantly evaluating our measures of anemia management and will consider measures that address the pediatric population in future years.

Final Rule Action: After consideration of public comments received, we are finalizing the removal of the Healthcare Personnel Influenza Vaccination reporting measure, the Pain Assessment and Follow-Up reporting measure, the Anemia Management reporting measure, and the Serum Phosphorus reporting measure beginning with the PY 2021 ESRD QIP.

2. Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2021 ESRD QIP

In the CY 2018 ESRD PPS final rule (82 FR 50763 through 50764) we finalized that for PY 2021, the performance standards, achievement thresholds, and benchmarks for the clinical measures would be set at the 50th, 15th, and 90th percentile, respectively, of national performance in

CY 2017, because this would give us enough time to calculate and assign numerical values to those performance standards prior to the beginning of the performance period for that payment year. We stated in the CY 2019 ESRD PPS proposed rule (83 FR 34340) that we did not have the necessary data to assign numerical values to those performance standards, achievement thresholds, and benchmarks because we did not yet have complete data from CY 2017. Nevertheless, we stated that we could estimate these numerical values based on the most recent data available at the time we issued the CY 2019 ESRD PPS proposed rule. We have since updated those values based on more recently available data. In Table 14, we provide the estimated numerical values for all finalized PY 2021 ESRD QIP clinical measures, as shown in the CY 2019 ESRD PPS proposed rule (83 FR 34340). We also provide updated values for the clinical measures, using CY 2017 data that facilities submitted in the first part of CY 2018 in Table 15.

TABLE 14—ESTIMATED NUMERICAL VALUES FOR THE PERFORMANCE STANDARDS FOR THE PY 2021 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement threshold	Benchmark	Performance standard
Vascular Access Type:			
Standardized Fistula Rate	0.518	0.752	0.628
Long-Term Catheter Rate	19.23%	5.47%	12.02%
Kt/V Composite	91.09%	98.56%	95.64%
Hypercalcemia	2.41%	0.00%	0.86%
Standardized Transfusion Ratio	1.683	0.200	0.846
Standardized Readmission Ratio	1.273	0.630	0.998
NHSN BSI	1.598	0	0.740
SHR measure	1.249	0.670	0.967
ICH CAHPS: Nephrologists' Communication and Caring	57.36%	78.09%	67.04%
ICH CAHPS: Quality of Dialysis Center Care and Operations	53.14%	71.52%	61.22%
ICH CAHPS: Providing Information to Patients	73.31%	86.83%	79.79%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	76.57%	62.22%
ICH CAHPS: Overall Rating of Dialysis Center Staff	48.84%	77.42%	62.26%
ICH CAHPS: Overall Rating of the Dialysis Facility	52.24%	82.48%	66.82%

Data sources: VAT measures: 2016 CROWNWeb; SRR, STrR, SHR: 2016 Medicare claims; Kt/V: 2016 CROWNWeb; Hypercalcemia: 2016 CROWNWeb; NHSN: 2016 CDC, ICH CAHPS: CMS 2015 and 2016.

In previous rulemaking, we have finalized that if final numerical values for the performance standard, achievement threshold, and/or benchmark are worse than they were for that measure in the previous year of the ESRD QIP, then we would substitute the previous year's performance standard, achievement threshold, and/or benchmark for that measure. In the CY 2017 ESRD PPS final rule, we finalized an update to that policy because in certain cases, it may be appropriate to re-baseline the National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) clinical measure, such that expected infection rates are calculated on the basis of a more recent year's data (81 FR 77886). In such cases, we stated that numerical values assigned to performance standards may appear to decline, even though they represent higher standards for infection prevention. For PY 2021 and future payment years, we proposed to continue use of this policy.

The comments and our responses regarding the estimated performance values and our proposal to continue our policies for substituting the performance standard, achievement threshold, and benchmark in appropriate cases, are set forth below.

Comment: Commenters generally supported the continued use of benchmarks, attainment and improvement standards, and payment penalty tiers in the QIP. One commenter recognized of the importance of the NHSN re-baselining process and its impact on the NHSN BSI clinical measure.

Response: We thank the commenters for their support.

Comment: Commenter requested that we consider new approaches to care, such as Transitional Care Dialysis units, when developing QIP standards, and suggested that we consider an acuity adjustment when scoring facilities in the QIP.

Response: We thank the commenter for this suggestion. At this time, we do not believe it is feasible to implement an acuity adjustment for scoring facilities in the QIP. However, as we discussed earlier in this final rule, we are continuing to consider appropriate adjustments to account for social risk factors in the ESRD QIP's measurements and in our other VBP and quality reporting programs.

Comment: Commenter called on us to consider incorporating flexibility into our performance standards to ensure that facilities failing to achieve Kt/V performance standards due to patient preferences can still perform well on the measure. The commenter suggested that treatment changes that would enable a facility to score more highly on the measure would not be desirable if those treatment changes were not consistent with the patients' preferences.

Response: We thank the commenter for their feedback. However, the methodology that we employ to performance standards reflects national performance on quality measures because we believe that setting national standards of care will drive quality improvement in this sector. We agree with the commenter that quality measurements that do not accord with the patients' preferences would not be a desirable outcome, but we believe that dialysis adequacy as measured by Kt/V remains a critically important indicator of clinical quality for all dialysis patients.

Comment: A commenter requested that CMS provide adequate notice if the achievement thresholds and benchmarks change after the final rule is published.

Response: We will make every effort to notify all stakeholders if the achievement thresholds and benchmarks change after we publish the final rule. Potential notification options include (but are not limited to) correction notices, email blasts, and announcements on our website.

Comment: Commenter suggested that STrR's benchmark for PY 2021 is too

low at 0.2 and should be higher, stating that the ratio of the number of observed transfusions being ⅕ of the number of those expected seems unrealistic and difficult to achieve, especially if it was the 90th percentile of national performance in 2016. The commenter also stated that few providers received a 10 on the STrR measure.

Response: We thank the commenter for this feedback, but we disagree and note that national data dictates the performance standards levels that we adopt under the ESRD QIP.

Final Rule Action: After consideration of public comments, we are finalizing our proposal to substitute performance standards, achievement thresholds, and benchmarks if they are worse than they were in the prior payment year and to periodically re-baseline the BSI measure as needed, in PY 2021 and future payment years. In the performance standards we are finalizing for the PY 2021 ESRD QIP in Table 15, we applied this substitution policy to four measures: the SRR measure, the SHR measure, the ICH CAHPS: Overall Rating of Nephrologists) measure, and the ICH CAHPS: Overall Rating of the Dialysis Facility measure.

We are also updating the performance standards, achievement thresholds, and benchmarks for the finalized PY 2021 ESRD QIP clinical measures as shown in Table 15, using the most recently available data.

TABLE 15—FINALIZED PERFORMANCE STANDARDS FOR THE PY 2021 ESRD QIP CLINICAL MEASURES USING THE MOST RECENTLY AVAILABLE DATA

Measure	Achievement threshold	Benchmark	Performance standard
Vascular Access Type:			
Standardized Fistula Rate	51.79%	75.22%	62.80%
Catheter Rate	19.20%	5.47%	12.01%
Kt/V Composite	92.98%	99.14%	96.88%
Hypercalcemia	1.86%	0.00%	0.58%
Standardized Transfusion Ratio	1.684	0.200	0.847
Standardized Readmission Ratio	1.268	0.629	0.998
NHSN Bloodstream Infection	1.479	0	0.694
SHR measure	1.249	0.670	0.967
ICH CAHPS: Nephrologists' Communication and Caring	58.09%	78.52%	67.81%
ICH CAHPS: Quality of Dialysis Center Care and Operations	54.16%	72.03%	62.34%
ICH CAHPS: Providing Information to Patients	73.90%	87.07%	80.38%
ICH CAHPS: Overall Rating of Nephrologists	49.33%	76.57%	62.22%
ICH CAHPS: Overall Rating of Dialysis Center Staff	49.12%	77.46%	63.04%
ICH CAHPS: Overall Rating of the Dialysis Facility	53.98%	82.48%	67.93%

Data sources: VAT measures: 2016 CROWNWeb; STrR, SHR: 2016 Medicare claims; SRR: 2017 Medicare claims; Kt/V: 2017 CROWNWeb and Medicare claims; Hypercalcemia: 2017 CROWNWeb; NHSN: 2017 CDC, ICH CAHPS: CMS 2017.

3. Update to the Scoring Methodology Previously Finalized for the PY 2021 ESRD QIP

As described in the CY 2019 ESRD PPS proposed rule (83 FR 34334 through 34335), we discussed our establishment of the Meaningful Measures Initiative to help guide and focus measure development efforts across settings. In order to align the ESRD QIP more closely with the priorities of that initiative, we proposed to remove four reporting measures from the ESRD QIP measure set, beginning with PY 2021 (83 FR 34339 through 34340). As described above, we are finalizing that proposal. We also proposed to make changes to the measure domains and weights (83 FR 34341 through 34342).

a. Revision to Measure Domains Beginning With the PY 2021 ESRD QIP

To more closely align with the Meaningful Measures Initiative, in the CY 2019 ESRD PPS proposed rule (83 FR 34341 through 34342), we proposed to eliminate the Reporting Domain and to reorganize the Clinical Domain into three distinct domains: Patient & Family Engagement Domain (currently part of the Patient and Family Engagement/Care Coordination Subdomain), Care Coordination Domain (currently part of the Patient and Family Engagement/Care Coordination Subdomain), and Clinical Care Domain (currently the Clinical Care Subdomain). We stated that adopting these topics as separate domains would result in a measure set that is more closely aligned with the priority areas in the Meaningful Measures Initiative. The proposed Clinical Care Domain would align with the Meaningful Measure Initiative priority to promote effective prevention and treatment of chronic disease. The proposed Patient & Family Engagement Domain would align with the Meaningful Measures Initiative priority to strengthen person and family engagement as partners in their care. The proposed Care Coordination Domain would align with the Meaningful Measures Initiative priority to promote effective communication and coordination of care. We also proposed to continue use of the Patient Safety Domain. We stated that the Patient Safety Domain would align with the Meaningful Measures Initiative priority to make care safer by reducing harm caused in the delivery of care. We also proposed to eliminate the Reporting Measure Domain from the ESRD QIP measure set, beginning in the PY 2021 Program, because there would no longer be any measures in that domain if our measure removal proposals in section IV.B.1.c of the CY 2019 ESRD PPS proposed rule and our proposals in section IV.B.3.b of the CY 2019 ESRD PPS proposed rule to reassign the Ultrafiltration Rate, and Clinical Depression Screening and Follow-Up Reporting measures to the Clinical Care Measure Domain and the Care Coordination Measure Domain, respectively, were finalized.

Comment: Commenter supported our proposal to restructure the ESRD QIP's domains, suggesting that such efforts streamline the Program and ensures that patient and family engagement is a cornerstone of the QIP. Another commenter supported our proposal to remove the Reporting Domain, noting that the policy will enable CMS to focus on metrics that improve clinical outcomes and reduces complexity. Another commenter expressed support for reorganizing the Clinical Domain into three distinct domains.

Response: We thank the commenters for their support.

Comment: Commenter urged us to develop a pediatric CAHPS Survey to allow pediatric dialysis facilities to participate fully in the QIP, noting that our proposed domain changes will leave these facilities able to participate in only 3 of the new domains in the absence of a CAHPS Survey that captures their population.

Response: We thank the commenter for this feedback. The current ICH CAHPS measure excludes pediatric patients because the survey is not validated for pediatric patients. We intend to examine what modifications to the survey might be necessary to include these patients in the future.

Final Rule Action: After considering public comments, we are finalizing our proposal to update the measure domains, beginning with the PY 2021 ESRD QIP, without change. The finalized domains beginning in PY 2021 are the Patient & Family Engagement Domain, the Care Coordination Domain, the Clinical Care Domain, and the Safety Domain.

b. Revisions to the PY 2021 Domain and Measure Weights Used To Calculate the Total Performance Score (TPS)

We proposed to update the domain weights to reflect our proposed removal of the Reporting Domain and our proposed reorganization of the Clinical Domain into three distinct domains, as shown in Table 16. We stated our belief that this proposed domain weighting best aligns the ESRD QIP's measure set with our preferred emphasis on clinical outcomes by assigning the two largest weights in the Program to the domains most focused on clinical outcomes (Clinical Care Domain and the Care Coordination Domain). Of those two domains, we proposed to assign the Clinical Care Domain the highest weight because it contains the largest number of measures. We proposed to assign the remaining two domains a smaller share of the total performance score (TPS) (both 15 percent) because they are more focused on measures of clinical processes and less on measures of patient outcomes. We stated that we continue to believe that the measures in the Patient & Family Engagement and Safety domains address important clinical topics, but we also concluded that placing more weighting on measures more directly tied to clinical outcomes would be the most appropriate method to structure the ESRD QIP's measure domains.

We also proposed to adjust the PY 2021 measure weights that were finalized in the CY 2018 ESRD PPS final rule (82 FR 50781 through 50783), as shown in Table 16. We stated that our proposal was intended to reflect our preferred emphasis on weighting measures that directly impact clinical outcomes more heavily. We also took into consideration the degree to which a facility can influence a measure rate by assigning a higher weight to measures where a facility has greater influence compared to measures where a facility has less influence.

TABLE 16—PROPOSED DOMAIN AND MEASURE WEIGHTING FOR THE PY 2021 ESRD QIP

Proposed measures/measure topics by domain	Proposed measure weight as percent of TPS
PATIENT & FAMILY ENGAGEMENT MEASURE DOMAIN	
ICH CAHPS measure	15.00
	15.00
CARE COORDINATION MEASURE DOMAIN	
SRR measure	14.00
SHR measure	14.00
Clinical Depression and Follow-Up reporting measure	2.00
	30
CLINICAL CARE MEASURE DOMAIN	
Kt/V Dialysis Adequacy Comprehensive measure	6.00
Vascular Access Type measure topic*	6.00
Hypercalcemia measure	3.00
STrR measure	22.00
Ultrafiltration Rate reporting measure	3.00
	40
SAFETY MEASURE DOMAIN	
NHSN BSI measure	9.00
NHSN Dialysis Event reporting measure	6.00
	15

*The VAT Measure Topic is weighted for each facility based on the number of eligible patients for each of the two measures in the topic, with each measure score multiplied by the respective percentage of patients within the topic to reach a weighted topic score that will be unique for each facility (76 FR 70265, 70275).

As shown in Table 16, we proposed to decrease the weight of the following measures: In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) measure (18.75 to 15 percent), Kt/V Dialysis Adequacy Comprehensive measure (13.5 to 6 percent), and Vascular Access Type (VAT) measure

topic (13.5 to 6 percent). We also proposed to increase the weights of the following measures: Standardized Readmission Ratio (SRR) measure (11.25 to 14 percent), Standardized Hospitalization Ratio (SHR) measure (8.25 to 14 percent), Clinical Depression and Follow-Up measure (1.66 to 2 percent), Hypercalcemia measure (1.5 to 3 percent), STrR measure (8.25 to 22 percent), and Ultrafiltration reporting measure (1.66 to 3 percent). We proposed these changes to reflect our continued evaluation of the ESRD QIP's measures and their contribution to the TPS in light of the proposed domain structure and weights as well as the proposed removal of the four reporting measures. We did not propose any changes to the two measures included in the Safety Measure Domain: NHSN BSI and NSHN Dialysis Event measures. We stated that we continue to believe that the Safety domain appropriately contains these two NHSN measures and we believe their assigned weights—9 percent and 6 percent respectively—reflect the importance that we place on measures of patient safety for the PY 2021 ESRD QIP.

We invited public comment on our proposed domain and measure weighting proposals.

Comment: A commenter supported our proposal to reduce the weight assigned to the ICH CAHPS Survey from 18 percent to 15 percent given the challenges associated with the survey, including low response rates, and the large percentage of facilities that cannot be scored on the measure.

Response: We thank the commenter for its support.

Comment: A commenter expressed concern that the VAT measure topic has a proposed topic weight of only 6 percent of the TPS, stating that vascular access is highly leveraged with respect to patient morbidity and mortality. The commenter noted that since 2004, CMS has advocated for a ''Fistula First Catheter Last'' approach for vascular access use. The commenter also noted that catheter use rates have leveled off since 2013, and stated that this recent trend is an indication that progress on shifting the balance of vascular access use has halted. The commenter also stated that given the lack of progress in shifting the balance in recent years, it is counterproductive to decrease the VAT topic's weight below the current level of 13.5 percent. In addition, the commenter suggested adding to the VAT measure topic some or all of the 14 percentage points currently proposed to be added to the STrR measure.

Response: We thank the commenter for this feedback and agree that the VAT measure topic's proposed weight of 6 percent is too low given the importance of vascular access for patient outcomes. After further consideration of the importance of the VAT measure topic to clinical outcomes for dialysis patients, we are finalizing that the VAT measure topic will receive 12 percent weight.

Comment: Several commenters were concerned about the weight assigned to the STrR measure. One commenter was concerned about our proposal to increase the STrR measure's weight given the validity issues associated with the ICD–10–CM/PCS transition. The commenter noted that the proposal would make the STrR measure the highest-weighted measure in the QIP even though the measure tracks a clinical condition that may not reflect anemia management at the dialysis facility. The commenter also noted that many hospitals may not code blood transfusions accurately given the increased specificity requirements of the ICD–10–CM/PCS system and encouraged us to assess the measure's validity before attributing significant weight to it. Another commenter recommended reducing the weight of the STrR measure, stating that transfusions are only a surrogate for very low hemoglobin, are not typically in the dialysis facility's control, and may not be accurately ascertained due to hospital reporting patterns. The commenter noted that many facilities do not have sufficient ICH CAHPS Surveys to be scored on the measure and for those facilities, the STrR measure will have a weight that is more than 25 percent of their TPS. Another commenter was concerned that facilities are not currently able to independently validate the third-party data used for STrR calculations and cannot correct hospital or outpatient facility claims. Another commenter believed that anemia management is a critically important clinical outcome but suggested that heavy weighting proposed for the STrR measure is concerning given the coding and validity concerns associated with the measure. The commenter noted that blood transfusions often occur in the hospital setting, which is outside the dialysis facility's control. The commenter stated that we should not place that much weight on a single measure unless we identify a significant performance gap, the measure has met NQF's standards for reliability and validity, and clinicians and patients agree that the measure addresses a critical opportunity for quality improvement.

Another commenter did not agree with the proposed weight for the STrR measure, suggesting that patients often need transfusions for reasons unrelated to ESRD, and that dialysis facilities should not be penalized for transfusions unrelated to dialysis care. The commenter also noted that hospital-based dialysis facilities often accept all patients regardless of acuity or comorbidities, resulting in higher transfusion ratios than standalone facilities, and believed that weighting the STrR measure at 22 percent could affect access to care if facilities start limiting the number of high acuity patients they accept.

Response: We thank the commenters for this feedback. Given the concerns these commenters have raised about the STrR measure's validity and the significant percentage of facilities that are not eligible to receive an ICH CAHPS score, we will finalize a lower weight (10 percent) than proposed for the STrR measure and, after additional consideration of our clinical priorities as shaped by the Meaningful Measures Initiative, will adjust certain other measures' weights within the Clinical Care domain to account for that change. We are not adjusting weights in the other domains and will finalize the weights of the measures in those domains as proposed. However, as we discuss in more detail later in this final rule, we are also finalizing a different weighting redistribution policy to account for commenters' concerns about how the measures would be re-weighted if a facility reports data for some, but not all, of the measures in a domain.

Specifically, after further consideration of the public comments, the validity concerns raised about the STrR measure, the importance of the VAT measure topic to dialysis patients, and our clinical priorities as shaped by the Meaningful Measures initiative, we are finalizing that the STrR measure will be weighted at 10 percent of the TPS, instead of 22 percent as proposed. We determined that a 10 percent weight for the measure more appropriately captures the measure's clinical significance, as shaped by the Meaningful Measures Initiative's priorities, and addresses concerns raised by commenters about the measure's validity and that the measure could be weighted too highly when facilities are missing scores from other measures. We are also finalizing that the VAT measure topic will be weighted at 12 percent of the TPS. To account for these changes and retain the same overall domain weight for the Clinical Care domain, we are finalizing that that the Kt/V measure will be weighted at 9 percent of the TPS and the Ultrafiltration measure will be weighted at 6 percent of the TPS. We

believe that these changes respond to commenters' concerns about the proposed measure weights, and ensure that our clinical quality priorities continue to be reflected in the Program's scores.

Comment: Some commenters raised concerns about the reliability and validity of the StrR measure and the measure's sensitivity to changes in coding practices related to the ICD–10 conversion. The commenters also believed that the STrR measure should be replaced because facilities are being penalized for transfusions that occur outside of that facility's control.

Response: We thank the commenters for their feedback. As already noted, we are finalizing a lower weight for the STrR measure due to commenters' concerns about the overall measure weighting proposal. However, we do not agree that the STrR measure is invalid, and we continue to believe that the STrR measure ensures that dialysis facilities do not underutilize ESAs and, as a result, play a role in more frequent red-blood-cell transfusions. Additionally, we continue to believe that the STrR measure, along with other measures in the ESRD QIP, ensure that dialysis facilities fulfill their shared responsibilities to work with other types of providers to provide the best possible care and ensure their patients' continued health.

Comment: A commenter requested that we provide additional justification for our proposals to update the PY 2021 measure weights, noting that two measures (dialysis adequacy and vascular access measures) are set to decrease in weight by more than half, and that we proposed to more than double the weight assigned to the STrR measure.

Response: We thank the commenter for this feedback. We proposed the PY 2021 domain weighting changes to reflect what we believed to be the clinical priorities assessed by the quality measures, informed by the Meaningful Measures Initiative. However, as noted in response to other comments, we are finalizing a lower weight for the STrR measure than proposed and will finalize a 9 percent weight for the Kt/V measure to account for the lower STrR weight.

Comment: A commenter was concerned about the proposed domain changes, stating that our proposal to provide a TPS to any facility with at least one measure in at least two domains would only result in a small number of additional facilities receiving a TPS.

Response: We thank the commenter for this feedback. However, while the commenter may be correct that the proposal may only result in a small number of additional facilities receiving a TPS, we believe that adjustment to our policies to be warranted to ensure that the ESRD QIP can provide incentives to improve care quality in as many dialysis facilities as possible and to accommodate the changes that we proposed to the measure set. While the policy's effect may be small, we believe it to be an appropriate policy change to encourage participation in the Program.

Comment: A commenter expressed significant concern about the proposed new domain weights and the influence that the StrR and ICH CAHPS measures have on the total performance score, especially because the commenter believed the two measures have validity issues. Commenter suggested that CMS weight the catheter measure higher than the fistulas, contending that equal weighing of the two measures and the lack of a graft measure has resulted in patients experiencing clinically inappropriate AV fistula placement attempts. Commenter also stated that the evidence that AV fistulas and AV grafts are preferable for improved outcomes is significant, and that giving the catheter measure a greater weight supports a ''catheter last'' approach.

Another commenter raised concerns the VAT measure topic weight is too low. The commenter stated that vascular access is critically important to patients, is modifiable by dialysis facilities, and is a key factor influencing infection risk, hospitalizations, and death. The commenter also stated that the VAT topic's near topped out status can be addressed in other ways, including through modified achievement thresholds that permit greater individualization and incorporation of the newly revised VAT measures that account for some patient factors. Another commenter suggested that we increase the weight placed on the VAT measure topic to incentivize facilities to promote fistula use.

Response: We thank the commenters for their feedback. We may consider differential weighting for the VAT measure in the future, but we do not believe it would be appropriate to separate the measures for weighting purposes at this time. Catheter reduction and increased use of AV fistula are both important steps to improve patient care, and are tightly interrelated, so we do not want to penalize providers or facilities twice for related outcomes. Further details about our view of the appropriateness of maintaining the VAT measures as a topic are available in the CY 2013 ESRD PPS final rule (76 FR 70264). As discussed in response to other commenters, we proposed these domain weight changes to reflect the clinical importance we ascribe to each quality measure, as informed by the Meaningful Measures Initiative's priorities, but after consideration of the comments, we are finalizing a lower weight for the STrR measure and a higher weight for the VAT measure topic.

We do not believe that the ICH CAHPS Survey has validity issues that would necessitate a change to its weighting. However, we will continue monitoring survey performance and will consider additional ways to improve its administration to minimize the burden undertaken by facilities and beneficiaries, and to otherwise improve its efficiency.

Comment: Commenter recommended that we maintain the StrR measure weight near the CY 2018 level of 8.25 percent, suggesting that the proposed increase in measure weight from 8.25 percent to 22 percent in PY 2021 is disproportionate compared to other measures of equal or greater clinical importance, especially given its concerns previously raised about the STrR measure.

Response: We thank the commenter for this suggestion. As discussed more fully above, we are finalizing a 10 percent weight for the STrR measure to reflect the concerns raised by commenters, and we believe this final policy is responsive to the commenter's concern about disproportionate weight being assigned to the STrR measure.

Comment: A commenter recommended reducing the weight of the STrR measure from 22 percent to 12 percent (equal to the SRR and SHR measures) and suggesting that CMS consider increasing the current weight of the ICH CAHPS and Depression reporting measures.

The commenter also recommended a series of changes to the proposed domain weights for PY 2021, including reducing the SRR and SHR measure weights slightly, increasing the Clinical Depression and Follow-up measure weights from 2 percent to 4 percent, increasing the Kt/V measure and VAT topic weights to 12 percent, reducing the STrR measure weight to 5 percent, maintaining the Anemia Management reporting measure in the QIP with a 4 percent weight, and increasing the Ultrafiltration Rate reporting measure to 4 percent.

Another commenter recommended increasing the weights of Kt/V and VAT measures to 11 and 15 percent respectively, stating that dialysis facilities are most likely to be able to influence these measures.

Response: We thank the commenters for their feedback. We are finalizing the STrR measure's weight at 10 percent and reweighting certain other measures within the Clinical Care domain to reflect the change to the STrR measure's weight because we believe that the Clinical Care domain should remain the most significant within the ESRD QIP, at a total domain weight of 40 percent. As previously noted, we believe that that this domain weighting best aligns the ESRD QIP's measure set with our preferred emphasis on clinical outcomes by assigning the two largest weights in the Program to the domains most focused on clinical outcomes (Clinical Care Domain and the Care Coordination Domain). Of those two domains, we believe that is appropriate to assign the Clinical Care Domain the highest weight because it contains the largest number of measures.

Comment: A commenter expressed concern that the dialysis facilities that are not eligible to be scored on certain measures will be subject to an even more distorted weighting approach if CMS finalizes its domain weighting proposals. The commenter stated that the StrR measure weight would increase from 22 percent to 26 percent of TPS for the 49 percent of facilities ineligible for an ICH CAHPS score, based on CY 2016 industry data. The commenter also believed that the measure weighting imbalance would be even more extreme for facilities that predominantly or exclusively care for patients who dialyze at home, as they are do not have enough data for the ICH CAHPS, NHSN BSI, NHSN dialysis event reporting, and ultrafiltration reporting measures and most are ineligible for the VAT measures. In addition, the commenter stated that for these facilities, 82 percent of the TPS would be based on 3 measures (SHR, SRR, and STrR) and that this weighting approach may hinder greater adoption of home modalities. The commenter also suggested the development of an alternative measure weighing approach for home-only facilities.

Another commenter expressed concern that home-only dialysis programs will be scored on only two domains—Care Coordination and Clinical Care—using the proposed domain and weighting approach. The commenter stated that four measures currently do not apply to home-only programs due to either patient-level or facility-level exclusions: ultrafiltration, ICH CAHPS, HSNH BSI, and NHSN Dialysis Event. The commenter also stated that it is important to assess patient and family engagement among home dialysis patients, in part to address burn out issues. In addition, the commenter stated that infection complications are a well-recognized challenge for both home hemodialysis and peritoneal dialysis. The commenter was also concerned that the TPS of home-only programs will be heavily influenced by 3 claims-based measures: SHR, SRR, and STrR, and that STrR will comprise one-third of the TPS. The commenter also raised concerns that for small home-only programs, SHR and STrR are not estimated. The commenter stated CMS to correct these distortions.

Another commenter stated that we should develop an alternative weighting scheme for facilities that predominantly or exclusively treat patients dialyzing at home. The commenter stated that the current makeup of the QIP score could be a barrier to home dialysis uptake because low scores on a small number of measures can drastically affect facilities' TPSs. The commenter suggested that we consider applying the current low-volume scoring adjustment separately to home dialysis patients at each facility, which would alleviate the small sample size problem for those providers' scores.

Another commenter requested that CMS align the weights of applicable measures for all programs, including home-only programs, with a consistent definition of quality. The commenter stated that the QIP currently includes measures for programs that offer in-center hemodialysis, large home-only programs, and small home-only programs. The commenter also stated that this approach is not in the interest of CMS and Medicare ESRD beneficiaries who may use multiple dialysis modalities in multiple programs.

Response: We thank the commenters for their feedback. We acknowledge that the exclusions specified for the ICH CAHPS measure, the NHSN BSI measure, the NHSN dialysis event reporting measure, the Ultrafiltration reporting measure, and the measures comprising the VAT measure topic prevent most if not all facilities that predominantly or exclusively care for patients who dialyze at home from receiving a score on those measures. We are finalizing a lower weight for the STrR measure than proposed, and we believe the change will result in the STrR, SRR, and SHR comprising a smaller percentage of the TPS for these facilities.

Our intent is to include as many facilities in the Program as possible to provide broad-reaching incentives for facilities to improve the quality of care provided to their patients. We appreciate the commenter's concern regarding home dialysis facilities. However, we do not believe it is equitable to develop a separate policy for facilities that serve a large number of home dialysis facilities, as the Program currently accounts for these issues through policies that reweight the TPS to account for missing measures. We will continue examining issues associated with home dialysis quality.

Comment: A commenter suggested that CMS conduct a more comprehensive review and update of the measure weights prior to the next annual update of the QIP, including giving stakeholders an opportunity to submit feedback and measure specific quantitative analysis of the measures' reliability and the opportunity for improvement provided for each measure. The commenter also recommended not finalizing the proposed weights and working with the kidney care community to refine the weighting policy.

Another commenter urged CMS to consider adopting additional criteria when determining measure and domain weights in the QIP, including the following: strength of evidence (including suggestive clinical or epidemiological studies or theoretical rationale); opportunity for improvement (including assessing the coefficient of variation for each measure); and clinical significance (which the commenter suggested could serve as a refinement to ''clinical priorities'' and could focus on the number of patients affected by measure compliance and the impact that compliance has on patient outcomes).

Response: While we understand the commenter's concern about opportunities for stakeholder input, the public comment period subsequent to the publication of the CY 2019 ESRD PPS proposed rule afforded stakeholders and the public an opportunity to provide feedback to CMS on the weights and this final rule provides an opportunity for CMS to respond to that feedback and revise the proposed weights if needed. As we have already noted, we are revising the weights of four measures in response to public comments on the CY 2019 ESRD PPS proposed rule. We intend to re-assess how the ESRD QIP domain weights being finalized in this final rule affect TPSs awarded under the Program in the future, and we always welcome stakeholder feedback on our policies and suggestions for improvement.

We take numerous factors into account when determining appropriate domain and measure weights, including clinical evidence, opportunity for improvement, clinical significance, and patient and provider burden, and we

therefore believe we considered the factors suggested by one of the commenters. We also consider criteria previously used to determine appropriate domain and measures weights (see the CY 2015 ESRD PPS final rule, (79 FR 66214)), including (1) The number of measures and measure topics in a proposed domain; (2) how much experience facilities have had with the measures and measure topics in a proposed domain; and (3) how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD (that is, the Meaningful Measures Initiative priorities, which includes our preferred emphasis on patient outcomes).[13] However, we will consider the commenter's specific suggestions for suggestive clinical studies, assessing coefficients of variation, and the number of patients affected by measure compliance in future rulemaking.

Comment: Some commenters opposed the proposed weight of 9 percent for the NHSN BSI measure, suggesting that the BSI measure counts all infections regardless of whether the infection was acquired at the ESRD facility or elsewhere. One commenter did not believe that ESRD facilities should be held accountable for infections acquired in other care settings and believed that we should reduce the BSI measure's weight or revise it to include only vascular access-related bloodstream infections. Another commenter supported the Safety Domain's weight but recommended that we convert that domain to a reporting domain due to the lack of validity in the NHSN BSI measure. The commenter recommended that at a minimum, the NHSN Dialysis Event reporting measure should be assigned a higher value than the NHSN BSI clinical measure. The commenter stated that it is more critical to provide incentives for facilities to accurately track and examine their infection data and that this assessment will promote high quality dialysis care.

Response: We disagree with commenters' concerns about the BSI measure. As we stated when we adopted the NHSN BSI measure in the CY 2014 ESRD final rule (78 FR 72204 through 72207), healthcare-acquired infections are a leading cause of preventable mortality and morbidity across different settings in the healthcare sector, including dialysis facilities. BSIs are a pressing concern in a population where individuals are frequently immunocompromised and depend on regular vascular access to facilitate dialysis therapy. We continue to believe that accurately reporting dialysis events to the NSHN by dialysis facilities supports national goals for the reduction of healthcare-acquired infections. In light of the importance of monitoring and preventing infections in the ESRD population, and because a clinical measure would have a greater impact on clinical practice by holding facilities accountable for their actual performance, we adopted the NSHN BSI measure as a clinical measure. We continue to believe that tracking these infection events and rewarding facilities for minimizing these events is of critical importance to protecting patient safety and improving the quality of care provide to patients with ESRD.

Comment: A commenter suggested reducing the proposed weight of the Hypercalcemia measure, explaining its view that many patients continue experiencing challenges outside of dialysis facilities' control, including a lack of access to medications and poor health outcomes related to surgery for hyperparathyroidism and hypercalcemia.

Response: We thank the commenter for this feedback. We are not finalizing a different weight for the Hypercalcemia measure in response to comments received on the CY 2019 ESRD PPS proposed rule because we believe that a weight of 3 percent aligns with the Meaningful Measure Initiative—specifically its priority to promote effective prevention and treatment of chronic disease.

Comment: One commenter opposed decreasing the Patient and Family Engagement Domain weight to 15 percent of the TPS. The commenter disagreed with our stated reasoning that this policy emphasizes the two domains most focused on clinical outcomes, suggesting instead that the Patient & Family Engagement focuses on patient outcomes and should therefore not be assigned decreased weight. The commenter noted that the NQF views patient assessments of their experience as a patient-reported outcome and suggested that the ICH CAHPS measure therefore assesses patient outcomes. The commenter also stated that the ICH CAHPS measure is closely aligned with Meaningful Measure objectives because it is outcome-based, patient-centered, and meaningful to patients, in addition to providing a significant opportunity for improvement. The commenter recognized the importance of clinical outcome measures in the Care Coordination and Clinical Care Domains but expressed concern that the proposed change demonstrates that less focus should be placed on improving patient experience.

Response: While we appreciate the commenter's concerns and agree in general that patients' assessments of their experience are important for clinical quality measurement, we are also cognizant of the challenges that many facilities have submitting enough ICH–CAHPS data to be scored on that measure. We have balanced the domain weight that we proposed for the ICH CAHPS Survey in accordance with that consideration as well as the high clinical priority that we place on the patient experience. We will continue monitoring facilities' focus on improving the patient experience and will consider whether we should revisit the ICH CAHPS Survey's weighting in the future.

Comment: A commenter recommended that CMS refrain from decreasing the Patient and Family Engagement Domain weight and instead assign equal weights to the four domains for PY 2012 and future years. The commenter noted that the impact of the six ICH CAHPS measures is relatively smaller in the ESRD QIP compared to other CMS VBP programs. The commenter used the Hospital VBP Program as an example of a program that attributes equal weight to its four domains, noting that this approach encourages hospitals to focus on improvement in each of the four domains.

Response: While the commenter is correct that the Patient & Family Engagement domain receives less weight than the Care Coordination or Clinical Care domains under our proposals, we note that the Patient & Family Engagement domain contains just one measure: The ICH CAHPS Survey. After the reduction to the STrR measure that we are finalizing, the ICH CAHPS Survey will be the most heavily weighted measure in the QIP. We believe such a domain weighting will ensure that facilities focus on improving the patient experience. With respect to the commenter's suggestion that we consider equal domain weighting, or 25 percent for each domain, we do not believe assigning such a significant weight to the Patient & Family Engagement domain with its single measure would be appropriate or reflect our clinical priorities for dialysis patients because it would entail reducing significantly the weights that we have assigned to other measures, such as those placed in the Clinical Care domain, and increasing the weights of the measures that we have placed in the Safety domain.

[13] In the CY 2015 ESRD PPS final rule (79 FR 66214), we referred to ''subdomains'' in two of these criteria. Since we are finalizing a domain structure that no longer employs subdomains, we have reworded to use the term ''domains'' instead.

Final Rule Action: After considering the public comments received, we are finalizing our domain and measure weighting policy for PY 2021 as reflected in Table 17. We are finalizing as proposed; the weights of the measures in the Patient & Family Engagement Domain, the Care Coordination Domain, and the Safety Domain. We are also finalizing as proposed the weight of the Hypercalcemia measure, which is assigned to the Clinical Care Domain. We are finalizing different weights for the other measures in the Clinical Domain than we proposed. Specifically, we are increasing the Kt/V measure weight from 6 to 9 percent of the TPS; increasing the VAT measure topic weight from 6 to 12 percent of the TPS; decreasing the STrR measure weight from 22 to 10 percent of the TPS; and increasing the Ultrafiltration measure weight from 3 to 6 percent of the TPS.

TABLE 17—FINALIZED MEASURE AND DOMAIN WEIGHTING FOR THE PY 2021 ESRD QIP

Proposed measures/measure topics by domain	Proposed measure weight as percent of TPS
PATIENT & FAMILY ENGAGEMENT MEASURE DOMAIN	
ICH CAHPS measure	15.00
	15.00
CARE COORDINATION MEASURE DOMAIN	
SRR measure	14.00
SHR measure	14.00
Clinical Depression and Follow-Up reporting measure	2.00
	30
CLINICAL CARE MEASURE DOMAIN	
Kt/V Dialysis Adequacy Comprehensive measure	9.00
Vascular Access Type measure topic*	12.00
Hypercalcemia measure	3.00
STrR measure	10.00
Ultrafiltration Rate reporting measure	6.00
	40
SAFETY MEASURE DOMAIN	
NHSN BSI measure	9.00
NHSN Dialysis Event reporting measure	6.00
	15

*The VAT Measure Topic is weighted for each facility based on the number of eligible patients for each of the two measures in the topic, with each measure score multiplied by the respective percentage of patients within the topic to reach a weighted topic score that will be unique for each facility (76 FR 70265, 70275).

Update to Eligibility Requirement for Receiving a TPS for a PY and New Weighting Redistribution Policy (Reassignment of Measure Weights)

In the CY 2017 ESRD PPS final rule (81 FR 77888 through 77889), we finalized that to be eligible to receive a TPS, a facility must be eligible to be scored on at least one measure in the Clinical Measure Domain and at least one measure in the Reporting Domain. In the CY 2019 ESRD PPS proposed rule (83 FR 34342), we proposed to revise this policy due to our proposed removal of the Reporting Domain from the ESRD QIP measure set and our proposal to increase the number of domains overall from three to four. We proposed that to be eligible to receive a TPS, a facility must be eligible to be scored on at least one measure in any two out of the four domains in the ESRD QIP measure set. We stated that the proposed approach is consistent with our previously finalized policy because it would allow facilities to receive a TPS with as few as two measure scores. We also stated that the proposed approach would enable us to maximize the number of facilities that can participate while ensuring that ESRD facilities are scored on a sufficient number of measures to create a sufficiently-reliable TPS.

Because of this proposed eligibility requirement to receive a TPS, we stated in the CY 2019 ESRD PPS proposed rule that we had concluded that we must also consider how to reassign measure weights in those cases where facilities do not receive a score on every measure but receive scores on enough measures to receive a TPS. We considered two alternatives to address this issue: (1) Redistribute the weights of missing measures evenly across the remaining measures (that is, we would divide up the missing measure weights equally across the remaining measures), and (2) redistribute the weights of missing measures proportionately across the remaining measures, based on their weights as a percentage of TPS (that is, when dividing up missing measure weights, we would shift a larger share of the weights to measures with higher assigned weights; measures with lower weights would gain a smaller portion of the missing measure weights).

We stated that while the first policy alternative is administratively simpler to implement, this option would not maintain the Meaningful Measures Initiative priorities in the measure weights as effectively, and therefore, we proposed the second policy alternative.

We proposed an approach for reweighting the domains and measures in the ESRD QIP for PY 2021 based on the priorities identified in the Meaningful Measures Initiative. Under this approach, we proposed to assign a higher weight to measures that focus on outcomes and a lower weight to measures that focus on clinical processes. We stated that if we adopted the first policy alternative, measures that we consider a lower priority would represent a much larger share of TPS relative to measures that we consider a higher priority, in situations where a facility is missing one or more measure scores. Under the second policy alternative, when a facility is not scored on a measure, the weight of lower priority measures relative to higher priority measures would be more consistent with the weights assigned to the complete measure set.

Therefore, based on these considerations, we proposed that in cases where a facility does not receive a score on one or more measures but receives scores on enough measures to receive a TPS, we would redistribute the weights of any measures for which the facility does not receive a score to the remaining measures proportionately based on their measures weight as a percent of the TPS. This redistribution would occur across all measures, regardless of their domain, and would be effective beginning PY 2021. We stated that we had concluded that this policy would more effectively maintain the Meaningful Measure Initiative's priorities in the ESRD QIP's measure weights in situations where a facility does not receive a score on one or more measures. We also stated that we believed that this proportional reweighting would ensure ESRD QIP TPSs are calculated in a fair and equitable manner.

We invited public comment on this proposal.

Comment: A commenter was concerned that under our weighting redistribution proposal, a facility could receive a TPS based solely on two measures (as long as they are assigned to different domains). The commenter believed that two measures is not sufficient to accurately assess the quality of care provided at a facility. The commenter was also concerned that the proposed policy could result in lower TPSs for home-only facilities because those facilities are the most likely to be eligible for scoring on a limited number of QIP measures.

Response: We thank the commenter for this feedback. However, we disagree with the commenter's view that facility performance on two measures is insufficient to accurately assess the quality of care provided at a facility. The Program's current policy, which allows facilities to receive a TPS if they receive a score on at least one reporting measure and at least one clinical measure, is a longstanding policy and one we believe that facilities understand well. As discussed in the CY 2012 ESRD PPS final rule (76 FR 70275), where we initially adopted that policy, we believe that maintaining a two-measure score minimum for receipt of a TPS continues to achieve this goal and provides as many dialysis facilities as possible with the opportunity to participate in the ESRD QIP.

We will continue monitoring the effects of the ESRD QIP's policies carefully and will continue assessing the effects that this eligibility policy will have on home-only dialysis facilities and other types of dialysis facilities that may receive scores on only a few measures. It is not our intention to affect access to home dialysis services negatively, and we do not believe that our policy does so. Rather, we intend to ensure that the Program provides incentives to improve care quality as broadly as possible among dialysis facilities and enables patients to pursue their preferred treatment modalities. However, we note that we intend for the ESRD QIP to provide incentives to improve quality no matter what treatment modality the patient prefers, which includes home dialysis.

Comment: A commenter recommended modifying the proposed policy where a facility is eligible to be scored on at least one measure in any two out of four domains, so that the two measures cannot both be reporting measures. The commenter also suggested that CMS require one clinical measure and one reporting measure in any of the four domains.

Response: We thank the commenter for this feedback. Because we are finalizing the removal of four reporting measures, we do not believe it is likely that a facility would receive a TPS based entirely on two reporting measures, but in any case, we do not share the commenter's concern that a TPS based on two reporting measures would be invalid on its face. We have not seen any evidence that a TPS based on two reporting measures would be invalid. We have adopted this policy to ensure that the ESRD QIP can reach as many dialysis facilities as possible, and thus improve quality in as many facilities as possible. We do not believe that we should narrow the Program's reach in this form at this time, but we will consider whether we should adopt this type of requirement in the future.

Comment: A commenter was concerned about our proposal to redistribute domain weighting proportionately for facilities that do not receive a score on all ESRD QIP measures. The commenter stated that this approach could result in one or two quality measures, including the STrR, determining the majority of a facility's TPS. The commenter recommended that we redistribute the weights for missing measures equally across remaining measures, and more equally weight the measures generally.

Response: We appreciate the commenter's feedback and concerns that the STrR measure's weight will comprise a significant share of the TPS for some facilities. Given these concerns, as well as others raised by other commenters and summarized earlier in this section—specifically, that the StrR measure weight would increase from 22 percent to 26 percent of TPS for the roughly 49 percent of facilities ineligible for an ICH CAHPS score, and that facilities that predominantly or exclusively care for patients that dialyze at home would be scored predominately on only a handful of measures—we are not finalizing our proposed weight redistribution policy. Instead, we are finalizing that if a facility does not receive a score on any of the measures in a domain, then that domain's weight will be redistributed evenly across the remaining domains and then evenly across the measures within each of those domains on which the facility receives a score. Additionally, if a facility receives a score on some, but not all of the measures within a domain, the weight of the measure(s) for which a score is missing will be redistributed evenly across the other measures in that domain.

The weighting redistribution policy we are finalizing differs from the two policy alternatives discussed in the CY 2019 ESRD PPS proposed rule (83 FR 34342). We are not finalizing our proposed weight redistribution policy because we agree with commenters' concerns that certain facilities could receive a TPS that is dominated by the scores of only a few measures. We also reconsidered the other policy alternative discussed in the CY 2019 ESRD PPS proposed rule but still believe that this policy alternative would not maintain the Meaningful Measures Initiative priorities in measure weights as effectively as we prefer.

We then considered how best to address commenters' concerns while maintaining the Meaningful Measures Initiative priorities and determined that the policy we are finalizing accomplishes this objective. Our

finalized policy maintains the Meaningful Measures Initiative priorities and our preferred emphasis on those topic areas because when a facility is not scored on a measure, the domain weights will be the same as the domain weights of a complete measure set (unless an entire domain's worth of measures is missing, in which case the domain's weight would be redistributed across the remaining domains; for example, if a facility did not receive an ICH CAHPS score, one-third of the Patient & Family Engagement Domain's weight of 15 percent would be distributed to each of the three remaining domains). Our finalized policy also addresses commenters concerns that certain facilities could receive a TPS that is dominated by the scores of only a few measures because the weight of measures for which a facility does not receive a score is redistributed evenly within its domain rather than proportionately across the entire measure set; measures with high weights will not receive the largest share of redistributed weights.

Final Rule Action: After considering the public comments we received, we are not finalizing our proposed weighting redistribution policy or the alternative discussed in the CY 2019 ESRD PPS proposed rule. Instead, we are finalizing that we will redistribute the weight of any measures within a domain for which a facility does not receive a score evenly across the other measures in that domain, and if a facility does not receive a score on any measures within a domain, we will redistribute that domain's entire weight evenly across the remaining domains, and then evenly across the measures within each of those domains on which the facility receives a score. We are also finalizing our proposal to consider facilities eligible to receive a TPS if they receive at least one measure score in two of the four domains.

4. Update to the Requirement To Begin Reporting Data for the ESRD QIP

In the CY 2013 ESRD PPS final rule, we finalized our current policy to begin counting the number of months in which a facility is open on the first day of the month after the facility's CMS Certification Number (CCN) Open Date (77 FR 67512 through 67513). In response to comments suggesting that facilities be required to begin reporting on the first day of the third month after its CCN Open Date, we agreed that a facility needs time to ensure that its systems are in place to report the data, and we adopted policies that would allow new facilities to be exempted from scoring on individual measures based on their CCN Open Date. Despite these policies, we have continued to receive feedback that new facilities need additional time to deploy their information systems and enroll in CROWNWeb and NHSN. This feedback was presented both through the rulemaking process (80 FR 69066), and during the period in which facilities preview their scores. In response to this continued feedback, we have taken another look at our eligibility policies for new facilities, keeping in mind that Program requirements have become more complex over time, and have concluded that our existing policy may not provide new facilities with sufficient time to enroll in CROWNWeb and the NHSN, or otherwise prepare to report the data needed for the ESRD QIP.

Accordingly, for PY 2021 and beyond, we proposed to update this policy. We stated that under the proposed policy, facilities would be required to collect data for purposes of the ESRD QIP beginning with services furnished on the first day of the month that is 4 months after the month in which the CCN becomes effective. For example, if a facility has a CCN effective date of January 15, 2019, that facility would be required to begin collecting data for purposes of the ESRD QIP beginning with services furnished on May 1, 2019. We stated that the proposed policy would provide facilities with a longer time period than they are given now to become familiar with the processes for collecting and reporting ESRD QIP data before those data are used for purposes of scoring. We also stated our belief that this policy would appropriately balance our desire to incentivize prompt participation in the ESRD QIP with the practical challenges facing new ESRD facilities as they begin operations.

We invited public comments on this proposal.

Comment: Some commenters expressed support for the grace period provided to new facilities before they are required to begin reporting QIP data. One commenter appreciated that CMS is continuing to take provider feedback on this issue into consideration and stated that the extension for new facilities will allow them to complete the necessary steps to enroll in NHSN. Another commenter appreciated that the policy relies on the CCN effective date rather than the facility open date.

Response: We thank the commenters for their support.

Comment: A commenter strongly supported the proposal to update the requirement to begin reporting data for the QIP, noting that this policy update takes into consideration the time it takes new facilities to get up to speed on all required web-based data collection systems. The commenter supported using a full year's worth of data for both NHSN measures and strongly suggested requiring a full year's worth of data for all other standardized measures. The commenter requested clarification on how the updated policy affects measure eligibility and whether the updated policy should be changed to beginning 4 months after the month of certification.

Response: We thank the commenter for its support and will consider whether we should require a full year's worth of data for all measures in cases when a facility is new. We do not believe it is necessary to shift the reporting deadline from the first day of the month that is 4 months after the CCN eligibility date. We believe the policy as proposed is simpler for facilities to understand than adjusting reporting dates based on the specific day of the month that the facility received its CCN.

Table 18 summarizes the minimum data requirements for measure eligibility, including the updated requirement for new facilities.

TABLE 18—ELIGIBILITY REQUIREMENTS SCORING ON ESRD QIP MEASURES

Measure	Minimum data requirements	CCN Open date	Small facility adjuster
Dialysis Adequacy (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.
Vascular Access Type: Long-term Catheter Rate (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Vascular Access Type: Standardized Fistula Rate (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.

TABLE 18—ELIGIBILITY REQUIREMENTS SCORING ON ESRD QIP MEASURES—Continued

Measure	Minimum data requirements	CCN Open date	Small facility adjuster
NHSN Bloodstream Infection (Clinical).	11 qualifying patients	Before October 1 of the performance period that applies to the program year.	11–25 qualifying patients.
NHSN Dialysis Event (Reporting)	11 qualifying patients	Before October 1 of the performance period that applies to the program year.	11–25 qualifying patients.
SRR (Clinical)	11 index discharges	N/A	11–41 index discharges.
STrR (Clinical)	10 patient-years at risk	N/A	10–21 patient years at risk.
SHR (Clinical)	5 patient-years at risk	N/A	5–14 patient-years at risk.
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period.	Before October 1 of the performance period that applies to the program year.	N/A.
Depression Screening and Follow-Up (Reporting).	11 qualifying patients	Before April 1 after the performance period that applies to the program year.	N/A.
Ultrafiltration Rate (Reporting)	11 qualifying patients	Before April 1 after the performance period that applies to the program year.	N/A.

Comment: A commenter suggested that we consider applying the proposed updated new facility policy to NHSN measures, noting that facilities with CCN eligibility dates late in the year may be penalized for complying with the new requirement but not submitting a full 12 months of data to NHSN.

Response: We thank the commenter for this suggestion. Under our current policy, facilities that do not submit a full 12 months of data to NHSN are not eligible to be scored on the NHSN measures under the ESRD QIP for that payment year and, as a result, are scored only on the measures for which they have submitted sufficient data.

Final Rule Action: After considering comments received, we are finalizing our proposed update to the requirement for new facilities to begin reporting ESRD QIP data, beginning with the PY 2021 ESRD QIP.

5. Estimated Payment Reductions for the PY 2021 ESRD QIP

Under our current policy, a facility will not receive a payment reduction in connection with its performance under the PY 2021 ESRD QIP if it achieves a minimum TPS that is equal to or greater than the total of the points it would have received if: (1) It performs at the performance standard for each clinical measure; and (2) it receives the number of points for each reporting measure that corresponds to the 50th percentile of facility performance on each of the PY 2019 reporting measures (82 FR 50787 through 50788).

In the CY 2019 ESRD PPS proposed rule (83 FR 34343), we stated that we were unable to calculate a minimum a TPS for PY 2021 in the CY 2018 ESRD PPS final rule because we were not yet able to calculate the performance standards for each of the clinical measures. We also stated in the CY 2018 ESRD PPS final rule (82 FR 50787 through 50788) that we would publish the minimum TPS for the PY 2021 ESRD QIP in the CY 2019 ESRD PPS final rule.

Based on the estimated performance standards that we described in the CY 2019 ESRD PPS proposed rule (83 FR 34340), we estimated in the CY 2019 ESRD PPS proposed rule that a facility must meet or exceed a minimum TPS of 56 for PY 2021. For all of the clinical measures, we stated that these estimates were based on CY 2017 data. We also proposed that a facility that achieves a TPS below the minimum TPS that we set for PY 2021 would receive payment reduction based on the estimated TPS ranges indicated in Table 19.

TABLE 19—ESTIMATED PAYMENT REDUCTION SCALE FOR PY 2021 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction (%)
100–57	0
56–47	0.5
46–37	1.0
36–27	1.5
26–0	2.0

We stated in the CY 2019 ESRD PPS proposed rule (83 FR 34343) that we intended to finalize the minimum TPS for PY 2021, as well as the payment reduction ranges for that PY, in the CY 2019 ESRD PPS final rule.

We received a number of comments on the estimated payment reductions.

Comment: Several commenters expressed concern about the effects of the proposed domain weighting changes on payment reductions under the QIP, noting that an analysis of PY 2018 data showed that the proposed weighting system would result in a slightly lower median TPS and an increasing number of individual facilities with a decrease in their TPS. Another commenter requested that we provide a policy rationale for the projected increases in payment penalties. One commenter recommended that CMS work with the community to modify the TPS methodology, suggesting that the increase in projected payment penalties over the past few rule cycles does not reflect underlying measure performance trends. One commenter also expressed concern about the estimates showing that southern states will experience larger payment reductions than other parts of the country and suggested that we consider scoring facilities within peer groups rather than on a national basis.

Response: We understand the commenters' concern and we are willing to work with the community to understand specific concerns about the TPS calculation. However, we note that the TPS's specific composition changes

year over year as we propose and adopt new measures and as we weight those measures in accordance with our priorities. Our adoption of several outcome and patient experience of care measures (such as the STrR measure and the ICH CAHPS survey) with large variation in aggregate performance and room for improvement in more recent years of the QIP has contributed to an increase in the number of facilities that are receiving payment reductions. We also proposed domain weights changes to reflect the ESRD QIP's changing measure set. These changes have included shifts in clinical priorities, removing measures where there is little room for improvement, and adding measures where facilities' performance is broader. We believe that some increases in payment penalties are inevitable as the Program's measure set changes, particularly as we accumulate sufficient data to assess facilities on measure performance and not simply on reporting. As a result of these policy changes, we believe it is reasonable for the payment reductions to shift even if performance on some measures is comparatively high. We will continue monitoring regional and other differences in ESRD QIP performance scores by facility type or other factors.

Comment: A commenter requested that CMS extend the preview period for PY 2021 and PY 2022 to at least 60 days given the number of facilities estimated to receive a payment reduction in those years, stating that facilities need more time to analyze their TPSs.

Response: We do not believe we need to extend the preview period at this time because we have not observed any relationship between the number of facilities receiving a payment reduction and submitted inquiries. That is, we do not believe that a facility's receiving a payment reduction necessitates a preview period request, and to date, the 30-day period has been long enough to accommodate facilities' requests. We will monitor this issue and if necessary, will propose to address it in the future.

Final Rule Action: After consideration of the public comments received and an analysis of the most recently available data, we are finalizing that the minimum TPS for PY 2021 will be 56. We are also finalizing the payment reduction scale shown in Table 20.

TABLE 20—FINALIZED PAYMENT REDUCTION SCALE FOR PY 2021 BASED ON THE MOST RECENTLY AVAILABLE DATA

Total performance score	Reduction (%)
100–56	0
55–46	0.5
45–36	1.0
35–26	1.5
25–0	2.0

6. Data Validation Policies for PY 2021 and Subsequent Years

In the CY 2019 ESRD PPS proposed rule (83 FR 34343), we stated that one of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. The ESRD QIP currently includes two validation studies for this purpose: The CROWNWeb pilot data validation study (OMB Control Number 0938–1289) and the NHSN dialysis event validation study (OMB Control Number 0938–1340).

Since the PY 2016 ESRD QIP, we have validated data submitted to CROWNWeb for each payment year by sampling no more than 10 records from 300 randomly selected facilities (78 FR 72223 through 72224). In the CY 2018 ESRD PPS final rule, we finalized that for PY 2020, we would continue validating these data using the same methodology, but also finalized that we would deduct 10 points from a facility's TPS for PY 2020 if the facility was selected for validation but did not submit the requested records within 60 calendar days of receiving a request (82 FR 50766 through 50767).

Since we issued the CY 2018 ESRD PPS final rule, we have considered whether it is appropriate to continue to refer to this validation of CROWNWeb data as a study. We noted in the CY 2019 ESRD PPS proposed rule that we had analyzed the CROWNWeb data that we used for purposes of the PY 2016 validation study to determine how reliable the current methodology is, and our analysis showed an overall match rate of 92.2 percent among the facilities selected for participation. Additionally, based on our statistical analyses, we stated that we had concluded that the validation study is well-powered when we sample 10 records per facility from 300 facilities, meaning that a validation study implemented with those sampling requirements will meet our needs when assessing the accuracy and completeness of facilities' CROWNWeb data submissions.

We stated that based on this analysis, we believed that our validation methodology produces reliable results and can be used to ensure that accurate ESRD QIP data are reported to CROWNWeb. Therefore, we proposed to validate the CROWNWeb data submitted for the ESRD QIP, beginning with CY 2019 data submitted for PY 2021, using the methodology we first adopted for the PY 2016 ESRD QIP and updated for the PY 2020 ESRD QIP. Under this methodology, we would sample no more than 10 records from 300 randomly selected facilities each year, and we would deduct 10 points from a facility's TPS if the facility was selected for validation but did not submit the requested records.

We also discussed the data that is submitted to the NSHN, and how we have been developing and testing a protocol for validating those data on a statistically relevant scale. For PY 2020, our methodology for this feasibility study is to randomly select 35 facilities and require that each of those facilities submit 10 patient records covering 2 quarters of data reported in CY 2018. Our selection process targets facilities for NHSN validation by identifying which facilities that are at risk for under-reporting. For additional information on this methodology, we refer readers to the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767).

We stated that we have continued to work with the Centers for Disease Control and Prevention (CDC) to determine the most appropriate sample size for achieving reliable validation results through this NSHN dialysis event validation study. Based on recent statistical analyses conducted by the CDC, we also stated that we had concluded that to achieve the most reliable results for a payment year, we would need to review approximately 6,072 charts submitted by 303 facilities. This sample size would produce results with a 95 percent confidence level and a 1 percent margin of error. Based on these results and our desire to ensure that dialysis event data reported to the NHSN for purposes of the ESRD QIP is accurate, we proposed in the CY 2019 ESRD PPS proposed rule (83 FR 34343 through 34344) to increase the sample sizes used for the NHSN dialysis event validation study, over a 2 year period, to 300 facilities and 20 records per quarter for each of the first 2 quarters of the CY for each facility selected to participate in the study.

Specifically, for PY 2021, we proposed to increase the number of facilities that we would select for validation to 150, and then for PY 2022, to increase that number to 300. With

respect to the number of patient records that each selected facility would be required to submit to avoid a 10 point deduction to its TPS for that payment year, we proposed that for both PY 2021 and PY 2022, each selected facility must submit 20 patient records per quarter for each of the first 2 quarters of the CY, within 60 calendar days of receiving a request. We also proposed to continue targeted validation.

We invited comments on these proposals. We also invited comments on potential future policy proposals that would encourage accurate, comprehensive reporting to the NHSN, such as introducing a penalty for facilities that do not meet an established reporting or data accuracy threshold, introducing a bonus for facilities that perform above an established reporting or data accuracy threshold, developing targeted education on NHSN reporting, or requiring that a facility selected for validation that does not meet an established reporting or data accuracy threshold be selected again the next year.

The comments and our responses to the comments on our data validation proposals are set forth below.

Comment: A commenter supported our proposal to increase the number of facilities selected for NHSN validation, noting that accurate reporting by all facilities will ensure that we are able to set accurate benchmarks and performance standards.

Response: We thank the commenter for its support.

Comment: A commenter supported the expansion of the NHSN validation study and the adaptation of the CROWNWeb validation study into a permanent feature of the Program.

Response: We thank the commenter for its support.

Comment: A commenter supported our proposal to expand the NHSN validation study in PY 2021 and PY 2022 but suggested that we should consider expanding the validation sample to 10 percent of all facilities.

Response: We thank the commenter for its support. However, we do not believe that a 10 percent sample is appropriate at this time principally because such an increase in sample size would represent a significant increase in the reporting burden for facilities selected for validation. We considered several factors when developing our sample size proposal, including the overall burden to facilities, number of facilities validated, and reliability of validation results at the facility level.

Our goal for the NHSN validation study is to ensure that the data reported for purposes of the QIP is accurate. We are committed to validating data, monitoring the quality of submitted data, and identifying opportunities to improve the accuracy of data reported.

Comment: A commenter supported reselecting for the following year facilities that have undergone NHSN validation and have not met the established reporting or data accuracy threshold. The commenter believed that lessons learned from validation are important to share with all ESRD facilities as a way to ensure overall NHSN data quality.

Response: We thank the commenter for its feedback.

Comment: Several commenters expressed support for increasing the number of facilities included in the NHSN validation study to 300. One commenter also raised concerns that this facility increase will not resolve substantial underlying problems with the NHSN BSI measure.

Response: We thank the commenters for their support. We believe that validating NHSN data will ensure that NHSN measures' data are accurate and complete and will therefore enable us to address any further methodological issues with NHSN measures as needed.

Comment: A commenter strongly opposed expanding the validation program as proposed. The commenter stated that a validation program expansion suggests that previous validation cycles have identified problems or inconclusive results on measure validity. The commenter suggested that prior results should be released and once the data collection tools are validated, the validation program should continue under a process that ensures facilities due process rights under the U.S. Constitution. The commenter believed that the current timeframes and penalties do not give facilities due process and that CMS is auditing facilities, not validating their data. The commenter also stated that this audit should include the right to appeal adverse decisions.

Response: We thank the commenter for this feedback. The purpose of our validation program is to assess the accuracy and completeness of data reported to NHSN and scored under the ESRD QIP, and we have expanded it to ensure that we have the sufficient statistical power to do so.

We intend to publish the results of our CY 2018 validation studies at the end of 2019, but we do not agree with the commenter's characterization of our validation studies as audits. As we noted in the CY 2017 ESRD PPS final rule (81 FR 77895), the ultimate objective of our validation studies is to improve the validity of QIP data reported to CROWNWeb and to NHSN, not to penalize facilities for reporting invalid data. We note further that we have never penalized facilities for reporting invalid data in either of the validation studies, and if we were to consider proposing to do this in the future, we would also consider implementing an appeal process. We also note that the ESRD QIP Inquiry Period currently gives facilities an opportunity to inquire and receive feedback on their performance score and associated payment, and we will consider whether to incorporate feedback mechanisms into our validation processes in the future.

Comment: Some commenters opposed the NHSN validation study's expansion to 40 records per facility and recommended that it be reduced to 20 records per facility. One commenter supported targeting NHSN studies for dialysis facilities that might be under-reporting, requested information about the NHSN study results, and suggested that poor results should trigger an update to the benchmarks and achievement thresholds for the BSI measure. The commenter also noted that CMS requested ideas related to penalizing facilities that do not meet established reporting or data accuracy thresholds but noted that both validation studies already include a penalty associated with measure performance. The commenter supported targeted education, raised concerns that the annual training is not checked to ensure it is completed, and suggested having targeted training within the NHSN system itself. The comment also supported introducing a bonus such as adding points to the TPS, to encourage accurate reporting.

Another commenter believed that it is inappropriate to try to validate an invalid measure by imposing a burdensome data validation program on any provider. The commenter recommended that CMS suspend the use of the NHSN BSI measure and the reporting measure until they are validated outside of the QIP. Another commenter expressed concern that CMS has not validated CROWNWeb data or data for the NHSN Bloodstream Infection clinical measure and has not released the report summarizing the results of efforts to validate those data collection tools to date. The commenter requested that CMS first establish reliability and validity for the BSI measure before using it in the QIP and the TPS since CMS has noted in previous rulemaking that up to 60–80 percent of dialysis events are underreported and this high rate of

underreporting would not be present in a valid and reliable measure.

Response: We thank the commenters for their support for targeted NHSN validation and will consider whether we should introduce a scoring adjustment for accurate NHSN reporting.

We disagree that NHSN measures are unreliable, and we firmly believe that a robust validation effort will ensure that facilities are reporting accurate and comprehensive data to NHSN. We also disagree with comments stating that the measure is clinically invalid. The BSI measure is endorsed by the NQF, which closely reviews measures for clinical validity and evidence base. We therefore do not agree that we should suspend the BSI measure at this time.

Further, our NHSN dialysis event validation study has focused primarily on the feasibility of undertaking more comprehensive data validation activity. Prior pilot studies were initially conducted on nine dialysis facilities and subsequently on 35 randomly selected facilities. Validation studies on small sample sizes focused on improving our understanding of the time and resources required to accomplish validation activity on a larger scale. A small sample size below thresholds lacks precision and is subject to large sampling variability. Hence, as a next step after the feasibility studies phase, we believe expanding the sample size of facilities to be validated is warranted to accurately and precisely estimate the extent of errors in dialysis event case classification (both under- and over-reporting).

In addition, as already noted, we intend to publish the results of our CY 2018 validation studies in 2019.

Comment: A commenter was concerned about the burden associated with validation activities and encouraged us to consider alternative approaches to data validation, potentially including requesting records related only to the specific clinical topic being validated, allowing a longer timeline such as 90 days for facilities to respond to requests, and electronic information exchange.

Response: While the focus of NHSN Dialysis Event validation lies on positive BSI, other candidate events (pus, increased redness or swelling, and IV antibiotic start) tend to co-occur frequently. Since most of these events are uncommon, to assure that at least 10 candidate events are reviewed per facility for the validation timeframe, additional patient lists for example, individuals with pus, increased redness or swelling, and individuals with IV antibiotic start (in addition to positive BSI) are also requested.

We believe that allowing 90 days for facilities to respond to requests is not feasible because our goal is to provide facilities with timely feedback about reporting accuracy. Validation studies are conducted within a timeframe of 24-through 30 weeks and addition of more facility response time is prohibitive due to the time constraints.

There is a potential that future exchange of medical records could be accomplished via electronic information exchange. As validation studies progress we aim to make the process less burdensome for facilities.

Comment: A commenter strongly agreed with our policy goal of reducing rates of bloodstream infections, but worried that NHSN-based reporting of these infections does not differentiate between those related to dialysis and those that are unrelated. The commenter also urged us to consider working with CDC to allow facilities to validate third-party data submitted to NHSN on BSIs.

Response: We thank the commenter for their feedback and we will consider it in future payment years. However, we would like to clarify that data validation is an ESRD QIP policy intended to ensure the accuracy of NHSN data scored under the QIP. We will continue to work with CDC on appropriate NHSN data accuracy policies.

Final Rule Action: After considering public comments received, we are finalizing our proposals to update the NHSN validation study and to adopt CROWNWeb validation as a permanent feature of the ESRD QIP, as proposed without change.

C. Requirements for the PY 2022 ESRD QIP

1. Continuing and New Measures for the PY 2022 ESRD QIP

Since we are finalizing our proposal to remove four measures beginning with the PY 2021 ESRD QIP, the PY 2021 ESRD QIP measure set will have 12 measures. In the CY 2013 ESRD PPS final rule, we finalized that once a quality measure is selected and finalized for the ESRD QIP through rulemaking, the measure would continue to remain part of the Program for all future years, unless we remove or replace it through rulemaking or notification (if the measure raises potential safety concerns) (77 FR 67475). In addition to continuing all of the measures included in the PY 2021 ESRD QIP, we proposed to adopt two new measures beginning with the PY 2022 ESRD QIP: Percentage of Prevalent Patients Waitlisted clinical measure and the Medication Reconciliation for Patients Receiving Care at Dialysis Facilities reporting measure.

a. Percentage of Prevalent Patients Waitlisted (PPPW) Clinical Measure

We proposed to add one new transplant clinical measure to the ESRD QIP measure set beginning with PY 2022: (1) Percentage of Prevalent Patients Waitlisted (PPPW). The proposed new PPPW measure would align the ESRD QIP more closely with a Meaningful Measures Initiative priority area—increased focus on effective communication and coordination. The proposed measure assesses the percentage of patients at each dialysis facility who were on the kidney or kidney-pancreas transplant waitlist.

Background

The benefits of kidney transplantation over dialysis as a modality for renal replacement therapy for patients with ESRD are well established. Although no clinical trials comparing the two have ever been done due to ethical considerations, a large number of observational studies have been conducted demonstrating improved survival and quality of life with kidney transplantation.[14] Despite the benefits of kidney transplantation, the total number of transplants performed in the U.S. has stagnated since 2006.[15] There is also wide variability in transplant rates across ESRD networks.[16] Given the importance of kidney transplantation to patient survival and quality of life, as well as the variability in waitlist rates among facilities, we stated in the CY 2019 ESRD PPS proposed rule that a quality measure to encourage facilities to coordinate care with transplant centers to waitlist patients is warranted.

This measure emphasizes shared accountability between dialysis facilities and transplant centers.

Data Sources

The proposed PPPW measure uses CROWNWeb data to calculate the denominator, including the risk adjustment and exclusions. The Organ Procurement and Transplant Network

[14] Tonelli M, Wiebe N, Knoll G, et al. Systematic review: kidney transplantation compared with dialysis in clinically relevant outcomes. American Journal of Transplanatation 2011 Oct; 11(10):2093–2109.

[15] Schold JD, Buccini LD, Goldfarb DA, et al. Association between kidney transplant center performance and the survival benefit of transplantation versus dialysis. Clin J Am Soc Nephrol. 2014 Oct 7; 9(10):1773–80.

[16] Patzer RE, Plantinga L, Krisher J, Pastan SO. *Dialysis facility and network factors associated with low kidney transplantation rates among United States dialysis facilities.* Am J Transplant. 2014 Jul; 14(7):1562–72.

(OPTN) is the data source for the numerator (patients who are waitlisted. The OPTN is a public-private partnership established by the National Organ Transplant Act in 1984. The private nonprofit organization, United Network for Organ Sharing (UNOS) handles administration of the waitlist under a contract with the federal government. The Nursing Home Minimum Dataset and Questions 17u and 22 on the Medical Evidence Form CMS–2728 are used to identify ESRD patients who were admitted to a skilled nursing facility (SNF) because those patients are excluded from the measure. A separate CMS file that contains final action claims submitted by hospice providers is used to identify ESRD patients who have been admitted to hospice because those patients are also excluded from the measure.

Outcome

The PPPW measure tracks the percentage of patients attributed to each dialysis facility during a 12-month period who were on the kidney or kidney-pancreas transplant waitlist. The measure is a directly standardized percentage, in that each facility's percentage of kidney transplant patients on the kidney transplant waitlist is based on the number of patients one would expect to be waitlisted for a facility with patients of similar age and co-morbidities.

Cohort

The PPPW measure includes ESRD patients who are under the age of 75 on the last day of each month and who are attributed to the dialysis facility. We would create a treatment history file using a combination of Medicare dialysis claims, the Medical Evidence Form CMS–2728, and data from CROWNWeb as the data source for the facility attribution. This file would provide a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or until the measurement period ends. For each patient, a new record would be created each time he or she changes facility or treatment modality. Each record would represent a time period associated with a specific modality and dialysis facility. Each patient-month would be assigned to only one facility. A patient could be counted up to 12 times in a 12-month reporting period, and home dialysis would be included.

Inclusion and Exclusion Criteria

The PPPW measure excludes patients 75 years of age or older on the last day of each month. Additionally, patients who are admitted to a SNF or hospice during on the date that the monthly count takes place are excluded from the denominator for that month. An eligible monthly patient count takes place on the last day of each month during the performance period.

Risk Adjustment

The PPPW measure is adjusted for patient age. The measure is a directly standardized percentage, in the sense that each facility's percentage of patients on the waitlist is adjusted to the national age distribution. Further information on the risk adjustment model can be found in the PPPW Methodology Report (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*). We assume a logistic regression model for the probability that a prevalent patient is waitlisted.

2017 Measures Application Partnership Review

We submitted the PPPW measure to the Measures Application Partnership in 2017 for consideration as part of the pre-rulemaking process, and Measures Application Partnership's final recommendations may be found at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972*.

The Measures Application Partnership expressed conditional support for the PPPW measure for inclusion in the ESRD QIP. The Measures Application Partnership acknowledged that the measure addresses an important quality gap in dialysis facilities, but discussed a number of factors that it believed should be balanced when implementing the measure. The Measures Application Partnership reiterated the critical need to help patients receive kidney transplants to improve their quality of life and reduce their risk of mortality. The Measures Application Partnership also noted that there are disparities in the receipt of kidney transplants and there is a need to incentivize dialysis facilities to educate patients about waitlisting processes and requirements. The Measures Application Partnership also acknowledged that a patient's suitability to be waitlisted may not be within the control of a dialysis facility or transplant centers. The Measures Application Partnership also noted the need to ensure that the measure is appropriately risk-adjusted and recommended that CMS explore whether it would be appropriate to adjustment the measure for social risk factors and proper risk model performance. The Measures Application Partnership conditionally supported the measure with the condition that CMS submit it to the NQF for consideration of endorsement. Specifically, the Measures Application Partnership recommended that this measure be reviewed by NQF's Scientific Methods Panel as well the Renal Standing Committee. The Measures Application Partnership recommended that as part of the endorsement process, the NQF examine the validity of the measure, particularly the risk adjustment model and if it appropriately accounts for social risk. Finally, the Measures Application Partnership noted the need for the Disparities Standing Committee to provide guidance on potential health equity concerns.

In response to these recommendations, we submitted the measure to the NQF for consideration of endorsement, and the Renal Standing Committee did not recommend the PPPW measure. Nonetheless, our understanding is that it will be evaluated by all of the committees that the Measures Application Partnership suggested. We note further that access to transplantation is a known area of disparity and has a known performance gap, and the Measures Application Partnership coordinating committee expressed conditional support for the measure.

For additional information on the Measures Application Partnership's evaluation of measures for the ESRD QIP, we refer readers to Measures Application Partnership's website at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972*.

Based on the benefits of kidney transplantation over dialysis as a modality for renal replacement therapy for patients with ESRD, and taking into account the Measures Application Partnership's conditional endorsement and our submission of the measure to the NQF for consideration of endorsement, we proposed to adopt the PPPW measure beginning with the PY 2022 ESRD QIP. We noted also that there are currently no NQF-endorsed transplant measures that we could have considered, and that we believed we could adopt this measure under section 1881(h)(2)(B)(ii) of the Act due to its clinical significance for the ESRD patient population.

We invited comments on this proposal.

The comments and our responses to the comments on our proposals are set forth below. We also address comments on the proposed Standardized Waitlist

Ratio (SWR) measure (discussed further in a subsequent section of this final rule) in this section because commenters frequently addressed the PPPW and SWR measures together.

Comment: One commenter strongly supported the proposed PPPW measure.

Response: We thank the commenter for this support.

Comment: A commenter strongly supported CMS' proposals to adopt the PPPW and SWR measures, stating that timely access to transplantation for ESRD patients is widely acknowledged as important, and that longer wait times for transplants are associated with poorer outcomes. The commenter also noted the key role that dialysis facilities play in placing patients on transplant wait lists. The commenter offered to work with CMS on additional risk adjustment policies as needed but stated that CMS should not wait to adopt the measures. Another commenter stated that the proposed measures will ensure that dialysis facilities are held accountable for access to transplantation.

Response: We thank the commenters for their support.

Comment: Commenter supported our proposed adoption of the PPPW measure for the ESRD QIP but suggested that we accelerate its adoption to PY 2019 rather than waiting until PY 2022.

Response: We thank the commenter for this support, but we do not believe it is possible to accelerate the measure's adoption to PY 2019 since that would have meant adopting the measure for the CY 2017 performance period. Furthermore, we are unable to accelerate the adoption of the PPPW measure earlier than PY 2022 due to operational constraints.

Comment: A commenter raised concerns that the risk models for the PPPW and SWR measures will not adequately discriminate performance, noting that risk model testing showed an overall C-statistic of 0.72 for the PPW measure and 0.67 for the SWR measure. The commenter stated that a minimum C-statistic of 0.8 is a more appropriate indicator of a model's goodness of fit, predictive ability, and validity to represent meaningful differences among facilities.

Response: We believe that the reliability of the PPPW and SWR measures is appropriate based on recent literature and note that their reliability estimates are similar to other current NQF endorsed quality measures implemented by CMS.

Commenter: Some commenters expressed concerns about the PPPW and SWR measures' use, noting that dialysis facilities do not have control over transplant waitlists and that dialysis facilities should not have incentives to refer all patients for transplants. One commenter stated that dialysis facilities are unable to meaningfully impact their performance on these measures. Another commenter stated that numerous factors outside the facility's control determine whether an individual is placed on a transplant waitlist or receives an organ transplant. Other commenters stated that the transplant center decides whether a patient is added to a waitlist, not the dialysis facility. One commenter stated that the evaluation process includes many obstacles and delays across multiple parties that are irrelevant to the dialysis facility and that this misattribution is misaligned with NQF's first ''Attribution Model Guiding Principle'', which says measure attribution models should fairly and accurately assign accountability. One commenter stated that other transplantation access measures more appropriately capture dialysis facilities' sphere of control over transplant waitlists. One commenter stated that hospitals set criteria for transplant waitlists and suggested that we work with transplant programs to find ways to align and streamline their criteria. The commenter also noted that transplant centers will not include patients on their waitlists unless they can prove they can pay for immunosuppressive drugs post-transplant.

One commenter suggested that patient-centered education about transplantation may be more useful for dialysis patients. Another commenter agreed that dialysis facilities have a role in educating patients about transplants, assisting patients with being evaluated, and keeping patients healthy enough to remain active on the waitlist but recommended that we work with the community to develop a more actionable transplant measure for dialysis facilities. The commenter suggested that we consider applying the PPPW measure to nephrologists participating in the Merit-Based Incentive Payment System.

Another commenter reiterated its belief that dialysis clinics should not be held accountable for transplants and urged us to report the transplant measures on the Dialysis Facility Compare site and not include them in the QIP. Another commenter suggested adoption of a transplant measures over which facilities have more control. Another commenter recommended that we develop alternative quality measures that more accurately reflect the care provided in dialysis facilities, such as measures of transplant education and/or referral for transplant evaluation.

Response: Waitlisting for transplantation is the culmination of a variety of preceding activities. These include (but are not limited to) education of patients about the transplant option, referral of patients to a transplant center for evaluation, completion of the evaluation process and optimizing the health of the patient while on dialysis. These efforts depend heavily and, in many cases, primarily, on dialysis facilities. Although some aspects of the waitlisting process may not entirely depend on facilities, such as the actual waitlisting decision by transplant centers, or a patient's choice about the transplantation option, these can also be nevertheless influenced by the dialysis facility. For example, through strong communication with transplant centers and advocacy for patients by dialysis facilities, as well as proper education, we believe dialysis facilities are well-positioned to provide encouragement and support of patients during their decision-making about the transplantation option. The waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis facilities. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis facilities can be and are already making towards access to transplantation, to the benefit of the patients under their care.

Comment: A commenter raised concerns about the PPPW and SWR measures. Commenter stated that many factors outside of dialysis facilities' control influence whether or not a patient is waitlisted, including changes in the patients' health status, overall transplant center performance, and the level of risk tolerance of a given transplant center. The commenter recommended adopting a reporting requirement for referrals to transplant centers instead, suggesting that it would increase CMS's understanding of referral patterns and assist with the development of appropriate policies and incentives to promote transplant in the future. The commenter also noted that the NQF declined to endorse the PPPW measure. The commenter suggested that CMS explore the development of a process measure related to patient education about modality options and its documentation in patients' care plans. The commenter also recommended that CMS collaborate with the community to develop measures that synergize across the dialysis and transplant settings.

Response: We will consider the commenters' suggestions for additional measures on the transplant topic in the future. However, as we stated in the CY 2019 ESRD PPS proposed rule (83 FR 34344), we believe that the benefits of kidney transplantation as a renal replacement therapy modality are well-established, and we continue to believe that dialysis facilities should make every effort to ensure that their patients are appropriately wait-listed for transplants.

Comment: Some commenters opposed the adoption of the PPPW and SWR measures. One commenter believed that the two measures will not encourage transplants due to poor design. The commenter recommended that CMS develop a transplant measure that is actionable by dialysis facilities. Another commenter recommended that CMS work with transplant programs to align and streamline waitlist criteria and consider ways to create a single point of access for patients and transplant physicians to access potential living donors.

Another commenter stated that any transplant measures should be actionable by dialysis facilities and should meet other scientifically-based criteria. The commenter stated that the proposed PPPW and SWR measures do not assess what they purport to measure, and therefore will not incentivize transplants.

Some commenters stated that the NQF has not endorsed either the PPPW or the SWR. One commenter stated that the NQF's Renal Standing Committee reviewed the measures in the spring of 2018 and did not recommend either measure for endorsement, finding that the submitted evidence was focused on the impact of transplantation on patient outcomes rather than the impact of transplant waitlisting, that the transplant facilities have varying selection criteria for their waitlists, and that the measure did not address patient preference to not receive a transplant. The commenter recommended the development of alternative measures that relate to the outcome of transplant rather than waitlisting.

Another commenter stated that ESRD facilities are not the barrier to placing patients on transplant lists. The commenter stated that the stagnant percentage of patients on waitlists since 2006 that we noted in the CY 2019 ESRD PPS proposed rule is due to the implementation of new conditions of participation for organ transplant centers in 2007, which may result in centers losing their CMS certification if enough organ grafts fail. The commenter further stated that transplant centers have thus become risk-averse and suggested that we review those conditions of participation again rather than adopt these measures. The commenter also stated that we should not incentivize ESRD facilities to increase the percentage of their patients on transplant waitlists if those patients are not appropriate for transplant services.

Response: We will consider working with transplant programs and stakeholders, including HRSA's Organ Procurement Organizations to align and streamline waitlist criteria within our current legal authorities. However, we disagree that the proposed measures will not encourage transplants. We believe that adopting these measures will encourage dialysis facilities to make every effort possible to place their patients on transplant waitlists and thereby ensure that their patients receive the benefits of that treatment modality.

We disagree with the concerns raised by the commenters about the PPPW and SWR measures not meeting scientifically-based criteria. We would like to clarify that the NQF submission included multiple high quality scientific studies demonstrating the positive impact of successful kidney transplantation on patient outcomes. Since deceased donation kidney transplant does not legally occur in the U.S. without waitlisting, we continue to believe that the literature focus of the measure's submission was appropriate. We respectfully disagree with the Renal Standing Committee's view that the evidence we provided on the benefits of kidney transplantation was insufficient.

Although it is true that transplant facilities contribute to the variation in waitlisting, it is also true that extensive variation in dialysis facility referrals results in facility-level variation in waitlisting that is not well explained by available risk adjustors. This dialysis facility-level variation strongly suggests an opportunity for improvement in patient access to kidney transplantation through incentivization of dialysis facility involvement in preparing patients for transplantation.

Patient preference for or against kidney transplantation may well depend, at least in part, on information about the relative benefits of chronic dialysis vs. transplant provided by the dialysis facility. As noted above, dialysis facility-level variation in referrals for evaluation and follow-up strongly suggests opportunities for improvement in educating and preparing patients for transplantation.

We believe that the transplant topic is an important issue that should be covered in the QIP; the benefits of kidney transplantation over dialysis as a modality for renal replacement therapy among ESRD patients are well-established.

We will consider reviewing the conditions of participation for organ transplant centers to evaluate whether prior policy changes have resulted in more risk-averse behavior by those centers. However, we do not agree that we should fail to adopt these measures as a result and note that measuring the percentage of patients waitlisted is a different clinical measurement than assessing patients that receive organ grafts. We believe a measure of patients waitlisted is more appropriate than a measure of patients receiving organ grafts due principally to the scarcity of kidneys for transplant and long waiting times. Further, we believe a measure of patients waitlisted ensures that facilities work with transplant centers to prepare as many patients as possible and clinically appropriate for those procedures.

We also believe that both the PPPW measure and the SWR measure are clinically appropriate measures covering the transplant topic. However, in response to public comments received and in accordance with our Meaningful Measures-based priority of adopting a smaller, more parsimonious measure set, we are finalizing our proposal to adopt the PPPW measure beginning in PY 2022, and as discussed further in section IV.D.1 of this final rule, we are not finalizing our proposal to adopt the SWR measure beginning in PY 2024. We believe that the PPPW measure is more appropriate to include in the QIP at this time because the PPPW measure affects more patients and includes the SWR measure's population; the SWR measure has a 3-year period of performance versus the PPPW measure's 1-year period of performance, and the PPPW measure's reliability is higher than the SWR measure's reliability (0.72 versus 0.67). We have therefore concluded that the PPPW measure is more consistent with our policy goals of promoting kidney transplantation, and in the interest of adopting a more effective measure set, will finalize it and will not finalize the SWR measure. Adoption of one transplant measure rather than both will also reduce facility burden under the QIP because facilities will only need to track their progress on one transplant measure.

Comment: A commenter supported exploring transplantation measures for dialysis care quality but did not support the proposal to adopt the PPPW or SWR measures due to geographic variability

in access to transplantation. The commenter stated that access to transplantation depends heavily on the dialysis facility's proximity to transplant programs. The commenter suggested that CMS instead evaluate each facility based on the historical percentage of patients waitlisted at each facility.

Response: We will consider whether evaluating a historical percentage of patients waitlisted at each facility represents a viable quality measurement option. We will also examine issues related to geographic variability in access to transplantation. However, we do not believe that these concerns necessitate not finalizing measures of transplantation given the clinical benefits associated with that treatment modality.

Comment: A commenter supported our proposal to adopt the PPPW measure, stating that kidney transplantation is widely regarded as a better ESRD treatment option than dialysis for patients' clinical and quality of life outcomes.

Response: We thank the commenter for this support.

Comment: A commenter supported our desire to include transplant measures in the QIP and stated that pediatric dialysis facilities will be able to report the PPPW measure successfully.

Response: We thank the commenter for this support.

Comment: A commenter expressed concerns that the proposed PPPW measure would not address underlying care disparities for pediatric patients and suggested that CMS consider additional exclusion criteria such as excluding patients under 2 years of age and exclusions for patients with medical and sociodemographic criteria that may preclude transplantation.

Another commenter recommended that CMS consider risk-adjusting the PPPW and SWR measures using factors that take into consideration regional differences, eligibility criteria at the transplant center, and demographic variables such as family support, and insurance issues that may influence the likelihood of transplant waitlisting. Another commenter expressed concerns about dialysis patients' being unable to receive premium support payments for commercial health insurance after transplantation, which may delay transplants as those patients cannot then demonstrate that they have a coverage source following the transplant.

Some commenters expressed concern that the PPPW and SWR measures include age as the only sociodemographic risk variable. They stated that transplant centers assess demographic factors such as family support, ability to adhere to medication regimens, capacity for follow-up, and insurance issues. One commenter stated that not accounting for other important biological and demographic variables raises concerns about validity for both measures but did not support adjusting for waitlisting based on economic factors or by race or ethnicity. Another commenter suggested examining geography as a risk variable, stating that regional variation in transplantation access is considerable and that these differences will change the share of patients waitlisted and affect performance measure scores. One commenter also raised concerns that the ''not eligible'' criteria for transplantation can differ by transplantation center location.

Response: We agree that financial and other social issues can pose substantial barriers to waitlisting for patients. However, they do not take away from the fact that many patients with these issues will still stand to benefit substantially from transplantation as compared with remaining on dialysis. As such, it is expected that dialysis facilities will work with transplant centers, advocate for patients and assist them in overcoming barriers to waitlisting to the extent possible. We also recognize that even with the best efforts, not all dialysis patients will ultimately be suitable candidates for waitlisting. Thresholds for the measures are assessed at the facility level. Examination of facility level measures essentially allows comparison of an individual facility's performance to a consensus standard, empirically set by the achievement of dialysis facilities across the nation. Through comparison with the performance of other facilities, these measures may help individual dialysis facilities identify opportunities for improvement in their waitlisting rates.

Regarding geography, we examined this issue extensively and ultimately decided against including an adjustment for the following reasons:

1. The transplant center's geographic rate adjustment is not statistically significant in the model and is unstable dependent on how a small percent of missing values are handled.

2. The C-Index (a measure of goodness of fit) for both the model with and without this geographic adjustment is 0.72, suggesting no improvement in discrimination with inclusion of the geographic effect.

We will continue to examine issues associated with the pediatric population, including possible additional exclusions from transplant measures.

Comment: A commenter expressed support for the exclusion of patients admitted to hospice during the month of evaluation based on its belief that the transplantation access measures should not apply to persons with a limited life expectancy.

Response: We thank the commenter for this support.

Comment: A commenter recommended indicating that the PPPW measure is an intermediate outcome measure rather than a process measure.

Response: We have consulted with the NQF on this topic, and it currently classifies this measure as a process measure. We agree with that assessment since the measure assesses a clinical process—placement on a waitlist—rather than an outcome, such as successful kidney transplants.

Comment: A commenter agreed with CMS that dialysis facilities and transplant centers need to coordinate care related to the transplant referral and waitlisting process, including starting the transplant evaluation and starting the multiple tests and consultations needed for that evaluation. However, the commenter raised concerns about adopting the PPPW measure as a clinical measure rather than a reporting measure. The commenter stated that when the technical expert panel (TEP) convened by CMS's contractor recommended that we adopt the PPPW as a clinical measure, the new kidney allocation system (KAS) on waitlisting was unknown. The commenter noted that the TEP also acknowledged recent evidence suggesting that the mere possibility that a PPPW measure was being developed for potential inclusion in the QIP has changed clinician behavior and reduced waitlisting rates. The commenter also stated that this change in clinician behavior may also be due to the new KAS, where wait-time begins at dialysis initiation, and has caused providers to wait until a patient has spent several years on dialysis prior to referral rather than refer patients early. In addition, the commenter raised concerns that a transplant evaluation conducted by a transplant center can take many months and that the distribution of transplant centers has geographic inequity. Another commenter also raised concerns that eligible patients may not be waitlisted due to factors outside of the dialysis facility's control, such as transplant center eligibility and the lack of NQF endorsement. The commenter recommended that CMS refer this issue

to the ESRD Networks for further discussion with facilities.

Response: We understand the commenter's concerns. However, we do not believe that these concerns should prevent us from finalizing the PPPW measure because the measure incentivizes facilities to do what they can to ensure that their patients are waitlisted as timely as possible. We will continue discussions with the stakeholder community about barriers to organ transplants, but we view transplants as a clinically appropriate goal for dialysis patients. We note further that the measure's testing involved analyses that controlled for geography, and we did not observe any effects on the measure's reliability associated with geographic inequity.

Comment: A commenter stated that one PPPW exclusion has been changed since the measure was originally developed and that the measure being proposed for the QIP now contains an exclusion for ''patients admitted to a skilled nursing facility at incidence or previously according to Form CMS 2728.'' The commenter expressed support for this change and recommended providing information on the impact of this exclusion on performance.

Response: We thank the commenter for its support. Our goal is to test all of our measures as a part of our measure maintenance and development process.

Comment: A commenter suggested that CMS provide for the PPPW and SWR measures a detailed description of measure scores, such as distribution by quartile, mean, median, standard deviation, and outliers, stating that this information is needed for stakeholders to assess the measures and review the measures' performance. The commenter also stated that with large sample sizes, statistically significant differences in performance may not be clinically meaningful.

Response: We thank the commenter for this feedback. We believe that this is a reasonable request and we will consider how to include this information in future versions of the measure methodology reports for each measure.

Comment: A commenter suggested that CMS develop a multi-pronged strategy to increase the kidney transplantation rate. The commenter suggested improving the consistency of information requirements for initial referrals across transplant centers and encouraging the exchange of information through electronic medical records. The commenter also suggested improving the organ donor supply, noting that increasing the number of patients on the waitlist without addressing the limited availability of health donor kidneys will have little effect on increasing the rate of successful transplantations.

Response: We thank the commenter for its suggestions. We will take them under consideration to the extent feasible within our legal authorities.

Comment: A commenter suggested that CMS consider adopting a measure on education for transplantation as a modality.

Response: We thank the commenter for its suggestion. We'll take it under consideration as part of our measure development work.

Comment: A commenter suggested that we consider adopting a measure comparing facilities' transplantation rates to their prior performance. The commenter suggested that this proposal, along with the PPPW measure, could ensure that dialysis facilities in all areas of the country (including those with differing waitlisting rates) work to improve their transplantation practices.

Response: We thank the commenter for its suggestion of a measure concept focused on improvement in transplantation rates. We will take it under consideration as part of our measure development efforts. We note, however, that we will assess performance on the PPPW on both achievement and improvement using the ESRD QIP's current measure scoring methodology. Based on our past experience using this methodology, we believe that dialysis facilities will be able to score points for improving their performance on the measure over time.

Comment: A commenter suggested that referral rates are more appropriate than waitlisting rates as a QIP measure but recognized that data challenges exist.

Response: We thank the commenter for its suggestion of a measure concept focused on transplantation referral rates. We will take it under consideration as part of our measure development work.

Final Rule Action: After considering public comments, we are finalizing our proposal to add the PPPW measure to the ESRD QIP measure set beginning with PY 2022.

b. Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) Reporting Measure

We proposed to adopt the New Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec) reporting measure for the ESRD QIP measure set, beginning with PY 2022. The MedRec measure assesses whether a facility has appropriately evaluated a patient's medications, an important safety concern for the ESRD patient population because those patients typically take a large number of medications. Inclusion of the MedRec measure in the ESRD QIP measure set would align with the Meaningful Measure Initiative priority area of making care safer by reducing harm caused by care delivery.

Medication management is a critical safety issue for all patients, but especially for patients with ESRD, who are often prescribed 10 or more medications simultaneously, take an average of 17 to 25 doses per day, have numerous comorbid conditions, have multiple healthcare providers and prescribers, and undergo frequent medication regimen changes.[17] Medication-related problems contribute significantly to the approximately $40 billion in public and private funds spent annually on ESRD care in the U.S.; for patients with chronic kidney disease alone, this figure is $10 billion.[18] We believe that medication management practices focusing on medication documentation, review, and reconciliation could systematically identify and resolve medication-related problems, improve ESRD patient outcomes, and reduce total costs of care.

Data Sources

The proposed MedRec measure is calculated using administrative claims and electronic clinical data from CROWNWeb, and facility medical records. For additional information on the measure, we refer readers to the measure steward's website; the Kidney Care Quality Alliance (KCQA): *http://kidneycarepartners.com/wp-content/uploads/2014/11/tbKCQA_NQFendorsedSpecs10-26-17.pdf.* The KCQA is funded by Kidney Care Partners (KCP), a coalition of patient advocates, dialysis professionals, care providers, and manufacturers, and was established in 2005 as an independent organization for the purpose of developing quality measures for use in the dialysis setting of care.

Outcome

The outcome of the MedRec measure is the provision of medication reconciliation services and their documentation by an eligible professional for patients attributed to dialysis facilities each month.

[17] Cardone KE, Bacchus S, Assimon MM, Pai AB, Manley HJ. Medication-related problems in CKD. Adv Chronic Kidney Dis. 2010;17(5):404–412.

[18] Parker WM and Cardone KE. Medication Management Services in a Dialysis Center: Patient and Dialysis Staff Perspectives. Albany College of Pharmacy and Health Services. January 2015. Available at: *http://www.acphs.edu.* Accessed March 22, 2016.

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The MedRec measure includes all patients attributed to a dialysis facility during each month of the performance period. The numerator is the number of patient-months for which medication reconciliation was performed and documented by an eligible professional during the reporting period. The denominator statement is the total number of eligible patient-months for all patients attributed to a dialysis facility during the reporting period.

Inclusion and Exclusion Criteria

The MedRec measure excludes in-center patients who receive less than 7 hemodialysis treatments in the facility during the reporting month.

Risk Adjustment

The MedRec measure is not risk-adjusted because it is process measure.

2017 Measures Application Partnership Review

We submitted the MedRec measure to the Measures Application Partnership in 2017 for consideration as part of the pre-rulemaking process, and the Measures Application Partnership addressed the measure in its February 2018 Hospital Workgroup report.[19] The Measures Application Partnership supported the measure for the ESRD QIP, noting that the measure is NQF-endorsed and addresses both patient safety and care coordination. The Measures Application Partnership also noted that the topic of medication reconciliation is currently a gap area in the ESRD QIP's measure set and that the measure has broad support across stakeholders. The Measures Application Partnership emphasized that medication reconciliation is an important issue for ESRD patients who see multiple clinicians and may require numerous medications. The Measures Application Partnership noted that administration of the wrong medication can have grave consequences for an ESRD patient.

For additional information on the Measures Application Partnership's evaluation of measures for the ESRD QIP, we refer readers to the Measures Application Partnership's website at: *https://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx.*

We agree with the Measures Application Partnership's assessment that the MedRec measure is appropriate for the ESRD QIP because medication reconciliation is currently a gap area in the Program's measure set and is an important issue for ESRD patients who receive care from multiple clinicians and providers and may require numerous medications. ESRD patients can be significantly harmed by medication administration errors. We continue to believe that care coordination is a critical quality improvement topic. Therefore, we proposed to adopt the MedRec measure beginning with the PY 2022 ESRD QIP and to place the measure into the Patient Safety Domain. We note further that, as required by section 1881(h)(2)(B)(i) of the Act, CMS is required to use endorsed measures in the ESRD QIP unless the exception at section 1881(h)(2)(B)(ii) of the Act applies. The MedRec measure is endorsed by NQF as #2988.

The comments and our responses to the comments on our proposal are set forth below.

Comment: Several commenters supported our proposal to adopt the MedRec measure, stating that the measure has clinical merit. One commenter stated that the measure is NQF endorsed and that patients on dialysis are on numerous medications, have multiple prescribers and have frequent changes. Another commenter noted that medication management is extremely important for ESRD patients that often receive multiple prescriptions from numerous health care providers. Another commenter stated that the measure will improve patient care and safety.

Response: We thank the commenters for their support.

Comment: A commenter supported the MedRec measure but suggested that the QIP should include a limited set of measures that can more broadly assess facility performance on clinical topics.

Response: We thank the commenter for its support. We agree that the QIP should include a focused quality measure set, which is why we proposed to remove several reporting measures beginning with the PY 2021 ESRD QIP. We intend to continue examining the ESRD QIP measure set to ensure that it remains as effective as possible at providing incentives for high-quality care while minimizing the reporting burden on participating facilities. Further, we believe that the MedRec measure broadly assesses facility performance by focusing on a topic critical to patient safety. By protecting patients from medication errors, dialysis facilities will ensure that their performance on quality measures accords with good clinical practices.

Comment: Two commenters supported the MedRec measure's adoption but suggested that we place it into the Care Coordination domain rather than the Safety domain in order to align with the Meaningful Measures Initiative priorities.

Response: We thank the commenter for their support. However, while we agree that medication reconciliation can be considered a measure of care coordination, we believe that it is more properly aligned with patient safety because patients can be harmed by medication errors.

Comment: A commenter supported our proposal to add the MedRec measure to the QIP beginning in PY 2022, noting that it is critically important for dialysis facilities to have the most accurate record possible of their patients' prescriptions, medications, and supplements.

Response: We thank the commenter for its support.

Comment: A commenter supported adoption of the MedRec measure. The commenter noted that requiring hospitals to provide data regarding patients' inpatient care to dialysis facilities would greatly facilitate dialysis facilities' ability to conduct medication reconciliation. The commenter also noted that the lack of interoperable EHRs hampers this type of data-sharing but recommended that CMS consider how it can better encourage hospitals to provide this information in a timely fashion.

Response: We thank the commenter for its support. We will take their feedback on the lack of interoperable EHRs into consideration in future years and will consider how we can better encourage hospitals to engage with dialysis facilities to share patient information as appropriate.

Comment: A commenter supported adding the MedRec measure to the QIP starting with PY 2022. The commenter noted that medication reconciliation is an example of a safety intervention that is effective in research settings but is difficult to implement successfully in general practice. The commenter stated that several reports show that dialysis patients have frequent discordant medication regimens and stated that medication reconciliation is the process for keeping an accurate medication list. The commenter noted that no information supports that medication reconciliation alone improves health outcomes and that it should be combined with medication assessment/comprehensive medication review focused on indication, effectiveness, and safety of drugs as well as patients' convenience. The commenter also stated

[19] Available at: *https://www.qualityforum.org/Publications/2018/02/2018_Considerations_for_Implementing_Measures_Final_Report_-_Hospitals.aspx.*

that multidisciplinary medication therapy management programs that provide both medication reconciliation and review services to dialysis patients have been shown to reduce hospital readmissions. In addition, the commenter recommended that CMS combine medication reconciliation with a comprehensive medication review.

Response: We thank the commenter for its support. We will take its suggestions into consideration in future years.

Comment: A commenter generally supported our proposal to adopt the MedRec measure but requested that we define ''eligible professional'' as any clinician who can perform medication reconciliation in accordance with state licensure requirements. The commenter noted that this could include registered nurses (RNs), advance practice registered nurses (APRNs), and physician assistants. The commenter also supported the exclusion of patients who receive fewer than 7 hemodialysis treatments in a reporting month. Another commenter requested that we consider adding licensed practical nurses (LPNs) to the measure's ''eligible professionals'' list to avoid causing burden to its RN staff.

Response: We thank the commenters for their feedback. We proposed to define ''eligible professional'' by incorporating the NQF's definition of that term (physicians, RNs, APRNs, PAs, pharmacists, and pharmacy technicians).[20] However, in response to this feedback, we are finalizing the MedRec measure with an expanded definition of ''eligible professional.'' Specifically, we will remove the reference to RNs and replace that reference with ''nurses.'' This change will allow all types of nurses, including LPNs, to perform medication reconciliations within the scope of their licenses.

Comment: A commenter supported medication reconciliation in concept, acknowledging that medication reconciliation is a critical safety issue for dialysis patients, but expressed concern about the continued reliance on measures of processes. The commenter was worried that process measures can be burdensome for providers to report. The commenter suggested that CMS consider addressing this topic through Medicare's conditions for coverage for ESRD facilities rather than adopting the measure.

Response: We disagree with the commenter's recommendation to address medication reconciliation through Medicare's conditions for coverage for ESRD facilities rather than adopting the MedRec measure in the QIP. Given that medication reconciliation is currently a gap area in QIP's measure set and is an important patient safety issue for the ESRD patient population, we believe that the benefits of the measure's inclusion outweigh the providers' reporting burden.

Comment: Commenter suggested adding an exclusion to MedRec for patients in their first month of treatment or transient patients.

Response: We disagree with the commenter's suggestion. It is important to engage in medication reconciliation during a patient's first month or their first visit because medication errors are more likely to occur during care transitions.

Final Rule Action: After considering public comments, we are finalizing our proposal to adopt the MedRec measure for the ESRD QIP beginning with PY 2022, with one change; as previously discussed. We are finalizing the definition of ''eligible professions'' to include all nurses, instead of RNs only.

2. Performance Period for the PY 2022 ESRD QIP

We proposed to establish CY 2020 as the performance period for the PY 2022 ESRD QIP for all measures. We continue to believe that a 12-month performance period provides us sufficiently reliable quality measure data for the ESRD QIP.

We invited comment on this proposal. However, we did not receive any comments specific to the PY 2022 ESRD QIP's performance period. We are therefore finalizing the PY 2022 performance period as proposed.

3. Performance Standards, Achievement Thresholds, and Benchmarks for the PY 2022 ESRD QIP and Subsequent Years

Section 1881(h)(4)(A) of the Act provides that ''the Secretary shall establish performance standards with respect to measures elected . . . for a performance period with respect to a year.'' Section 1881(h)(4)(B) of the Social Security Act (the Act) further provides that the ''performance standards . . . shall include levels of achievement and improvement, as determined appropriate by the Secretary.'' We use the performance standards to establish the minimum score a facility must achieve to avoid a Medicare payment reduction.

a. Performance Standards, Achievement Thresholds, and Benchmarks for Clinical Measures in the PY 2022 ESRD QIP

For the same reasons stated in the CY 2013 ESRD PPS final rule (77 FR 67500 through 76502), we proposed for PY 2022 to set the performance standards, achievement thresholds, and benchmarks for the clinical measures (including the proposed PPPW measure) at the 50th, 15th, and 90th percentile, respectively, of the national performance in CY 2018. We also proposed to apply these performance standards to all clinical measures we use for the ESRD QIP in future payment years. We invited comment on these proposals.

At the time of the CY 2019 ESRD PPS proposed rule's publication, we did not have the necessary data to assign numerical values to the proposed performance standards for the clinical measures because we did not yet have sufficient CY 2018 data. We stated our intent to publish these numerical values, using CY 2018 data received in CY 2018 and the first portion of CY 2019, in the CY 2019 ESRD PPS final rule. However, we erred in that statement, and should have said that we would publish those numerical values in the CY 2020 ESRD PPS final rule, as we would not be able to collect any data from the first portion of CY 2019 prior to the CY 2019 ESRD PPS final rule's publication.

We sought comments on the proposed performance standards for clinical measures. However, we did not receive any comments and are finalizing these performance standards as proposed without change.

b. Performance Standards for the PY 2022 Reporting Measures

In the CY 2016 ESRD PPS final rule, we finalized performance standards for the Screening for Clinical Depression and Follow-Up reporting measure (79 FR 66209). In the CY 2017 ESRD PPS final rule, we finalized performance standards for the Ultrafiltration Rate reporting measure (81 FR 77916) and the NHSN Dialysis Event reporting measure (81 FR 77916). In the CY 2019 ESRD PPS proposed rule (83 FR 34346), we proposed to continue use of these performance standards for these reporting measures for the PY 2022 and future payment years.

For the proposed MedRec reporting measure, we also proposed to set the performance standard for PY 2022 and future payment years as successfully reporting the following data elements for the measure to CROWNWeb, for

[20] See *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/NQF-2988-Patients-Receiving-Care-at-Dialysis-Facilities.pdf.*

each qualifying patient, on a monthly basis, during the performance period: (1) The date that the facility completed the medication reconciliation, (2) the type of clinician who completed the medication reconciliation, and (3) the name of the clinician.

We invited comments on these proposals. However, we did not receive any public comments and are finalizing the proposed performance standards as proposed for PY 2022 and future payment years.

4. Scoring the PY 2022 ESRD QIP and Subsequent Years

a. Scoring Facility Performance on Clinical Measures Based on Achievement

In the CY 2014 ESRD PPS final rule, we finalized a policy for scoring performance on clinical measures based on achievement (78 FR 72215). In the CY 2019 ESRD PPS proposed rule (83 FR 34346), we proposed to use this methodology for scoring achievement for each clinical measure, including the proposed PPPW measure, for the PY 2022 ESRD QIP and for future payment years.

We invited public comments on this proposal. However, we did not receive any public comments are finalizing our policy to score facility performance on clinical measures based on achievement as proposed for PY 2022 and future payment years.

b. Scoring Facility Performance on Clinical Measures Based on Improvement

In the CY 2014 ESRD PPS final rule, we finalized a policy for scoring performance on clinical measures based on improvement (78 FR 72215 through 72216). In the CY 2019 ESRD PPS proposed rule (83 FR 34346), we proposed that for the PY 2022 ESRD QIP, we would continue that policy, defining the improvement threshold as the facility's performance on the measure during the baseline period (which for PY 2022, would be CY 2019). We stated that the facility's improvement score would be calculated by comparing its performance on the measure during CY 2020 (the proposed performance period) to the improvement threshold and benchmark. We also proposed to use this same methodology for scoring the PPPW measure proposed in section IV.C.1.a of the CY 2019 ESRD PPS proposed rule. Finally, we proposed to continue this policy for subsequent years of the ESRD QIP.

We invited public comments on this proposal. However, we did not receive any public comments are finalizing our policy to score facility performance on clinical measures based on improvement as proposed for PY 2022 and future payment years.

c. Scoring Facility Performance on Reporting Measures

In the CY 2015 ESRD PPS final rule, we finalized policies for scoring performance on the Clinical Depression Screening and Follow-Up reporting measures in the ESRD QIP (79 FR 66210 through 66211). In the CY 2017 ESRD PPS final rule, we finalized policies for scoring performance on the Ultrafiltration Rate reporting measure (81 FR 77917). In the CY 2019 ESRD PPS proposed rule (83 FR 34346 through 34347), we proposed to continue use of these policies for the two continuing reporting measures for the PY 2022 ESRD QIP and subsequent years.

For the PY 2022 ESRD QIP, we also proposed to score facilities with a CCN Open Date before January 1st of the performance period year (which, for the PY 2022 ESRD QIP, would be 2020) on the proposed MedRec measure using a formula similar to the one previously finalized for the Ultrafiltration Rate reporting measure (81 FR 77917):

((# patient-months successfully reporting data)/(# eligible patient-months)*12) − 2)

As with the Ultrafiltration Rate reporting measure, we would round the result of this formula (with half rounded up) to generate a measure score from 0 through 10. We also proposed to score facilities using this methodology for subsequent years of the ESRD QIP.

We invited public comment on these scoring proposals. However, we did not receive any public comments specific to scoring facilities' performance on reporting measures. Therefore, we are finalizing our policies for scoring facility performance on the Clinical Depression Screening and Follow-up and Ultrafiltration Rate reporting measures, as proposed, for PY 2022 and future payment years. We are also finalizing our proposal to score the MedRec measure and will apply that scoring methodology to PY 2022 and future payment years.

d. Scoring the ICH CAHPS Clinical Measure

In the CY 2015 ESRD PPS final rule, we finalized a policy for scoring performance on the ICH CAHPS clinical measure based on both achievement and improvement (79 FR 66209 through 66210). We proposed to use this scoring methodology for the PY 2022 ESRD QIP and subsequent years.

We invited comments on this scoring proposal. However, we did not receive any public comments and are finalizing our policy to score facility performance on the ICH CAHPS reporting measure as proposed.

5. Weighting the Measure Domains TPS for PY 2022

For PY 2022, we proposed in the CY 2019 ESRD PPS proposed rule (83 FR 34347) to continue use of the domain weights proposed for PY 2021, and to update the individual measure weights in the Care Coordination Domain and Safety Domain to reflect the introduction of one new proposed measure in each of those domains. We proposed to assign the proposed PPPW measure to the Care Coordination Domain, with a weight of 4 percent of the TPS. To accommodate the addition of the PPPW measure to the Care Coordination Domain without having to adjust the domain's overall weight, we proposed to reduce the weight of two continuing measures in the Care Coordination Domain as follows: The SRR measure from 14 to 12 percent and the SHR measure from 14 to 12 percent. We proposed to assign the proposed MedRec measure to the Safety Domain, with a weight of 4 percent of the TPS (see Table 21). To accommodate the addition of the new MedRec measure to the Safety Domain without having to adjust the domain's overall weight, we proposed to reduce the weight of two continuing measures in the Safety Domain as follows: The NHSN BSI clinical measure from 9 to 8 percent and the NHSN Dialysis Event measure from 6 to 3 percent. To assign these proposed measure weights, we used the same rationale as proposed for PY 2021.

TABLE 21—PROPOSED REVISIONS TO MEASURE WEIGHTS FOR THE PY 2022 ESRD QIP

Measures/measure topics by subdomain	Measure weight within the domain (proposed for PY 2022)	Measure weight as percent of TPS (proposed for PY 2022)
CARE COORDINATION MEASURE DOMAIN		
SRR measure	40.00%	12.00%.
SHR measure	40.00%	12.00%.
PPPW measure	13.33%	4.00%.
Clinical Depression and Follow-Up reporting measure	6.67%	2.00%.
Total: Care Coordination Measure Domain	100% of Care Coordination Measure Domain.	30%
SAFETY MEASURE DOMAIN		
MedRec measure	26.67%	4.00%.
NHSN BSI clinical measure	53.33%	8.00%.
NHSN Dialysis Event reporting measure	20.00%	3.00%.
Total: Safety Measure Domain	100% of Safety Measure Domain.	15%

In the CY 2019 ESRD PPS proposed rule (83 FR 34347), we proposed that to be eligible to receive a TPS, a facility must be eligible to be scored on at least one measure in two of the four measure domains. We also stated that if that proposal is finalized, we would apply it to PY 2022 and subsequent payment years.

We invited comments on these proposals.

The comments and our responses to the comments on our weighting proposals are set forth below.

Comment: A commenter was concerned that we had not fully considered the reporting burden associated with each quality measure when reweighting for PY 2022, specifically with respect to the NHSN Dialysis Event Reporting measure. The commenter stated that dialysis facilities undertake significant effort to report data for that measure, and that its importance to care quality measurement means that its weight should not be reduced as proposed. The commenter requested that we reconsider lowering the Dialysis Event Reporting measure's weight.

Response: We disagree with the commenter's concern that the NHSN Dialysis Event reporting measure's proposed PY 2022 weight is too low. The measure's weight reflects the Meaningful Measures priorities and our preferred emphasis on weighting measures that directly impact clinical outcomes more heavily than other measures.

Final Rule Action: After considering the public comments received, we are finalizing our domain and measure weighting policy for PY 2022 as reflected in Table 22. These measure weighting changes are consistent with those finalized for PY 2021 (and thus incorporate the commenters' feedback on the PY 2021 domain weighting) (see Table 17) and accommodate the new measures that we are finalizing for PY 2022, which we are placing in the Care Coordination Domain (PPPW measure) and the Safety Domain (MedRec measure).

TABLE 22—FINALIZED MEASURE DOMAIN WEIGHTING FOR THE PY 2022 ESRD QIP

Measures/measure topics by subdomain	Measure weight as percent of TPS (finalized for PY 2022)
PATIENT & FAMILY ENGAGEMENT MEASURE DOMAIN	
ICH CAHPS measure	15.00
	15.00
CARE COORDINATION MEASURE DOMAIN	
SRR measure	12.00
SHR measure	12.00
PPPW measure	4.00
Clinical Depression and Follow-Up reporting measure	2.00
Total: Care Coordination Measure Domain	30
CLINICAL CARE MEASURE DOMAIN	
Kt/V Dialysis Adequacy Comprehensive measure	9.00
Vascular Access Type measure topic*	12.00

TABLE 22—FINALIZED MEASURE DOMAIN WEIGHTING FOR THE PY 2022 ESRD QIP—Continued

Measures/measure topics by subdomain	Measure weight as percent of TPS (finalized for PY 2022)
Hypercalcemia measure	3.00
STrR measure	10.00
Ultrafiltration Rate reporting measure	6.00
	40
SAFETY MEASURE DOMAIN	
MedRec measure	4.00
NHSN BSI clinical measure	8.00
NHSN Dialysis Event reporting measure	3.00
Total: Safety Measure Domain	15

6. Eligibility Requirements for the PY 2022 ESRD QIP and Subsequent Payment Years

Our policy is to score facilities on clinical and reporting measures for which they have a minimum number of qualifying patients during the performance period (77 FR 67510 through 67512). In the CY 2019 ESRD PPS proposed rule (83 FR 34347), we proposed to continue use of these minimum data policies for the PY 2022 ESRD QIP measure set and in subsequent years. We also proposed to use these same minimum data policies for the proposed PPPW measure and proposed MedRec measure for the PY 2022 ESRD QIP and subsequent years.

We invited comment on these eligibility proposals.

The comments and our responses to the comments on our proposal are set forth below.

Comment: A commenter stated that there is a lack of consistency in the minimum data requirements and a lack of clear and empirical rationale for the small facility adjuster. The commenter suggested that CMS adjust measures to yield a result with a reliability statistic of at least 0.70, which the commenter believed is consistent with how NQF assesses its evaluation of measures. The commenter stated that this change would prevent small facilities from receiving scores with random variability.

Response: We thank the commenter for this feedback. We would like to clarify that under our current policy, we will use a small facility adjuster threshold of 11 through 25 eligible patients for the PPPW measure. We would also like to clarify that NQF does not employ a specific standard for a quality measure's reliability statistic. We have adopted minimum data requirements and the small facility adjuster to accommodate the different types of quality measures that we have adopted in the ESRD QIP and the different types of data collected for them. We have concluded that different minimum data thresholds are appropriate. We further believe that the small facility adjuster appropriately ensures that small facilities do not receive measure scores with random variability. However, we will continue to examine this issue.

Final Rule Action: After considering public comments received, we are finalizing our eligibility policies, as proposed. Table 23 provides a summary of these eligibility policies for the PY 2022 ESRD QIP measure set and future years.

TABLE 23—ELIGIBILITY REQUIREMENTS FOR THE PY 2022 ESRD QIP MEASURE SET

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Dialysis Adequacy (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Vascular Access Type: Long-term Catheter Rate (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Vascular Access Type: Standardized Fistula Rate (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.
Hypercalcemia (Clinical)	11 qualifying patients	N/A	11–25 qualifying patients.
NHSN Bloodstream Infection (Clinical).	11 qualifying patients	Before October 1, 2019	11–25 qualifying patients.
NHSN Dialysis Event (Reporting).	11 qualifying patients	Before October 1, 2019	11–25 qualifying patients.
SRR (Clinical)	11 index discharges	N/A	11–41 index discharges.
STrR (Clinical)	10 patient-years at risk	N/A	10–21 patient years at risk.
SHR (Clinical)	5 patient-years at risk	N/A	5–14 patient-years at risk.
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities will not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period.	Before October 1, 2019	N/A.

TABLE 23—ELIGIBILITY REQUIREMENTS FOR THE PY 2022 ESRD QIP MEASURE SET—Continued

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Depression Screening and Follow-Up (Reporting).	11 qualifying patients	Before April 1, 2020	N/A.
Ultrafiltration Rate (Reporting).	11 qualifying patients	Before April 1, 2020	N/A.
Medication Reconciliation (Reporting).	In-center patients who receive 7 or more hemodialysis treatments in the facility during the reporting month.	Before October 1, 2019	N/A.
Percentage of Prevalent Patients Waitlisted (Clinical).	11 qualifying patients	N/A	11–25 qualifying patients.

7. Payment Reductions for the PY 2022 ESRD QIP

Section 1881(h)(3)(A)(ii) of the Act requires the Secretary to ensure that the application of the scoring methodology results in an appropriate distribution across facilities, such that facilities achieving the lowest TPSs receive the largest payment reductions. For additional information on payment reduction policies, we refer readers to the CY 2018 ESRD PPS final rule (82 FR 50787 through 50788).

Because we are not yet able to calculate the performance standards for each of the clinical measures, we are also not able to calculate a proposed minimum TPS at this time. In the CY 2020 ESRD PPS proposed rule, we will propose the minimum TPS based on CY 2018 data.

D. Requirements Beginning with the PY 2024 ESRD QIP

1. Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients Clinical Measure

In the CY 2019 ESRD PPS proposed rule, we proposed to add one new transplant measure to the ESRD QIP measure set beginning with PY 2024: Standardized First Kidney Transplant Waitlist Ratio for Incident Dialysis Patients (SWR). The proposed new SWR measure would align the ESRD QIP more closely with the Meaningful Measures Initiative priority area of increased focus on effective communication and coordination. The SWR Measure assesses the number of patients who are placed on the transplant waitlist or receive a living donor kidney within 1 year of the date when dialysis is initiated. We stated that we believe this measure would encourage facilities to more rapidly evaluate patients for transplant and coordinate the waitlisting of those patients.[21] Because the proposed SWR measure is limited to patients in their first year of dialysis, it is more limited in scope than the proposed PPPW measure, which includes patients who have been on dialysis for longer than 1 year. We proposed to introduce the SWR measure for PY 2024 rather than PY 2022 because the proposed SWR measure is calculated using 3 years of data.

Data Sources

The SWR Measure is calculated using administrative claims and electronic clinical data. CROWNWeb is the primary source used to attribute patients to dialysis facilities and dialysis claims are used as an additional source. Information regarding onset of ESRD, the first ESRD treatment date, death, and transplant is obtained from CROWNWeb (including the Medical Evidence Form CMS–2728 and the Death Notification Form CMS–2746) and Medicare claims, as well as the Organ Procurement and Transplant Network.

Outcome

The SWR Measure tracks the number of incident patients attributed to the dialysis facility under the age of 75 listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year of initiating dialysis. Similar to the PPPW measure, the SWR measure emphasizes shared accountability between dialysis facilities and transplant centers.

Cohort

The SWR measure includes patients under the age of 75 and attributed to the dialysis facility using CROWNWeb data and Medicare claims who are listed on the kidney or kidney-pancreas transplant waitlist or who received living donor transplants within the first year of initiating dialysis. Patients are attributed to the dialysis facility listed on the Medical Evidence Form CMS–2728.

Inclusion and Exclusion Criteria

The SWR measure excludes patients at the facility who were 75 years of age or older at initiation of dialysis and patients at the facility who were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis. Additionally, patients who are admitted to a SNF or hospice at the time of initiation of dialysis are excluded.

Risk Adjustment

The SWR measure is adjusted for incident comorbidities and age. Incident comorbidities were selected for adjustment into the SWR model based on demonstration of a higher associated mortality (hazard ratio above 1.0) and statistical significance (p-value in first year mortality model). More details about the risk adjustment model can be found in the SWR Methodology Report (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/061_TechnicalSpecifications.html*).

2017 Measures Application Partnership Review

We submitted the SWR measure to the Measures Application Partnership in 2017 for consideration as part of the pre-rulemaking process.

In its report (available on its website at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972*), the Measures Application Partnership acknowledged that the SWR measure addresses an important quality gap for dialysis facilities and discussed a number of factors that it believed should be balanced when implementing the measure. The Measures Application Partnership reiterated the critical need

[21] Meier-Kriesche, Herwig-Ulf, and Bruce Kaplan. ''Waiting time on dialysis as the strongest modifiable risk factor for renal transplant outcomes: A Paired Donor Kidney Analysis1.'' Transplantation 74.10 (2002): 1377–1381; Meier-Kriesche, H. U., Port, F. K., Ojo, A. O., Rudich, S. M., Hanson, J. A., Cibrik, D. M., Leichtman, A.B. & Kaplan, B. (2000). Effect of waiting time on renal transplant outcome. Kidney international, 58(3), 1311–1317.

to help patients receive kidney transplants to improve their quality of life and reduce their risk of mortality. The Measures Application Partnership also noted there are disparities in the receipt of kidney transplants and there is a need to incentivize dialysis facilities to educate patients about waitlist processes and requirements. The Measures Application Partnership also acknowledged concerns and public comment about the locus of control of the measure, where dialysis facilities may not be able to as adequately influence a patient's suitability to be waitlisted as well as the transplant center. The Measures Application Partnership also noted the need to ensure the measure is appropriately risk-adjusted and recommended the exploration of adjustment for social risk factors and proper risk model performance. The Measures Application Partnership ultimately conditionally supported the measure with the condition that it is submitted for NQF review and endorsement. Specifically, the Measures Application Partnership recommended that this measure be reviewed by the NQF Scientific Methods Panel as well the Renal Standing Committee. The Measures Application Partnership recommended the endorsement process examine the validity of the measure, particularly the risk adjustment model and if it appropriately accounts for social risk. Finally, the Measures Application Partnership noted the need for the Disparities Standing Committee to provide guidance on potential health equity concerns. Our understanding is that the NQF endorsement process covers all of the Measure Application Partnership's conditions, and we have submitted the measure for endorsement.

For additional information on the Measures Application Partnership's evaluation of measures for the ESRD QIP, we refer readers to Measures Application Partnership's website at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86972*.

Based on the benefits of kidney transplantation over dialysis as a modality for renal replacement therapy for patients with ESRD, and taking into account the Measures Application Partnership's conditional endorsement and our submission of the measure for NQF endorsement, we propose to adopt the SWR measure beginning with the PY 2024 ESRD QIP. We also proposed to place this measure in the Transplant Waitlist measure topic in the Care Coordination Domain, along with the PPPW measure proposed in section IV.C.1.a of this final rule, and to score the two measures accordingly as a measure topic. We note also that there are currently no NQF-endorsed transplant measures that we could have considered, and we believe that we should adopt this measure under section 1881(h)(2)(B)(ii) of the Act due to its clinical significance for the ESRD patient population.

We invited comments on this proposal. Because many public commenters addressed the PPPW and SWR measures together, we addressed some comments on the SWR measure in section IV.C.1.a of this final rule.

Additional comments and our responses to the comments on our proposal to add the SWR measure to the ESRD QIP measures set are set forth below.

Comment: Some commenters opposed our proposal to adopt the SWR measure, stating that the measure is limited in its action ability by the dialysis center because the waitlist decision is made by the transplant center, not the dialysis facility. One commenter noted that incident dialysis patients not listed for transplants may be more complex or have comorbidities that make them ineligible for the waitlist during the first year. The commenter also stated that the measure could create a perceived incentive to start advanced chronic kidney disease (CKD) patients on dialysis earlier because it would not recognize dialysis units' role in pre-education and care coordination for patients who have received a pre-emptive transplant. One commenter noted that disparities remain an issue in the pediatric population, and that facilities' ability to waitlist or coordinate transplant waitlists is limited. The commenter reiterated its view that a patient-centered educational effort would be more appropriate for use in the QIP than the SWR measure. The commenter also recommended us to revisit and expand the measure's exclusion criteria if it decides to finalize the measure.

Response: As we noted with respect to the PPPW measure above, waitlisting for transplantation is the culmination of a variety of preceding activities. These include (but are not limited to) education of patients about the transplant option, referral of patients to a transplant center for evaluation, completion of the evaluation process and optimizing the health of the patient while on dialysis. These efforts depend heavily and, in many cases, primarily, on dialysis facilities. Although some aspects of the waitlisting process may not entirely depend on facilities, such as the actual waitlisting decision by transplant centers, or a patient's choice about the transplantation option, these can also be nevertheless influenced by the dialysis facility. The waitlisting measures were therefore proposed in the spirit of shared accountability, with the recognition that success requires substantial effort by dialysis facilities. In this respect, the measures represent an explicit acknowledgment of the tremendous contribution dialysis facilities can be and are already making towards access to transplantation, to the benefit of the patients under their care.

With respect to the commenter's concern about potentially creating an incentive for nephrologists to start advanced ESRD patients on dialysis earlier, we believe that dialysis facilities have a responsibility to ensure that they furnish proper care to their patients.

Comment: A commenter opposed our proposal to adopt the SWR measure, stating that its adoption seems to conflict with stricter outcome guidelines that we have adopted for transplant centers. The commenter also suggested that it would be helpful if we developed CROWNWeb software changes proactively for new quality measures, as the SWR measure could require significant resources and time to report.

Response: We will develop CROWNWeb software changes as proactively as is feasible for new measures to ensure that dialysis facilities are able to understand those changes and report their quality measure data as promptly and effectively as possible.

However, as we discuss further below, we are not finalizing the SWR measure at this time, so such changes will not be necessary. We disagree that the SWR measure's adoption would conflict with guidelines that we have adopted for transplant centers, however, as the goal of the measure is to ensure that patients are appropriately waitlisted for transplants and not that they must receive transplants. While we appreciate that transplant centers must focus on clinical outcomes, the purpose of adopting a measure of transplant waitlisting for dialysis facilities is not to encourage unnecessary transplants but to ensure that patients can receive the benefit of that treatment modality when appropriate.

Comment: A commenter expressed concern that it is unable to discern how widely reliability varies across the spectrum of facility sizes because CMS has not provided stratification of reliability scores by facility size for the PPPW measure and the SWR measure. The commenter expressed concern that the reliability for small facilities may be significantly lower than the overall inter-unit reliabilities (IURs), as the

commenter explained is the case with other CMS standardized ratio measures. The commenter expressed special concern for the SWR, which has an IUR of 0.6 and is considered moderately reliable by statistical convention. The commenter suggested that CMS demonstrate reliability for all facilities by providing data by facility size.

Response: We acknowledge the commenter's concern about smaller facilities. For each measure respectively, facilities with fewer than two expected events (SWR) or 11 eligible patients (PPPW) are not included in the respective measure calculations.

In regards to the specific comment about IUR, the IUR for these measures is ''moderate'' and similar to or higher than many other population-based measures used in public reporting and VBP programs. IUR is a general expression of the distribution of within and between facility variance in the population of facilities. The formula for IUR includes a term for patient number, so IUR will always be lower for smaller facilities and higher for larger facilities regardless of the measure. The IUR for all facilities is what the NQF uses to evaluate the measure, so we believe including values stratified by different facility size would be misleading for the public. For public reporting, our method for identifying outlier facilities utilizes the empiric null approach, which adjusts for flagging rates by facility size; that is, smaller facilities that have more extreme outcomes compared to other smaller facilities will be flagged.

Comment: A commenter expressed a preference for normalized rates or year-over-year improvement in rates for the SWR measure instead of a standardized ratio, suggesting that comprehension, transparency, and utility to stakeholders is superior with a scientifically valid rate methodology.

Response: Placing a facility's risk adjusted rate in context requires reference to a standard rate that applies to the population as a whole. The ratio estimate that we proposed is the ratio of the facility adjusted rate to the standard rate. The ratio is also a scientifically valid approach and, in our experience, most people find the ratio to be understandable and to sufficiently convey the rates. Most regression analyses (of binary or count responses) in the clinical and epidemiologic literature are based on ratios. Ratio measures are well accepted in the published literature. Additionally, the risk-adjustment approach currently used for the STrR, SHR, SRR, and SWR measures are based on indirect standardization which also forms the basis of many measures implemented in the ESRD QIP and other CMS quality reporting and VBP programs, and we believe that this approach leads naturally to a standardized ratio. This ratio compares the rate for this facility with the national rate, having adjusted for the patient mix and as such is relatively straightforward.

Comment: A commenter raised concerns about the validity of CMS Form 2728—the source for 11 of the SWR's incident comorbidities—and urged CMS to work with the community to assess this issue in further detail.

Response: We disagree with the commenter's concerns about the validity of CMS form 2728. Comorbidities reported on this form have been found to be useful predictors of mortality, suggesting that the most salient comorbidities are reported.22 The comorbidities from the CMS Form 2728 included in the SWR model were chosen based on their association with first year mortality. Additionally, we believe that it is reasonable to expect dialysis facilities to have an awareness of patient comorbidities at incidence. When dialysis facilities receive an intake call, they receive an extract of the patient's chart, which includes current conditions/comorbidities. Facilities should be reviewing that chart before accepting a patient. Dialysis facilities also attest to the accuracy of the information reported on the 2728 prior to submitting the form to CMS.

Comment: A commenter requested information as to why the proposed SWR measure does not include an exclusion for patients with a previous transplant. The commenter noted that during the NQF Renal Standing Committee's consideration of the SWR measure, CMS said that this exclusion would be present in the measure's specifications.

Response: We thank the commenter for their feedback. The following exclusion is incorporated into the denominator definition for the PPPW and SWR measures:

- *Preemptive patients:* patients at the facility who had the first transplantation prior to the start of ESRD treatment; or were listed on the kidney or kidney-pancreas transplant waitlist prior to the start of dialysis.

We will modify the technical specifications to make sure that the exclusion is fully and clearly stated in the posted materials to prevent any misunderstanding.

Comment: A commenter raised concerns about the exclusion of patients waitlisted prior to the start of dialysis, noting that this may be a disincentive to those nephrologists actively attempting to enable preemptive transplantation as a viable alternative to dialysis. The commenter recommended that CMS remove that exclusion if the SWR measure is included in the final rule.

Response: We thank the commenter for this concern. However, as noted above, we are not finalizing the SWR measure at this time. We will consider addressing this exclusion if we propose to adopt the SWR measure in the future.

Final Rule Action: After considering the public comments that we have received, we are not finalizing our proposal to add the SWR measure to the Program.

2. Performance Period for the SWR Measure

Because the SWR measure is calculated using 36 months of data, we proposed to establish a 36-month performance period for the proposed SWR measure. With respect to PY 2024 ESRD QIP, this period would be CY 2019 through 2021. We continue to believe that a 36-month performance period for the SWR measure would enable us to calculate sufficiently reliable measure data for the ESRD QIP.

Final Rule Action: We are not finalizing the SWR measure, therefore, we are not finalizing the performance period for the SWR measure.

3. Performance Standards, Achievement Thresholds, and Benchmarks for the SWR Measure in the PY 2024 ESRD QIP

We stated that, if finalized, we would score the proposed SWR measure using a 36-month performance period for purposes of achievement and a corresponding 36-month baseline period for purposes of improvement. For the PY 2024 ESRD QIP, these periods would be CY 2017 through 2019 for achievement and CY 2018 through 2020 for improvement.

We also stated that at the time of the CY 2019 ESRD PPS proposed rule's publication, we did not have the necessary data to assign numerical values to the performance standards for the SWR measure, because we did not yet have data from CY 2017 through CY 2020.

We welcomed public comments on the performance standards for the SWR measure. However, we did not receive any public comments specific to the SWR measure's performance standards.

Final Rule Action: As discussed above, we are not finalizing the SWR measure, and we are therefore not finalizing the performance standards for the SWR measure.

V. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

A. Background

Section 1847(a) of the Social Security Act (the Act), as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary of the Department of Health and Human Services (the Secretary) to establish and implement competitive bidding programs in competitive bidding areas (CBAs) throughout the United States (U.S.) for contract award purposes for the furnishing of certain competitively priced DMEPOS items and services. The competitive bidding programs of the Medicare Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP), mandated by section 1847(a) of the Act, are collectively referred to as ''DMEPOS CBP''. A final rule published on April 10, 2007 in the **Federal Register**, titled ''Competitive Acquisition for Certain DMEPOS and Other Issues'', (72 FR 17992), referred to as ''2007 DMEPOS final rule'', established competitive bidding programs for certain Medicare Part B covered items of DMEPOS throughout the U.S. The competitive bidding programs, which were phased in over several years, utilize bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items and services. Section 1847(a)(2) of the Act describes the items and services subject to the DMEPOS CBP:

- Off-the-shelf (OTS) orthotics for which payment would otherwise be made under section 1834(h) of the Act.
- Enteral nutrients, equipment and supplies described in section 1842(s)(2)(D) of the Act.
- Certain DME and medical supplies, which are covered items (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.

The DMEPOS CBP was modeled after successful demonstration programs from the late 1990s and early 2000s, discussed in the proposed rule published on May 1, 2006 in the **Federal Register**, titled ''Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues'' (71 FR 25654) referred to as ''2006 DMEPOS proposed rule''. We received substantial advice in the development of the DMEPOS CBP from the Program Advisory and Oversight Committee (PAOC), which was mandated through section 1847(c) of the Act, as amended by section 302(b)(1) of the MMA, to establish a committee to provide advice to the Secretary with respect to the following functions:

- The implementation of the Medicare DMEPOS CBP.
- The establishment of financial standards for entities seeking contracts under the Medicare DMEPOS CBP, taking into account the needs of small providers.
- The establishment of requirements for collection of data for the efficient management of the Medicare DMEPOS CBP.
- The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d) of the Act), and individuals.
- The establishment of quality standards for DMEPOS suppliers under section 1834(a)(20) of the Act.

As authorized under section 1847(c)(2) of the Act, the PAOC members were appointed by the Secretary of the Department of Health and Human Services (the Secretary) and represented a broad mix of relevant industry, consumer, and government parties. The representatives had expertise in a variety of subject matter areas, including DMEPOS, competitive bidding methodologies and processes, and rural and urban marketplace dynamics.

In the DMEPOS CBP, suppliers bid for contracts for furnishing multiple items and services, identified by Healthcare Common Procedure Coding System (HCPCS) codes, under several different product categories. Section 1847(a)(1)(B) and (D) of the Act mandated the phase in of the DMEPOS CBP in nine of the largest MSAs (Round 1), followed by 91 additional large MSAs (Round 2), and finally in additional areas, which do not necessarily need to be tied to MSAs. Round 1 and Round 2 CBAs that included more than one state have been subdivided into state-specific CBAs. More information on the different rounds of competitions and general information regarding the CBP is available on the following website: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html*. The CBP is currently operating in 130 CBAs throughout the nation, and those CBAs contain approximately half of the enrolled Medicare Part B population. The other half of the Medicare Part B population resides in areas where the CBP has not yet been phased in, including approximately 275 MSAs. In addition, CMS phased in a national mail order program for diabetic testing supplies in 2013. In the Round 1 2017 and Round 2 Recompete competitions, the product categories currently include: Enteral Nutrients, Equipment and Supplies; General Home Equipment and Related Supplies and Accessories (including hospital beds, pressure reducing support surfaces, commode chairs, patient lifts, and seat lifts); Nebulizers and Related Supplies; Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories; Respiratory Equipment and Related Supplies and Accessories (including oxygen and oxygen equipment, continuous positive pressure airway devices, and respiratory assist devices); Standard Mobility Equipment and Related Accessories (including walkers, standard manual wheelchairs, and standard power wheelchairs); and Transcutaneous Electrical Nerve Stimulation (TENS) Devices and Supplies. Since there are multiple items in each product category, a ''composite'' bid is calculated for each supplier to determine which supplier's bids would result in the greatest savings to Medicare for the product category. A supplier's composite bid for a product category currently is calculated by multiplying a supplier's bid for each item in a product category by the item's weight and taking the sum of these numbers across items. This calculation is reflected in the current definition of composite bid under existing § 414.402, which we are further modifying in this final rule. The weight of an item is based on the annual utilization of the individual item compared to other items within that product category based on recent Medicare national claims data. Item weights are used to reflect the relative market importance of each item in the product category. Item weights ensure that the composite bid is directly comparable to the costs that Medicare would pay if it bought the expected bundle of items in the product category from the supplier.

Currently, each supplier submits a bid amount for each item in the product category, and multiple contracts must be awarded for each product category in each CBA. Section 1847(b)(5) of the Act mandates a single payment amount (SPA) for each item based on bids submitted and accepted from suppliers, so various options for calculating the SPA were addressed in the 2006 DMEPOS proposed rule (71 FR 25679). The methods of using the minimum winning bid amount for each item, the maximum winning bid amount for each item, the median of the winning bid amounts for each item, and an average

adjusted price based on the method used during the demonstrations were discussed during this rulemaking. The SPA calculation method using the median of the winning bids was finalized in the 2007 DMEPOS final rule (72 FR 18044) based on the rationale that the median of winning bids represents the bid amounts of the winning suppliers as a whole, whereas the minimum and maximum bids did not; it is a simpler method than the average adjusted price method; and it is consistent with the longstanding Medicare payment rules for DMEPOS that established allowed payment amounts based on average reasonable charges rather than minimum or maximum charges.

To implement section 522(a) of the Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA), we published a final rule on November 4, 2016 in the **Federal Register**, titled ''End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model'' (81 FR 77834), referred to as ''2016 ESRD PPS final rule''.

Section 1847(a)(1)(G) of the Act, as added by section 522(a) of MACRA, requires bidding entities to secure a bid surety bond by the deadline for bid submission. Section 1847(a)(1)(G) of the Act provides that, with respect to rounds of competitions under section 1847 of the Act beginning not earlier than January 1, 2017 and not later than January 1, 2019, a bidding entity may not submit a bid for a CBA unless, as of the deadline for bid submission, the entity has (1) obtained a bid surety bond, in the range of $50,000 to $100,000, in a form specified by the Secretary consistent with paragraph (H) of section 1847(a)(1) of the Act, and (2) provided the Secretary with proof of having obtained the bid surety bond for each CBA in which the entity submits its bid(s). We believe that section 522(a) of MACRA was drafted under the assumption that the next round of competitive bidding would have been implemented at some point between January 1, 2017 and January 1, 2019. We have interpreted section 522(a) of MACRA as applying to the next round of competitive bidding even though the next round of competition will begin after the time period specified in the statute. Section 1847(a)(1)(H)(i) of the Act provides that in the event that a bidding entity is offered a contract for any product category for a CBA, and its composite bid for such product category and area was at or below the median composite bid rate for all bidding entities included in the calculation of the SPAs for the product category and CBA, and the entity does not accept the contract offered, the bid surety bond(s) for the applicable CBAs will be forfeited and the Secretary will collect on the bid surety bond(s). In instances where a bidding entity does not meet the bid bond forfeiture conditions for any product category for a CBA as specified in section 1847(a)(1)(H)(i) of the Act, then the bid surety bond liability submitted by the entity for the CBA will be returned to the bidding entity within 90 days of the public announcement of the contract suppliers for such product category and area. As aforementioned, this requirement was implemented as part of the CY 2016 ESRD PPS final rule (81 FR 77834), so § 414.412(h) now requires that bidding entities obtain bid surety bonds, and if an entity is offered a contract for any product category for a CBA, and its composite bid for such product category and area is at or below the median composite bid rate for all bidding entities included in the calculation of the SPAs for the product category/CBA combination, and the entity does not accept the contract offered, the bid surety bond for the applicable CBA will be forfeited and CMS will collect on the bid surety bond via Electronic Funds Transfer from the respective bonding company. Further detailed conditions of the surety bonds were also clarified in that final rule (81 FR 77931). The bid bond requirement was mentioned in the background section of the proposed rule because bid bond forfeiture is tied to composite bids under the DMEPOS CBP, and this rule finalizes a change to how composite bids are defined and implements lead item pricing under the DMEPOS CBP (83 FR 34350).

Section 1847(b)(5) of the Act provides that Medicare payment for competitively bid items and services is made on an assignment-related basis and is equal to 80 percent of the applicable SPA, less any unmet Part B deductible described in section 1833(b) of the Act. Section 1847(b)(2)(A)(iii) of the Act prohibits the Secretary from awarding a contract to an entity unless the Secretary finds that the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid. The DMEPOS CBP also includes provisions to ensure beneficiary access to quality DMEPOS items and services. Section 1847(b)(2)(A) of the Act directs the Secretary to award contracts to entities only after a finding that the entities meet applicable quality and financial standards and beneficiary access to a choice of multiple suppliers in the area is maintained, that is, more than one contract supplier is available for the product category in the area.

Section 1847(b)(6)(A) of the Act provides that payment will not be made under Medicare Part B for items and services furnished under the CBP unless the supplier has submitted a bid to furnish those items and has been awarded a contract. Except in limited circumstances, in order for a supplier that furnishes competitively bid items in a CBA to receive payment for those items, the supplier must have submitted a bid to furnish those particular items and must have been awarded a contract. In past rounds of competition, CMS has allowed a 60-day bidding window for suppliers to prepare and submit their bids. Our existing regulation at § 414.412, which we are modifying in this final rule, specifies the rules for submission of bids under the DMEPOS CBP. Each bid submission is evaluated and contracts are awarded to qualified suppliers in accordance with the requirements and conditions for awarding contracts under section 1847(b)(2) of the Act and § 414.414, which we are also modifying in this final rule. Under the Round 2 and Round 1 Recompete competitions, 92 percent of suppliers accepted contract offers at the SPAs set through the competitions. In addition, CMS reviewed all contract suppliers based on financial standards when evaluating their bids. This process includes review of tax records, credit reports, and other financial data, which leads to the calculation of a score, similar to processes used by lenders when evaluating the viability of a company. All contract suppliers met the financial standards established for the program. Before awarding contracts, each bid is screened and evaluated to ensure that it is bona fide so that CMS can verify that the supplier can provide the product to the beneficiary for the bid amount, and those that fail are excluded from the competition. Approximately 94 percent of bids screened as part of the Round 2

and Round 1 Recompete competitions were determined to be bona fide.

Section 1847(b)(6)(D) of the Act requires that appropriate steps be taken to ensure that small suppliers of items and services have an opportunity to be considered for participation in the DMEPOS CBP. We have established a number of provisions to ensure that small suppliers are given an opportunity to participate in the DMEPOS CBP. For example, under § 414.414(g)(1)(i), we have established a 30 percent target for small supplier participation; thereby ensuring efforts are made to award at least 30 percent of contracts to small suppliers. Also, CMS worked in coordination with the Small Business Administration and based on advice from the PAOC to develop an appropriate definition of ''small supplier'' for this program. Under § 414.402, a small supplier is one that generates gross revenues of $3.5 million or less in annual receipts, including Medicare and non-Medicare revenue. Under § 414.418, small suppliers may join together in ''networks'' in order to submit bids that meet the various program requirements. A majority of the bids used in establishing SPAs come from small suppliers with a history of furnishing items in the CBAs.

B. Current Method for Submitting Bids and Selecting Winners

Currently, in the DMEPOS CBP, CMS awards contracts to suppliers for furnishing multiple items and services needed in a given CBA that fall under a product category (for example, respiratory equipment). The product categories are mostly large and include multiple items used for different purposes (for example, the respiratory equipment category includes oxygen equipment and positive pressure airway devices and multiple related accessories) based on past feedback from stakeholders to promote easy access for beneficiaries and referral agents to receive all items in a product category from one location, and to prevent instances where a supplier wins a contract for one product category but loses the competitions for several other product categories. Because multiple bids for individual items are submitted when competing to become a contract supplier for the product category of items and services as a whole, it is necessary to calculate a composite bid for each bidding supplier to determine the lowest bids for the category as a whole. In accordance with existing § 414.402, a composite bid means the sum of a supplier's weighted bids for all items within a product category for purposes of allowing a comparison across bidding suppliers. Using a composite bid is a way to aggregate a supplier's bids for individual items within a product category into a single bid for the whole product category.

In order to compute a composite bid, a weight must be applied to each item in the product category. In accordance with § 414.402, item weight is a number assigned to an item based on its beneficiary utilization rate using national data when compared to other items in the same product category. Item weights are used to reflect the relative market importance of each item in the product category. Table 26 depicts the calculation of the item weights for a supplier's bid. The expected volume for items A, B, and C are 5, 3, and 2 units, respectively, for a total volume of 10 units. The item weight for item A is 0.5 (5/10), the weight for item B is 0.3 (3/10), etc. The total item weight for the supplier's bid is 1.

TABLE 26—ITEM WEIGHTS

Item	A	B	C	Total
Units	5	3	2	10
Item Weight	0.5	0.3	0.2	1

The composite bid for a supplier equals the item weight multiplied by the item bid summed across all items in the product category. For example, supplier 1 bid $1.00 for item A, $4.00 for item B and $1.00 for item C. The composite bid for Supplier 1 = (0.5 * $1.00) + (0.3 * $4.00) + (0.2 * $1.00) = 1.90. Table 27 shows the expected cost of the bundle based on each supplier's bids. The expected costs are directly proportional to the composite bids; the factor of proportionality is equal to the total number of units (10) in the product category. The composite bid is used to determine the expected costs for all of the items in the product category based upon expected volume.

TABLE 27—COMPOSITE BIDS BY SUPPLIER

Item	A	B	C	Composite bid	Product category bid (cost of bundle)
Units	5	3	2	.....	.....
Item weight	0.5	0.3	0.2	.....	.....
Supplier 1 bid	$1.00	$4.00	$1.00	$1.90	$19.00
Supplier 2 bid	3.00	5.00	3.00	3.60	36.00
Supplier 3 bid	3.00	4.00	3.00	3.30	33.00
Supplier 4 bid	2.00	2.00	2.00	2.00	20.00
Supplier 5 bid	2.00	4.00	2.00	2.60	26.00
Supplier 6 bid	2.00	3.00	2.00	2.30	23.00
Supplier 7 bid	3.00	3.00	2.00	2.80	28.00
Supplier 8 bid	3.00	4.00	2.00	3.10	31.00
Supplier 9 bid	2.00	3.00	3.00	2.50	25.00
Supplier 10 bid	3.00	4.00	1.00	2.90	29.00
Supplier 11 bid	3.00	2.00	3.00	2.70	27.00

After computing composite bids for each supplier, a pivotal bid is established for each product category in each CBA. In accordance with § 414.402, pivotal bid means the lowest composite bid based on bids submitted

by suppliers for a product category that includes a sufficient number of suppliers to meet beneficiary demand for items in that category. As explained in the 2007 DMEPOS final rule (72 FR 18039), demand for items and services is projected using Medicare claims data for allowed services during the previous 2 years, trended forward to the contract period. Table 28 shows the pivotal bid is the point where expected combined capacity of the bidders is sufficient to meet expected demands of beneficiaries for items in a product category. In Table 28, the projected demand is 1,800 units, therefore the composite bid for supplier 7 represents the pivotal bid, since the cumulative capacity of 1,845 would exceed the projected demand of 1,800. In accordance with existing § 414.414(e)(6), all suppliers and networks whose composite bids are less than or equal to the pivotal bid for the product category, and that meet the supplier eligibility requirements in § 414.414(b) through (d) are selected as winning suppliers. Suppliers 1, 4, 6, 9, 5, 11 and 7 are selected as winning suppliers in the example below in Table 28. The composite bids for suppliers 10, 8, 3, and 2 are above the pivotal bid, so these suppliers are not selected as winning suppliers for the product category and are eliminated from the competition.

TABLE 28—DETERMINING THE PIVOTAL BID FOR PRODUCT CATEGORY POINT WHERE BENEFICIARY DEMAND (1,800) IS MET BY SUPPLIER CAPACITY

Supplier No. [1]	Composite bid	Supplier capacity	Cumulative capacity	Result
1	$1.90	250	250	Winning bid.
4	2.00	300	550	Winning bid.
6	2.30	0	550	Winning bid.
9	2.50	300	850	Winning bid.
5	2.60	360	1,210	Winning bid.
11	2.70	275	1,485	Winning bid.
7	2.80	360	1,845	Pivotal bid.
10	2.90	200	2,045	Losing bid.
8	3.10	300	2,345	Losing bid.
3	3.30	200	2,545	Losing bid.
2	3.60	25	2,570	Losing bid.

[1] By ascending composite bid.

C. Current Method for Establishing SPAs

For competitively bid items and services furnished in a CBA, the SPAs replace the Medicare allowed amounts established using the lower of the supplier's actual charge or the payment amount recognized under sections 1834(a)(2) through (7), 1834(h), and 1842(s) of the Act. We discussed various ways for determining the SPA for individual items under the DMEPOS CBP during the notice and comment rulemaking conducted in 2006 and 2007 (71 FR 25653 and 72 FR 17992, respectively), including using the minimum winning bid, using the maximum winning bid, using the median of winning bids, and using an average adjusted price methodology similar to the methodology used in competitive bidding demonstrations mandated by section 4319 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33). A detailed discussion of the various ways for determining the SPA for individual items under the DMEPOS CBP can be found in the 2007 DMEPOS final rule (72 FR 17992, 18044 through 18047). Under existing § 414.416, we finalized use of the median of winning bids for each item in each CBA to determine the SPA for each item in each CBA. The individual items within each product category are identified by the appropriate HCPCS codes. In cases where there is an even number of winning bids for an item, the SPA is equal to the average (mean) of the two bid prices in the middle of the array. Table 29 illustrates the current method.

TABLE 29—MEDIAN OF THE WINNING BIDS METHODOLOGY

Item	A	B	C	Composite bid
Supplier 1 bid	$1.00	$4.00	$1.00	$1.90
Supplier 4 bid	2.00	2.00	2.00	2.00
Supplier 6 bid	2.00	3.00	2.00	2.30
Supplier 9 bid (median A and B)	2.00	3.00	3.00	2.50
Supplier 5 bid (median C)	2.00	4.00	2.00	2.60
Supplier 11 bid	3.00	2.00	3.00	2.70
Supplier 7 bid (pivotal bid)	3.00	3.00	2.00	2.80
Median/SPA	2.00	3.00	2.00	

For a more complete discussion of this methodology, see section V.C of the CY 2019 ESRD PPS DMEPOS proposed rule.

D. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on DMEPOS CBP

In the CY 2019 ESRD PPS DMEPOS proposed rule, we proposed two reforms to simplify the DMEPOS CBP, eliminate the possibility for price inversions, and ensure the long term sustainability of the program. We proposed lead item pricing for all product categories under the DMEPOS CBP and calculation of SPAs using maximum winning bids for lead items. We proposed to amend §§ 414.402, 414.412, 414.414, and

414.416 to add and revise certain existing definitions, and revise the methodology for the calculation of SPAs and the evaluation of bids under the CBP to reflect and establish a lead item pricing methodology.

We received approximately 258 public comments on the proposed rules from manufacturers, suppliers, accrediting organizations, clinician organizations, Congress, government entities, hospital associations, beneficiary and industry representative groups, and other individual stakeholders. Several comments were outside the scope of this rulemaking.

In this final rule, we provide a summary of the proposed provisions, a summary of the public comments received and our responses to them, and the policies we are finalizing for DMEPOS CBP.

1. Lead Item Pricing for all Product Categories Under the DMEPOS CBP

In the CY 2016 ESRD PPS final rule (81 FR 77945), we established alternative rules for submitting bids and determining SPAs for certain groupings of similar items with different features under the DMEPOS CBP. As discussed in that rule, price inversions result under the CBP when different item weights are assigned to similar items with different features within the product category. To prevent price inversions from occurring under future competitions, we established an alternative ''lead item'' bidding method for submitting bids and determining single payment amounts for certain groupings of similar items (for example, walkers) with different features (wheels, folding, etc.) under the DMEPOS CBP. Under this alternative bidding method, one item in the grouping of similar items would be the lead item for the grouping for bidding purposes. The item in the grouping with the highest total national allowed services (paid units of service) during a specified base period would be considered the lead item of the grouping. CMS established a method for calculating SPAs for items within each grouping of similar items based on the SPAs for lead items within each grouping of similar items (81 FR 42878).

Under the CBP, in all rounds since 2011, we found price inversions for groupings of similar items within the following categories: Standard power wheelchairs, walkers, hospital beds, enteral infusion pumps, transcutaneous electrical nerve stimulation (TENS) devices, support surface mattresses and overlays and seat lift mechanisms. We consider the price of an item to be ''inverted'' when a more complicated item is cheaper than a simple version. For instance, when a walker without wheels costs more than a walker with wheels. The detailed method, examples, and responses to public comments regarding lead item bidding were explained in the CY 2016 ESRD PPS final rule (81 FR 77945 through 77949).

In the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34354 through 34359), we proposed to establish a lead item pricing methodology for all items and all product categories under the DMEPOS CBP. We proposed that the methodology would apply to all items in the product category. We also proposed that the lead item would be identified based on total national allowed charges. We proposed that the lead item pricing methodology would replace the current bidding method, where bids are submitted for each item in the product category, for all items. Since the bid for the lead item would be used to establish the SPAs for both the lead item and all other items in the product category, we referred to this proposed policy as ''lead item pricing'' rather than ''lead item bidding.'' We proposed to implement lead item pricing and change the methodology for establishing SPAs under the CBP for a number of reasons which are discussed in more detail in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34349). We stated that we believed that lead item pricing would greatly reduce the complexity of the bidding process and address all price inversions we have already identified as well as potential future price inversions for other items. It would also reduce the burden on suppliers since they would no longer have to submit bids for numerous items in a product category. For some product categories, there are hundreds of items, and many suppliers submit bids for multiple product categories and in multiple CBAs. The more bids a supplier has to submit, the more time it takes to complete the bidding process and the greater the risk for keying errors, which have disqualified bidders in the past, reducing the level of competition and opportunity for savings under the program. Lead item pricing would also eliminate the need for item weights and calculation of composite bids based on item weights. This would greatly eliminate the burden for suppliers since they would no longer have to submit bids for each individual item in a product category.

We refer readers to section V.D.2 of the CY 2019 ESRD PPS DMEPOS proposed rule for examples of how this pricing method would work.

We proposed to revise the current definition for ''composite bid'' under § 414.402 to mean ''the bid submitted by the supplier for the lead item in the product category.'' As discussed in section V.A of this final rule, section 1847(a)(1)(G) of the Act and our regulations require that bidding suppliers obtain bid surety bonds when participating in future competitions under the CBP. If the supplier is offered a contract for any product category for a CBA, and its composite bid for such product category and area is at or below the median composite bid rate for all bidding suppliers included in the calculation of the SPAs for the product category/CBA combination, the supplier must accept the contract offered or the supplier's bid surety bond for the applicable CBA will be forfeited. Because we proposed a change to the definition of composite bid (the composite bid would be defined as the supplier's bid for the lead item in the product category), we noted that the supplier's bid for the lead item would also be treated as the ''composite bid'' for the purpose of implementing the statutory and regulatory bid surety bond requirement (83 FR 34355). Under the lead item pricing method, suppliers would forfeit their bid surety bond for a product category in a CBA if their composite bid (their bid for the lead item) is at or below the median composite bid rate for all bidding suppliers included in the calculation of SPAs for the product category and CBA and they do not accept a contract offer for the product category and CBA. In other words, the median of the winning bids for the lead item in the product category would be calculated and used to implement the bid surety bond requirement at section 1847(a)(1)(H)(i) of the Act and § 414.412(h).

Currently under existing § 414.412(d)(2) the ''lead item'' in the product category is described as ''the code with the highest total nationwide allowed services for calendar year 2012,'' and ''total nationwide allowed services'' is defined in § 414.402 as meaning the total number of services allowed for an item furnished in all states, territories, and DC where Medicare beneficiaries reside and can receive covered DMEPOS items and services. We proposed to delete the lead item bidding provision that currently appears in § 414.412(d)(2) and replace it with the proposed lead item pricing provision. We proposed to replace the ''lead item'' description in § 414.412(d)(2) and ''total nationwide allowed services'' definition with a new definition of ''lead item'' in § 414.402 (83 FR 34414). We believed that using allowed charges rather than allowed services is a better way to identify the

lead item in a product category for the purpose of implementing lead item pricing because the item with the highest allowed charges is the item that generates the most revenue for the suppliers of the items in the product category. We also believed the item with the most allowed services is not always the item that generates the most revenue for the supplier.

Section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under the CBP unless the total amounts to be paid to contract suppliers in a CBA are expected to be less than the total amounts that would otherwise be paid. In order to implement this requirement for assurance of savings under the CBP, we proposed to revise § 414.412(b)(2) to require that the supplier's bid for each lead item and product category in a CBA cannot exceed the fee schedule amount that would otherwise apply to the lead item without any adjustments based on information from the CBP (83 FR 34414).

Finally, we proposed to amend the conditions for awarding contracts under the CBP in § 414.414(e) related to evaluation of bids under the CBP. Currently, this section specifies that CMS evaluates bids submitted for items within a product category, and that expected beneficiary demand in a CBA is calculated for items in the product category. We proposed to specify that CMS evaluates composite bids submitted for the lead item within a product category, and that expected beneficiary demand in a CBA is calculated for the lead item in the product category (83 FR 34414).

2. Calculation of Single Payment Amounts Using Maximum Winning Bids for Lead Items

We proposed to revise § 414.416 to change the methodology for calculating SPAs under the CBP. We proposed to base the SPA for the lead item in each product category and CBA on the maximum or highest amount bid for the lead item by suppliers in the winning range as illustrated in Table 30. The SPAs for all other items in the product category would be based on a percentage of the maximum winning bid for the lead item. Specifically, the SPA for a non-lead item in the product category would be equal to the SPA for the lead item multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, DC, Puerto Rico, and the U.S. Virgin Islands) for the item to the average of the 2015 fee schedule amounts for all areas for the lead item. Thus, since 2015 is the last year the fee schedule amounts were not adjusted based on information from the CBP, the SPAs for a non-lead item would be based on the relative difference in the fee schedule amounts for the lead and non-lead item before the fee schedule amounts were adjusted based on information from the CBP. For example, if the average 2015 fee schedule amount for a non-lead item such as a wheelchair battery is $107.25, and the average 2015 fee schedule amount for the lead item (Group 2, captains chair power wheelchair) is $578.51, the ratio for these two items would be computed by dividing $107.25 by $578.51 to get 0.18539. Multiplying $578.51 by 0.18539 then generates the amount of $107.25. Under the lead item pricing methodology, if the maximum winning bid for the lead item in this example (Group 2, captains chair power wheelchair) is used to compute an SPA of $433.88 for this lead item, then the SPA for the non-lead item in this example (wheelchair battery) would be computed by multiplying $433.88 by 0.18539 to generate an SPA of $80.44 for the non-lead item (wheelchair battery). Under the proposed revised definition of composite bid, each supplier's bid for the lead item would be their composite bid. The proposed methodology of using the maximum winning bids to establish SPAs is illustrated in Table 30. We believe lead item pricing would greatly reduce the complexity of the bidding process and the burden on suppliers since they would no longer have to submit bids for numerous items in a product category. For a more complete discussion of the rationale for this methodology, see section V.D.2 of the CY 2019 ESRD PPS DMEPOS proposed rule.

TABLE 30—PROPOSED MAXIMUM WINNING BIDS METHODOLOGY

Supplier bids	Bid amounts for the lead item
Supplier 1 bid	$1.00
Supplier 4 bid	2.00
Supplier 6 bid	2.00
Supplier 9 bid	2.00
Supplier 5 bid	2.00
Supplier 11 bid	3.00
Supplier 7 bid (pivotal bid)	3.00
Maximum bid/SPA	3.00

Finally, we invited feedback from the public on whether or not certain large CBAs should be split into smaller size CBAs to create more manageable service areas for suppliers, as has been done for the New York, Los Angeles, and Chicago CBAs. We solicited feedback that we could consider in potentially adjusting the size and boundaries of CBAs for future competitions. We noted there are currently nine CBAs with more than 7,000 square miles: Phoenix-Mesa-Scottsdale, Arizona; Boise City, Idaho; Dallas-Fort Worth-Arlington, Texas; Riverside-San Bernardino-Ontario, California; Houston-The Woodlands-Sugar Land, Texas; Bakersfield, California; Salt Lake City, Utah; San Antonio-New Braunfels, Texas; and Atlanta-Sandy Springs-Roswell, Georgia.

The comments and our responses to the comments on our proposals are set forth below.

Comment: Many commenters supported the proposal to establish lead item pricing for all items and product categories in the CBP because it simplifies the bidding process and eliminates price inversions. Some commenters supported the proposal to establish lead item pricing for all items and product categories in the CBP, but only if the product categories were discrete categories of like items that are generally provided together to address a beneficiary's medical needs. The commenters recommended that large product categories with varying items (such as standard mobility equipment) be subdivided. Some commenters recommended that some product categories (such as power wheelchairs) include subcategories with lead items for each subcategory (such as power wheelchair bases, batteries, etc.). One commenter representing suppliers of oxygen and oxygen equipment was concerned that maintaining the term ''composite bid'' could lead to confusion, but indicated that they are committed to working with CMS to ensure that defining this term to mean the lead item bid is well understood by suppliers.

Response: We appreciate the support for this proposal. Although product categories are not defined through rulemaking, we will be taking into consideration the various product category recommendations, including the recommendation to structure product categories to ensure that they contain discrete categories of like items that are generally provided together to address a beneficiary's medical needs, when implementing future rounds of competition under the CBP. We appreciate the one commenter's willingness to educate suppliers regarding the revised definition for composite bid.

Comment: One commenter expressed concern that the lead item pricing method effectively makes it possible for suppliers to submit bids on lead items without verifying they can furnish the entire category. The commenter recommended that when awarding

contracts, CMS consider not only bid price, but also a supplier's range of available supplies and devices.

Response: We do not agree. Suppliers are educated at the start of each round of competitive bidding that they are responsible for furnishing all items in the product category for which they are submitting bids. Under lead item pricing, which we are adopting in this final rule, we will educate suppliers that their bid for the lead item is a bid for furnishing all items in the product category. We will also educate suppliers on how the payment amounts for the items in the product category will be established based on the maximum winning bid for the lead item. If the product categories are discrete categories of like items as commenters have suggested, a supplier that can furnish the lead item in the product category should have the capacity to furnish all other items in the product category as well. For example, if the supplier bids in the power mobility devices product category, the supplier would need to be accredited and meet the quality standards applicable to power mobility devices, namely part II of Appendix B of the Medicare DMEPOS Quality Standards. If the supplier meets these standards, then they should have the ability to furnish all of the different types of power mobility devices. If a supplier historically has furnished certain types of power mobility devices, such as standard weight captains chair products, and not others, such as heavy duty sling seat products, it should be relatively easy for the supplier to purchase the additional types of power mobility devices and deliver those items as well. It is important to note that under competitive bidding, CMS ensures that a sufficient number of contract suppliers are available to meet the expected demand for a product in each CBA. In accordance with section 1847(b)(2)(A) of the Act and § 414.414, a supplier cannot be awarded a contract unless they meet certain financial standards that ensure they have an ability to expand their capacity beyond their historic capacity. The amounts suppliers bid and the capacity they report are reviewed to ensure they are bona fide. In addition, a special analysis of the supplier's reported capacity is performed and the supplier's reported capacity is adjusted to their historic levels of performance if there is any question regarding their ability to expand their capacity. CMS awards contracts to a sufficient number of contract suppliers to meet projected demand in each CBA.

The supplier's bid for the lead item would reflect the cost of furnishing the various types of power mobility devices and related accessories in the product category. Even if the current product categories are maintained as is, a supplier would have to be able to furnish all of the items in the product category in order to be considered for a contract. Under the terms of the DMEPOS CBP contracts, a contract supplier must furnish every item in the product category for which it was awarded a contract. All suppliers are educated at the time of bidding that in accordance with § 414.422(e)(1), a contract supplier must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier. Suppliers are made aware of this requirement and understand that they must have the capacity to furnish every item in the product category if they want to be a contract supplier. If the supplier does not comply with this regulation or a term of their contract, then the supplier would be in breach and CMS could terminate the contract.

Comment: One commenter expressed concern that it would be inaccurate to assume that the bid rate for a single lead item is representative of the entire product category and believes the ratios that would be used to price the non-lead items do not accurately reflect the difference in cost of the items in the product category because of lack of consistency in how the fee schedule amounts for the items were established (that is, average reasonable charges for some items and gap-filling using supplier price lists for other items). Another concern was related to the supplier's inability to control the bid price of non-lead items without adjusting their lead item bid amount. For example, if the supplier is willing to accept payment for the lead item at an amount that is 50 percent below the historic, unadjusted fee schedule amount for the lead item, but is not willing to accept that large of a payment reduction for a non-lead item, the supplier would not be able to submit a bid for the lead item that is 50 percent below the historic, unadjusted fee schedule amount for the lead item. A commenter also mentioned that there could be little to no commonality in the manufacturing processes between lead item and non-lead items, which could lead to excessive or discounted payments for non-lead items.

Response: We understand that the inability of the supplier to submit specific bid amounts for non-lead items in order to determine the payment amounts for these items is a cost or negative aspect of lead item pricing. However, we believe that the benefits associated with lead item pricing outweigh this cost. Lead item pricing would greatly reduce the complexity of the bidding process and address all price inversions we have already identified as well as potential future price inversions for other items. It would also reduce the burden on suppliers since they would no longer have to submit bids for numerous items in a product category. Under lead item pricing, suppliers will be educated on how the payment amounts for the items in the product category will be established based on the maximum winning bid for the lead item, and that they should consider their costs for furnishing all items in the product category in formulating their bid for the lead item. In the example provided above, a supplier that cannot accept a payment reduction of 50 percent for a non-lead item would need to factor this fact into what they bid for the lead item, because the bid for the lead item would also represent their bid for furnishing all of the items in the product category. They may have to bid an amount that is higher than the amount they would bid if they were bidding for the lead item alone in order to factor in the cost of furnishing all of the other items in the product category. If the historic differences in the fees for the various items in the product category do not align well with the actual differences in the cost of the items, the supplier will need to take this into consideration when submitting their bid for the lead item. The ratios that will be used to price the non-lead items are based on the historic differences in the fee schedule amounts for the items, and we do not think that these historic ratios inaccurately reflect the relative differences in the cost of the items. Rather, the ratios usually follow a logical pattern. For example, the historic fees for manual hospital beds are lower than the historic fees for semi-electric hospital beds, and the historic fees for manual hospital beds without side rails are lower than the historic fees for manual hospital beds with side rails. Suppliers are given an opportunity, by bidding for the lead item, to control the minimum amount (that is, under lead item bidding, suppliers are paid at least what they bid or higher) that they would be paid for any non-lead item, as illustrated in the supplier non-lead item bidding example directly above. Suppliers must take this and other factors into consideration when

determining how much to bid based on what they are willing to accept as payment for the items in the product category as a whole. Again, we believe that the benefits associated with lead item pricing, as explained above and in the CY 2019 ESRD PPS DMEPOS proposed rule, outweigh the cost of less flexibility in setting payment rates for non-lead items. We are not sure what point the commenter was making regarding little to no commonality in the manufacturing processes between a lead item and non-lead items, and how this could lead to excessive or discounted payments for non-lead items. We will educate suppliers regarding how their bid for the lead item is used to generate the payment amounts for the non-lead items and that they should ensure that the payment amounts for all of the other items in the product category, which are established based on their bid for the lead item, would be sufficient to cover their costs for furnishing all of the items in the product category in the CBA.

Comment: A few commenters suggested that bids from suppliers added to meet the small supplier target be included in the calculation of the SPAs.

Response: We appreciate the comment, however, we do not agree. The small supplier target was established due to the statutory mandate to ensure that small suppliers are considered for participation under the CBP. Small suppliers that are offered contracts after the pivotal bid is determined are not needed to meet projected demand. We do not think that payment to suppliers needed to meet projected demand should be based on higher bids from suppliers that are not needed to meet projected demand.

Comment: Several commenters offered suggestions on how to determine the capacity of bidding suppliers to meet projected demand for items and services. For example, some commenters suggested that the actual historic capacity of suppliers should be used and should not be adjusted. One commenter suggested capping assumed supplier capacity at 25 or 33 percent of total projected demand. Many commenters recommended that the process of determining projected demand and supplier capacity should be transparent and that the determinations should be made publically available to ensure the bid evaluation is accurate.

Response: As a part of the competitive bidding program, we strive to ensure a sufficient number of contract suppliers are available to meet the expected demand for a product in each CBA. As a part of the bid evaluation process, bidders are required to report their capacity to furnish bid items on the bid form. CMS awards contracts to a sufficient number of contract suppliers to meet projected demand in each CBA. CMS purposely sets a high demand target by increasing historic utilization using two trending factors (national growth in DME utilization and change in enrolled beneficiaries in the CBA) rather than just one. In addition, if the change in enrolled beneficiaries in a CBA is negative, CMS does not decrease the demand target number based on this negative trend in the beneficiary population in the area and still increases the number based on the national growth in utilization for the item. In addition, the projected demand for DME items is not reduced based on the number of items that would likely be furnished by grandfathered suppliers, which typically furnish approximately 15 percent of rented DME items and related accessories. Each supplier's capacity is capped at 20 percent of total projected demand, and each supplier's capacity is evaluated, scrutinized and adjusted if necessary to ensure that they are not relied upon to furnish more items and services than they can based on their financial strength and ability to expand their historic capacity. This approach to estimating demand and capacity has worked well over the past eight years to ensure that a sufficient number of contracts are awarded under the CBP. We thank the commenters for their suggestions and will take them into consideration.

Comment: In response to our request for feedback about the risk that under our proposed methodology, the maximum winning bid could be an outlier bid that is much higher than the other winning bids, most commenters generally felt that this risk was minimal, some suggested, as long the product categories are evaluated in detail. Another commenter believed the risk was minimal because the lead item SPA is capped at the historical fee schedule amount. One commenter suggested an approach to limit maximum winning bids that are more than double the next highest winning bid. Under the suggested approach, the average of the maximum winning bid and the next highest winning bid would be used to establish the lead item SPA. Another commenter suggested we monitor the range of winning bids in each product category to assess risks in the next round of bidding. One commenter believed that SPAs based on the maximum winning bids could result in excessive payment rates if beneficiary demand is overestimated or supplier capacity is underestimated.

Response: We thank the commenter that provided a suggestion to address the scenario of an outlier bid. At this time, however, we have no reason to believe this will be a problem and have set certain limits under the CBP. For example, the SPA must be less than or equal to the amount that would otherwise be paid. CMS may only award a contract to a bidder if it finds that the total amounts to be paid to suppliers in a CBA are expected to be less than the total amounts that would otherwise be paid. CMS will monitor the program and make changes in the future if such situations occur. We agree that basing the SPAs on maximum winning bids could result in excessive payment rates if beneficiary demand is overestimated or supplier capacity is underestimated. As explained in response to the preceding comment, CMS inflates historic demand by double trending the numbers, does not reduce the number for DME items to account for grandfathered suppliers, and scrutinizes and adjusts supplier capacity to ensure that a sufficient number of contracts are awarded under the CBP. To the extent that more contracts are awarded than necessary as a result of this process, this could result in higher payment amounts than would otherwise be paid if fewer contracts were awarded. However, we note that this is true regardless of whether SPAs are based on maximum winning bids or the median of winning bids. We intend to closely monitor the impact of the new pricing methodology to determine if it results in excessive payment rates and whether the process for estimating demand and capacity should be revised to eliminate excessive payment rates.

Comment: Regarding bid surety bonds, one commenter suggested that a supplier should forfeit the bond if their bid is at or below the maximum winning bid for the lead item, rather than the median of the winning bids for the lead item, and the supplier does not accept the contract offer. One commenter recommended that any winning bidder that does not accept a contract offer should forfeit the bid surety bond.

Response: We appreciate the suggestions but the statute at section 1847(a)(1)(H)(i) of the Act specifically mandates forfeiture of a bidding supplier's bid bond in cases where the supplier's composite bid is at or below the median composite bid rate for all bidding entities included in the calculation of the SPAs and the entity does not accept the contract offered.

Comment: Most commenters provided negative feedback in response to our solicitation of comments on whether nine large CBAs should be subdivided into smaller size CBAs to create more manageable service areas for suppliers. The commenters contended that subdividing the CBAs would result in increasing administrative complexity and costs. The commenters discussed increased costs to prepare bids for more geographic areas, including obtaining more bid surety bonds for more geographic areas. Also, the commenters discussed increasing complexity for referrals, prescribers, and beneficiaries to coordinate furnishing DMEPOS items with different contracted suppliers based on more CBAs and the home zip code of the Medicare beneficiary. One commenter stated that the CBAs as currently set are appropriate for defining markets in which the costs are aligned and subdividing the CBAs could reduce the economies of scale achievable in these areas. Also, the commenters expressed concern that subdividing CBAs could lead to substantially different payment amounts for similar products furnished in close proximity geographic areas. To further specify, several commenters did not support subdividing the CBA areas for Atlanta-Sandy Springs-Roswell, GA MSA, the Houston-The Woodlands-Sugar Land, TX MSA and Boise City, ID MSA. In contrast, one commenter provided positive feedback to our solicitation on whether certain large CBAs should be subdivided into smaller size CBAs to create more manageable service areas for suppliers for the Riverside-San Bernardino-Ontario CA MSA. Also commenters did not provide specific feedback to our solicitation regarding the following CBAs: Phoenix-Mesa-Scottsdale, Dallas-Fort Worth-Arlington, Bakersfield, CA, Salt Lake City, Utah, and San Antonio-New Braunfels, Texas. Some commenters recommended that CMS consult with the suppliers in the specific CBA before finalizing a subdivision of a CBA. One commenter described an example that if the San Francisco-Oakland-Fremont, CA CBA is subdivided beneficiaries could experience access problems in Fremont but not San Francisco. The commenters recommended further consideration for subdividing areas should be considered from both contracting and oversight perspectives.

Response: We appreciate the range of the comments we received. We will consider these comments carefully as we contemplate future policies.

Final Rule Action: After consideration of comments received on the CY 2019 ESRD PPS DMEPOS proposed rule and for reasons we set forth previously in this final rule, we are finalizing the proposed revisions to § 414.402 to change the definitions of bid, composite bid, and lead item. We are also finalizing the proposed revisions to § 414.414 and § 414.416 to change the processes for submitting bids, evaluating bids and calculating SPAs based on lead item pricing. However, to eliminate confusion over the inclusion of the words ''maximum or highest bid,'' in the language of the proposed rule, we are finalizing a slight change to the language in § 414.416 to refer to the ''maximum bid'' submitted for an item rather than the ''maximum or highest bid'' submitted for an item. We are also making some minor technical changes to § 414.412. In the CY ESRD PPS DMEPOS proposed rule, we incorrectly noted the conforming changes to remaining paragraphs in § 414.412 as a result of the proposal to delete paragraph (d) of § 414.412, which currently requires suppliers to submit separate bids for each item in the product category. Therefore, along with the removal of paragraph (d), we are finalizing § 414.412 with technical edits to re-designate paragraphs (e) through (h) as paragraphs (d) through (g), respectively. Additionally, in newly redesignated paragraph (e)(2), we are removing the reference to paragraph ''(f)(1)'' and adding in its place the reference ''(e)(1)''; and in newly redesignated paragraph (g)(2)(i)(D) we are removing the reference to ''paragraph (h)(3)'' and adding in its place the reference '' paragraph (g)(3)''.

VI. Adjustments to DMEPOS Fee Schedule Amounts Based on Information from the DMEPOS CBP

A. Background

For DME furnished on or after January 1, 2016, section 1834(a)(1)(F)(ii) of the Act requires the Secretary to use information on the payment determined under the DMEPOS CBP to adjust the fee schedule amounts for DME items and services furnished in all non-CBAs. Section 1834(a)(1)(F)(iii) of the Act requires the Secretary to continue to make these adjustments as additional covered items are phased in or information is updated as new CBP contracts are awarded. Similarly, sections 1842(s)(3)(B) and 1834(h)(1)(H)(ii) of the Act authorize the Secretary to use payment information from the DMEPOS CBP to adjust the fee schedule amounts for enteral nutrition and OTS orthotics, respectively, furnished in all non-CBAs. Section 1834(a)(1)(G) of the Act requires that in promulgating the methodology used in making these adjustments to the fee schedule amounts, the Secretary consider the costs of items and services in areas in which the adjustments would be applied compared to the payment rates for such items and services in the CBAs.

Section 16008 of the 21st Century Cures Act (the Cures Act) (Pub. L. 114–255) was enacted on December 13, 2016, and amended section 1834(a)(1)(G) of the Act to require in the case of items and services furnished in non-CBAs on or after January 1, 2019, that in making any adjustments to the fee schedule amounts in accordance with sections 1834(a)(1)(F)(ii) and (iii), 1834(a)(1)(H)(ii), or 1842(s)(3)(B) of the Act, the Secretary shall: (1) Solicit and take into account stakeholder input; and (2) take into account the highest bid by a winning supplier in a CBA and a comparison of each of the following factors with respect to non-CBAs and CBAs:

- The average travel distance and cost associated with furnishing items and services in the area.
- The average volume of items and services furnished by suppliers in the area.
- The number of suppliers in the area.

1. Stakeholder Input Gathered in Accordance With Section 16008 of the Cures Act

On March 23, 2017, CMS hosted a national provider call to solicit stakeholder input regarding adjustments to fee schedule amounts using information from the DMEPOS CBP. We also received 125 written comments from stakeholders. More than 330 participants called into our national provider call, with 23 participants providing oral comments during the call. In general, the commenters were mostly suppliers, but also included manufacturers, trade organizations, and healthcare providers such as physical and occupational therapists. These stakeholders expressed concerns that the level of the adjusted payment amounts constrains suppliers from furnishing items and services to rural areas. Stakeholders requested an increase to the adjusted payment amounts for these areas. The written comments generally echoed the oral comments from the call held on March 23, 2017, whereby stakeholders claimed that the adjusted fees are not sufficient to cover the costs of furnishing items and services in non-CBAs and that this is having an impact on access to items and services in these areas. For further detailed information, we refer readers to

section VI.A.1 of the CY 2019 ESRD PPS DMEPOS proposed rule.

2. Highest Winning Bids in CBAs Analysis

We considered the highest amounts bid by a winning supplier for a specific item (maximum bid) in the various CBAs in Round 1 2017 and Round 2 Recompete to see if maximum bids varied in different types of areas (that is, low volume versus high volume areas, large versus small delivery service areas, areas with few suppliers versus many suppliers). We analyzed maximum bids for the lead items in each product category (those with the highest allowed charges) and for other lower volume items. For lower volume items with low item weights, suppliers had less of an incentive to bid low on these items, and therefore, the maximum bids for many of these items are not significantly below the unadjusted fee schedule amounts. For the lead items, we focused primarily on items that clearly are delivered locally such as large bulky hospital beds and oxygen equipment (concentrators and tanks) since variations in maximum bid amounts from CBA to CBA due to differences in travel distances and costs would be most noticeable for these items. There are 130 CBAs in total in Round 1 2017 and Round 2 Recompete varying greatly in size, volume, and number of suppliers. We found no pattern indicating that maximum bids are higher for areas with lower volume than they are for areas with higher volume. For further detailed information, we refer readers to section VI.A.2 of the CY 2019 ESRD PPS DMEPOS proposed rule.

3. Travel Distance Analysis

We considered the average travel distances associated with furnishing items and services in CBAs and non-CBAs using two analyses. We first examined the average travel distances in CBAs versus non-CBAs by analyzing differences in the geographic size in square miles of CBAs versus non-CBAs consisting of MSAs and micropolitan statistical areas (micro areas). In non-CBAs, the majority of items that are subject to the fee schedule adjustments are furnished in these two geographic delineations. The U.S. Office of Management and Budget (OMB) delineates MSAs and micro areas, which are referred to collectively as ''core based statistical areas'' (CBSAs), or core area containing a substantial population nucleus, together with adjacent communities having a higher degree of economic and social integration with that core. We compared the average size of the different areas nationally and by Bureau of Economic Analysis (BEA) region and found that the CBAs have much larger service areas than the non-CBA MSAs and micro areas. Under the CBP, a contract supplier is required to furnish items to any beneficiary in the CBA that requests an item or service from the contract supplier. The size of CBAs can be compared to the size of non-CBAs to indicate how far a supplier located in or near the areas may have to travel to serve beneficiaries located in the various areas. As shown in Table 31, the average size of CBAs in each of the eight BEA regions is larger than the average size of both non-rural areas and rural areas classified as micro areas by OMB. Micro areas are areas where competitive bidding, for the most part, has not yet been implemented, and where the vast majority of items are not competitively bid.

TABLE 31—AVERAGE SIZE OF AREA

[Square miles]

BEA region	CBA	MSA	Micro
New England	1,241	1,175	968
Mideast	1,659	833	859
Great Lakes	2,061	942	638
Plains	3,700	1,880	1,029
Southeast	2,776	1,218	681
Southwest	5,737	3,637	1,992
Rocky Mountain	6,457	3,025	3,002
Far West	3,791	2,308	3,776
Average	3,428	1,877	1,618

The data in Table 32 shows what percentage of suppliers furnishing items and services subject to the fee schedule adjustments are located in the same areas where the items and services are furnished (that is, the percentage of suppliers located in the same area as the beneficiary). We separated the data by CBA, and then non-CBA MSA, micro area, or Outside Core Based Statistical Area (OCBSA), which are counties that do not qualify for inclusion in a CBSA. The data in Table 32 shows that the majority of suppliers furnishing items and services subject to the fee schedule adjustments are located in the same areas where these items and services are furnished. This means that the majority of suppliers serving non-CBAs are travelling no further than the distance of the non-CBAs they are located in, which again are much smaller than the CBAs.

TABLE 32—PERCENTAGE OF ITEMS AND SERVICES IN 2016 FURNISHED BY SUPPLIERS LOCATED IN THE SAME AREA AS THE BENEFICIARY

Beneficiary area	Hospital beds (%)	Oxygen (%)	All items (%)
CBAs	68	77	64
Non-CBA MSAs	68	63	65
Non-CBA Micro Areas	64	61	61
Non-CBA OCBSAs	78	82	81

In our second analyses, we compared the average travel distances for suppliers in the different areas using claims data for items and services subject to the fee schedule adjustments. For each allowed DME item and service, we used the shortest distance between the coordinates of the beneficiary's residential ZIP code and those of the supplier's ZIP code on the surface of a globe as a proxy of DME delivery distance. In addition, we prioritized 9-digit ZIP codes over 5-digit ZIP codes when determining the coordinates. The results in Table 33 are for hospital beds and oxygen and oxygen equipment, items that are most likely to be delivered locally by suppliers using company vehicles, as well as all items subject to the fee schedule adjustments. We compared average distances in CBAs versus non-CBAs broken out based on whether the beneficiary resided in an MSA, micro area, or a super rural (SR) area based on the definition of super rural area used in the ambulance fee schedule rules in § 414.610(c)(5)(ii). CBAs have greater average service distances than non-CBAs, with the exception of SR areas.

TABLE 33—AVERAGE NUMBER OF MILES BETWEEN SUPPLIER AND BENEFICIARY [1]

Beneficiary area	Hospital beds	Oxygen	All items
CBAs	25	21	27
Non-CBA MSAs	22	19	24
Non-CBA Micro Areas	23	21	27
SR Areas	36	35	41

[1] Claims where the supplier billing address is in the same or adjoining state as the beneficiary address, excluding claims from suppliers with multiple locations that always use the same billing address.

The average distances from the supplier to the beneficiary in the CBAs are the same or greater than the average distances from the supplier to the beneficiary in the non-CBA MSAs and micro areas where most of the items subject to the fee schedule adjustments are furnished. However, the average distances for super rural areas are greater than the average distances for the CBAs. For further detailed information, we refer readers to section VI.A.3 of the CY 2019 ESRD PPS DMEPOS proposed rule.

4. Cost Analysis

We examined four sources of cost data: (1) The Practice Expense Geographic Practice Cost Index (PE GPCI), (2) delivery driver wages from the Bureau of Labor Statistics (BLS), (3) real estate taxes from the U.S. Census Bureau's American Community Survey (ACS), and (4) gas and utility prices from the Consumer Price Index (CPI). Overall, we found that CBAs tended to have the highest costs out of the cost data that we examined, when compared to non-CBAs. For further detailed information, we refer readers to section VI.A.4 of the CY 2019 ESRD PPS DMEPOS proposed rule.

In the CY 2019 ESRD PPS DMEPOS proposed rule, we analyzed the aforesaid cost data, and overall, each cost variable was, for the most part, higher on average in the CBAs than it was for every other geographic delineation (MSA, micro, OCBSA). The more urbanized areas tended to have higher costs than the less urbanized areas. We think this may be due to several reasons.

The Bureau of Labor Statistics explains, ''. . . that the principal differences in overall expenditures between rural and urban households are the amounts spent on the chief elements of housing: mortgage interest and rental payments. These expenditures are affected by many different variables, but can be understood fundamentally by supply and demand, and are often dependent on location. Land is scarce in urban areas, and many people are vying for limited housing; therefore, rent is higher and houses are more expensive. In many rural areas, land is plentiful, so prices tend to be lower.'' [23]

With regard to CBAs generally having higher wages and PE GPCI values, values which attribute much of their calculation to wages, there are several reasons for this as well. A report prepared by RTI International for the Medicare Payment Advisory Commission (MedPac) describes how differences in local labor productivity are partly responsible for the observed differences in nominal wages, which are the wages that appear on paychecks.[24] The theory of compensating wage differentials was originally used to explain why nominal wages differ across workers. The report explains how ''[t]he term 'compensating' refers to attributes of jobs that attract or repel workers to specific occupations or geographic areas. A job that has repellent attributes commands a ''compensating'' amount. Conversely, holding constant other attributes, nominal wages can be lower for jobs that have attractive attributes. The theory of geographic wage differences, then, is the theory of compensating wage differentials applied to the geographic dimensions of wages.''

Additionally, the report describes how geographic variation in wages is affected by the amenities available in different areas. For instance, '''[a]menities' include such factors as climate and local cultural and recreational opportunities. High amenity areas do not need to pay as much to attract workers, hence wages in these areas will be lower relative to their cost-of-living than in areas with low levels of amenities. The reverse is also true; workers may also demand higher real (that is, cost-of-living-adjusted) wages for a job located in an area with unattractive features. The valuation of amenities will differ across individuals, partly related to systematic factors such as education and income, and partly due to idiosyncratic preferences. It may also vary across professions; for example, if physicians value location in an area with access to colleagues and multiple medical facilities, then they might demand a wage premium for locating in isolated rural communities.''

Furthermore, the report mentions that as more workers take jobs in high-wage industries in a given area, they tend to bid up the price of housing, which increases the cost of living and lowers the real wages of workers of other industries in the area.

Lastly, the U.S. Department of Agriculture (USDA) suggests there are several factors that may contribute to

[23] Expenditures of urban and rural households in 2011 *https://www.bls.gov/opub/btn/volume-2/expenditures-of-urban-and-rural-households-in-2011.htm.*

[24] Geographic Adjustment of Medicare Payments for the Work of Physicians and Other Health Professionals *http://www.medpac.gov/docs/default-source/contractor-reports/jun13_geoadjustment_contractor.pdf?sfvrsn=0.*

higher earnings in urban areas.[25] For one, ''[b]usinesses that provide skill-intensive employment may be clustered in urban areas, where a larger market allows for closer proximity to customers and suppliers, shared infrastructure, and better matching between employers and employees. The density of businesses and people in urban areas may also facilitate the promotion and adoption of innovative ideas. These benefits may enhance the productivity of businesses and workers, contributing to higher urban wages.'' However, the USDA concludes that other differences between urban and rural workers—such as work experience, job tenure, and ability—may also contribute to higher urban wages. For further detailed information, we refer readers to the CY 2019 ESRD PPS proposed rule (83 FR 34372).

5. The Average Volume of Items and Services Furnished by Suppliers in the Area Analysis

We found that in virtually all cases, the average volume of items and services for suppliers when furnishing those items to the various areas is higher in CBAs than non-CBAs. This is likely due to CBAs generally being located in the most populated areas of the country, with more beneficiaries, and therefore, more suppliers in these areas than in non-CBAs. For further detailed information, we refer readers to section VI.A.5 of the CY 2019 ESRD PPS DMEPOS proposed rule.

6. Number of Suppliers Analysis

We examined data regarding the number of suppliers serving the various CBAs and did not find any correlation between number of suppliers and SPA or maximum winning bid amount. We are not certain how much the number of suppliers in a given area might affect costs, but it does not appear to have been a factor under the competitive bidding program in terms of bids submitted in the various CBAs. For further detailed information, we refer readers to section VI.A.6 of the CY 2019 ESRD PPS DMEPOS proposed rule.

7. Fee Schedule Adjustment Impact Monitoring Data

In an effort to determine whether the fee schedule adjustments have resulted in adverse beneficiary health outcomes, we have been monitoring claims data from non-CBAs and it does not show any observable trends indicating an increase in adverse health outcomes such as mortality, hospital and nursing home admission rates, monthly hospital and nursing home days, physician visit rates, or emergency room visits in 2016, 2017, or 2018 compared to 2015 in the non-CBAs, overall. In addition, we have been monitoring data on the rate of assignment in non-CBAs and it remains high (over 99 percent) in most areas, which reflects when suppliers are accepting Medicare payment as payment in full and not balance billing beneficiaries for the cost of the DME. We solicited comments on ways to improve our fee schedule adjustment impact monitoring data (83 FR 34380).

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on Adjustments to DMEPOS Fee Schedule Amounts Based on Information from the DMEPOS CBP

In the CY 2019 ESRD PPS DMEPOS proposed rule, we proposed to base the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently rural or non-contiguous non-CBAs, on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the fee schedule amounts adjusted in accordance with the current methodologies under § 414.210(g)(1) through (g)(8). We proposed to pay the fully adjusted fee schedule rates for items and services furnished in non-rural and contiguous non-CBAs from January 1, 2019 through December 31, 2020. We proposed that in the event of a temporary gap in the CBP, we would adjust the fee schedule amounts applicable in each CBA based on the SPA for the area increased by the projected change in the consumer price index for all urban consumers (CPI–U) for the 12-month period ending on the date that the adjusted fee schedule amounts take effect (for example, January 1, 2019). The adjusted fee schedule amounts would be increased every January 1 by a similar update factor for as long as the temporary gap in the CBP continues. We received approximately 281 public comments on our proposals, including comments from homecare associations, DME manufacturers, suppliers, senior advocacy associations, the Medicare Payment Advisory Commission (MedPAC), Members of Congress, and individuals. Comments related to the paperwork burden are addressed in the ''Collection of Information Requirements'' section of this final rule. Comments related to the impact analysis are addressed in the ''Economic Analyses'' section of this final rule.

In this final rule, we provide a summary of the proposed provisions, a summary of the public comments received and our responses to them, and the policies we are finalizing.

1. Proposed Fee Schedule Adjustments for Items and Services Furnished in Non-Competitive Bidding Areas

The Round 2 Recompete, National Mail-Order Recompete, and Round 1 2017 contract periods of performance will end on December 31, 2018. Competitive bidding for items furnished on or after January 1, 2019 has not yet begun, and therefore, we do not expect that CBP contracts will be in place on January 1, 2019. Thus, we anticipate there will be a gap in the CBP beginning January 1, 2019. During a gap in the CBP beginning January 1, 2019, there will not be any contract suppliers and payment for all items and services previously included under the CBP will be based on the lower of the supplier's charge for the item or fee schedule amounts adjusted in accordance with sections 1834(a)(1)(F) and 1842(s)(3)(B) of the Act. We proposed specific fee schedule adjustments as a way to temporarily pay for items and services in the event of a gap in the CBP due to CMS being unable to timely recompete CBP contracts before the current DMEPOS competitive bidding contract periods of performance end.

We have taken into account the information mandated by section 16008 of the Cures Act. Section 16008 of the Cures Act first mandates that we take stakeholder input into account in making fee schedule adjustments based on information from the DMEPOS CBP for items and services furnished beginning in 2019. The information we collected included input from many stakeholders indicating that the fully adjusted fee schedule amounts are too low and that this is having an adverse impact on beneficiary access to items and services furnished in rural and remote areas. Industry stakeholders have stated that the fully adjusted fee schedule amounts are not sufficient to cover the supplier's costs, particularly for delivering items in rural, remote areas. We are monitoring outcomes, assignment rates, and other issues related to access of items and services such as changes in allowed services and number of suppliers. We believe it is important to continue monitoring these things before proposing a more long term fee schedule adjustment methodology using information from the CBP. If fee schedule amounts are too low, they could impact beneficiary access and potentially damage the businesses that furnish DMEPOS items

[25] Urban Areas Offer Higher Earnings for Workers With More Education *https://www.ers.usda.gov/amber-waves/2017/july/urban-areas-offer-higher-earnings-for-workers-with-more-education/*.

and services. If fee schedule amounts are too high, this increases Medicare program and beneficiary costs unnecessarily. For these reasons, we believe that we should proceed cautiously when adjusting fee schedules in the short term in an effort to protect access to items, while we continue to monitor and gather data and information. We plan to address fee schedule adjustments for items furnished on or after January 1, 2021, in future rulemaking after we have continued to monitor health outcomes, assignment rates, and other information.

Section 16008 of the Cures Act mandates that we take into the account the highest amount bid by a winning supplier in a CBA. However, as previously discussed in section VI.A.2 of this final rule, the highest winning bids from Round 2 Recompete varied widely across the CBAs and the variance does not appear to be based on any geographic factor (that is, there is no pattern of maximum bid amounts for items being higher in certain CBAs or regions of the country versus others). Thus, we did not find any supporting evidence for the development of a payment methodology for the non-CBAs based on the highest winning bids in a CBA.

Section 16008 of the Cures Act mandates that we take into account a comparison of the average travel distance and cost associated with furnishing items and services in the area. We found that the average travel distance and cost for suppliers in non-CBAs is generally lower than the average travel distance and cost for suppliers in CBAs. However, oftentimes costs in the non-contiguous areas of the U.S., particularly in Hawaii and Alaska, were higher than costs in the contiguous areas of the U.S., for most of the cost data that we examined and presented in this rule. As noted in section VI.A.1 of this final rule, this was confirmed by one commenter who stated that non-contiguous areas, such as Alaska and Hawaii, face unique and greater costs due to higher shipping costs, a smaller amount of suppliers, and more logistical challenges related to delivery. Additionally, from our analysis presented in this rule, the average distance traveled in CBAs is generally greater than in most non-CBAs. However, when looking at certain non-CBA rural areas such as FAR, OCBSAs, and super rural areas, suppliers, on average, must travel farther distances to beneficiaries located in these areas than beneficiaries located in CBAs and other non-CBAs. Thus, we believe this supports a payment methodology that factors in the increased costs in non-contiguous areas, and the increased travel distance suppliers face in reaching certain rural areas.

Section 16008 of the Cures Act mandates that we take into account a comparison of the average volume of items and services furnished by suppliers in the area. We found that in virtually all cases, the average volume of items and services for suppliers when furnishing those items is higher in CBAs than non-CBAs. We believe this finding supports a payment methodology that factors in and ensures beneficiary access to items and services in non-CBAs with relatively low volume.

Finally, section 16008 of the Cures Act mandates that we take into account a comparison of the number of suppliers in the area. According to Medicare claims data, the number of supplier locations furnishing DME items and services subject to the fee schedule adjustments decreased by 22 percent from 2013 to 2016. In 2016 alone there was a little over 6 percent decline from the previous year in the number of DME supplier locations furnishing items and services subject to the fee schedule adjustments. The number of DME supplier locations declined from 13,535 (2015) to 12,617 (2016), indicating that the number of DME supplier locations serving these areas continues to decline. There has been a further reduction in supplier locations of 9 percent in 2017. We can attribute a certain percentage of this decline in the number of suppliers to audits, investigations, and evaluations by CMS and its contractors that enhanced fraud and abuse controls to monitor suppliers. Furthermore, we have noted in section VI.A.6 of this final rule that instances of beneficiaries located in areas being served by one supplier were extremely rare, when looking at users of oxygen and oxygen equipment, and were mostly in non-contiguous areas of the country. The suppliers for these non-contiguous areas were all accepting the fully adjusted fee schedule amounts as payment in full 100 percent of the time in 2016 and 2017. Additionally, while the number of suppliers in the non-CBAs decreased by a little over 6 percent in 2016 overall, volume per supplier increased, suggesting a consolidation in the number of locations serving the non-CBAs. However, we are still concerned about the potential beneficiary access issues that might occur in more rural and remote areas based on this consistent decline in number of suppliers. As such, out of an abundance of caution, we believe that the consistent decline in number of suppliers supports adjusting the fee schedule amounts in a way that seeks to abate this declining trend and ensure access to items and services for beneficiaries living in rural areas and other remote areas such as Alaska, Hawaii, Puerto Rico and other U.S. territories.

Based on the stakeholder comments, the higher costs for non-contiguous areas, the increased average travel distance in certain rural areas, the significantly lower average volume per supplier in non-CBAs, especially in rural and non-contiguous areas, and the decrease in the number of non-CBA supplier locations, we believe the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in all areas that are currently rural or non-contiguous non-CBAs, should be based on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts in accordance with the current methodologies under § 414.210(g)(1) through (g)(8). We believe that since the information from the CBP comes from bidding in non-rural areas only and in all but one case in areas located in the contiguous U.S., that full adjustments based on this information should not be applied to fee schedule amounts for items and services furnished in rural and non-contiguous areas on or after January 1, 2019 because rural and non-contiguous face unique circumstances, such as lower volume, and in certain areas, higher costs. We believe that blended rates can help ensure beneficiary access to needed DME items and services in rural and non-contiguous areas, and better account for the differences in costs for these areas versus more densely populated areas. We believe the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in all areas that are currently non-CBAs, but are not rural or non-contiguous areas, should be based on 100 percent of the adjusted fee schedule amounts in accordance with the current methodologies under § 414.210(g)(1) through (g)(8). Although the average volume of items and services furnished by suppliers in non-rural non-CBAs is lower than the average volume of items and services furnished by suppliers in CBAs, the travel distances and costs for these areas are lower than the travel distances and costs for CBAs. Because the travel distances and costs for these areas are lower than the travel distances and costs for CBAs, we believe the fully adjusted fee schedule amounts are sufficient for suppliers in non-rural non-CBAs. We requested specific comments on the issue of whether the 50/50 blended rates

should apply to these areas as well (83 FR 34382).

We believe that the changes to the CBP that we outlined in section V ''Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)'' (which change bidding and the SPA calculation methodology under the CBP for future competitions) may warrant further changes to the fee schedule adjustment methodologies under § 414.210(g)(1) through (8). We would address further changes to the fee schedule adjustment methodologies in future rulemaking.

In summary, based on stakeholder input, the higher costs for suppliers in non-contiguous areas, the longer average travel distance for suppliers furnishing items in certain rural areas, the significantly lower average volume that most non-CBA suppliers furnish, and the decrease in the number of non-CBA supplier locations, we proposed to revise § 414.210(g)(9) and to adjust the fee schedule amounts for items and services furnished in rural and non-contiguous non-CBAs from January 1, 2019 through December 31, 2020, based on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts in accordance with the current methodologies under § 414.210(g)(1) through (g)(8). We proposed to adjust the fee schedule amounts for items and services furnished in non-rural and contiguous non-CBAs from January 1, 2019 through December 31, 2020, using the current methodologies under § 414.210(g)(1) through (g)(8). We plan to continue monitoring health outcomes, assignment rates, and other information and would address fee schedule adjustments for all non-CBAs for items furnished on or after January 1, 2021, in future rulemaking.

The comments on our proposals and our responses to the comments are set forth below.

Comment: Many commenters supported the proposal to base the fee schedule amounts for items and services furnished in rural and non-contiguous areas during the time period from January 1, 2019 through December 31, 2020 on a 50/50 blend of adjusted and unadjusted rates. Many commenters said that this would help suppliers stay in business and that it would help prevent access issues. Some commenters said rural areas have higher costs than urban areas. For instance, one commenter in Minnesota said that although costs, such as the utility cost and real estate tax data we presented in our CY 2019 ESRD PPS DMEPOS proposed rule, may be higher in urban areas than in some areas of the country, their experience in Minnesota has shown that operating costs for branches in rural areas can be significantly higher than those for urban areas. Another commenter talked about the costs that Native American reservations in very rural areas must face. They include frequent power failures, extreme weather, no running water, lack of cell phone service, and increased travel distances.

Response: We appreciate the support for that proposal.

Comment: Many commenters stated CMS should apply the 50/50 blended rate to items and services furnished in the non-rural non-CBAs. As support for this, commenters stated that the average volume of items and services furnished by suppliers in non-rural non-CBAs is lower than the average volume of items and services furnished by suppliers in CBAs, and that the decline in number of suppliers has occurred in both rural and non-rural areas, which they claim has resulted in problems obtaining access to items and services and health issues. Some commenters who were suppliers said that they no longer offer some products, and that they do not accept Medicare assignment on several products, and that this non-assignment would increase if the fee schedule amounts for non-rural non-CBAs are not increased. Some commenters discussed how suppliers in non-rural non-CBAs must travel far distances to deliver DME, and that this and a low population density causes costs to suppliers to be higher in non-rural non-CBAs than in CBAs. One commenter said that when looking at their costs in metropolitan areas, they have a much higher labor cost than rural areas, and the delivery costs are also significant, not because of the distance, but more so because of the downtime with traffic. Another commenter said that there are fewer people in rural non-CBAs than in non-rural non-CBAs, and there are fewer people in non-rural non-CBAs than there are in CBAs. The commenter also said that this serves as a proxy for the volume of patients in the non-rural non-CBAs, and that with fewer patients to spread the costs over, the costs are higher. A few commenters said that in addition to allowing fixed costs to be spread over more patients, there are greater efficiencies of scale available in the CBAs. Therefore, while some costs may increase in CBAs, such as those CMS listed in the CY 2019 ESRD PPS DMEPOS proposed rule, these costs are offset by these economies of scale and the ability of suppliers to spread their fixed costs over multiple patients. Another commenter said that the most significant variables that affect DME supplier costs are labor rates, transportation (fuel, trucks and related costs such as vehicle and driver insurance), population density, miles/time between points of service, and regulatory compliance costs. The commenter stated that the cost of fuel is therefore a significant cost factor, and that in recent years, fuel costs have risen significantly due to the rising cost of petroleum. The commenter then stated that those costs are significantly amplified in non-CBAs where the distances to travel to beneficiaries' homes are much greater.

Response: We agree that the average volume of items and services furnished by suppliers in non-rural non-CBAs is lower than the average volume of items and services furnished by suppliers in CBAs, and that total population and population density are both lower in non-rural non-CBAs than in CBAs. However, volume of services furnished is only one factor impacting the cost of furnishing DMEPOS items and services. A number of other factors affecting the costs of furnishing DMEPOS items and services such as wages, gasoline, rent, utilities, travel distance and service area size point to higher costs in CBAs than non-rural non-CBAs. Further, although the cost of fuel may have increased in recent years, as detailed in our CY 2019 ESRD PPS/DMEPOS proposed rule, the price of gas is overall slightly lower in non-CBAs, and travel distances are generally lower in non-CBAs than they are in CBAs. Travel distances were also only greater in certain non-CBAs, which were Frontier and Remote (FAR), OCBSAs, and Super Rural areas. Additionally, as one commenter pointed out, metropolitan areas generally have higher labor costs than rural areas, and the delivery costs can also be significant because of the downtime with traffic. However, we believe that these factors are likely only amplified in the more heavily populated CBAs.

Also, as discussed in our CY 2019 ESRD PPS DMEPOS proposed rule, past stakeholder input and studies suggest that delivery costs and wages affect a suppliers' overall costs more than equipment acquisition costs and volume discounts (83 FR 34378). In 2006, Morrison Informatics, Inc. conducted a study for the American Association for Homecare titled ''A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy'', which used a survey of 74 oxygen suppliers to determine which factors are more important in influencing oxygen suppliers' cost of furnishing oxygen and oxygen

equipment.[26] The study concluded that equipment acquisition only accounted for 28 percent of the cost of providing medically necessary oxygen to Medicare beneficiaries. This study concluded that services such as preparing and delivering equipment, driving to the home to repair and maintain equipment, training and educating patients, obtaining required medical necessity documentation, customer service, and operating and overhead costs accounted for 72 percent of overall costs.

Also, as a supplier increases their volume, the costs associated with labor, delivery, and overhead also increase proportionally. The conclusion drawn from the Morrison study is that although the average volume of oxygen and oxygen equipment furnished by suppliers in the CBAs may be higher than the average volume of oxygen and oxygen equipment furnished by suppliers in the non-CBA areas, this factor alone does not mean that the overall costs of furnishing oxygen and oxygen equipment in the CBAs is lower than the overall costs of furnishing oxygen and oxygen equipment in the non-CBAs. As we have previously indicated, our data indicates that the labor, delivery, and overhead costs of suppliers furnishing oxygen and oxygen equipment in CBAs are higher than the labor, delivery, and overhead costs of suppliers furnishing oxygen and oxygen equipment in non-CBAs, and the Morrison study concludes that these costs make up 72 percent of the oxygen supplier's overall costs.

We agree that the number of suppliers furnishing items and services subject to the fee schedule adjustments is decreasing in non-rural non-CBAs and we have been monitoring the impact of the fee schedule adjustments in these areas closely. In the non-rural non-CBAs, the percentage of participating suppliers, meaning suppliers who agree to accept Medicare payment for every claim and accept assignment for an entire year, has only slightly decreased in non-CBA non-rural areas from 29.66 percent in January 2015 to 27.73 percent in July 2018, when looking at claims data through week 34 of 2018. It is also worth noting that while volume is lower in the non-rural non-CBAs, and the total number of suppliers has been decreasing steadily since before the implementation of the adjusted fees in 2016, the services per supplier in the non-rural non-CBAs has been increasing during that time. Thus, while volume is generally less in non-rural non-CBAs than it is in CBAs, the volume per supplier in the non-rural non-CBAs has been increasing. For instance, when looking at data through week 34 of the respective year, from 2016–2017, the services per supplier in non-rural non-CBAs increased by 11.33 percent, and from 2017–2018 it increased by 12.88 percent.

We have not found evidence that this is causing access beneficiary problems or health outcomes issues. Health outcomes for both beneficiaries using items and services subject to the fee schedule adjustments and beneficiaries who may need items and services subject to the fee schedule adjustments have remained stable or have improved since the fully adjusted fees were implemented. Regarding beneficiary access, as shown in Table 34, allowed services for items and services subject to the fee schedule adjustments continue to increase each year and the rate that suppliers are accepting assignment of claims paid at the fully adjusted rates in non-rural non-CBAs remains very high and have increased in 2018 thus far.

TABLE 34—ALLOWED SERVICES AND ASSIGNMENT RATES FOR CLAIMS FOR ITEMS SUBJECT TO THE FEE SCHEDULE ADJUSTMENTS FURNISHED IN NON-RURAL NON-CBAS

Year	Full year data		Claims paid through week 34	
	Allowed services	Assignment (%)	Allowed services	Assignment (%)
2015	11,885,241	99.89	6,288,952	99.89
2016	12,266,590	99.85	6,520,165	99.88
2017	12,484,248	99.81	6,697,219	99.80
2018	n/a	n/a	6,954,277	99.83

As the number of suppliers has decreased in non-rural non-CBAs, the average volume of items and services furnished by suppliers in non-rural non-CBAs has increased, which may explain why the rate of assignment increased slightly in the first half of 2018 in these areas. The high rate of assignment and increase in allowed services indicate that payments in these areas are sufficient to cover the costs of furnishing the items and services in these areas.

Comment: Some commenters said that typically, the same DME suppliers are serving both the non-rural and the remaining non-CBAs, that financial viability and beneficiary access issues are therefore not limited to rural and non-contiguous non-CBAs, and that the blended 50/50 payment rates should thus not be limited to the rural and non-contiguous non-CBAs.

Response: As discussed in our CY 2019 ESRD PPS DMEPOS proposed rule, our data indicates that the majority of suppliers furnishing items and services subject to the fee schedule adjustments are located in the same areas where these items and services are furnished (that is, the percentage of suppliers located in the same area as the beneficiary). For this, we separated the data by CBA, and then non-CBA MSA (non-rural), micro area (rural), or Outside Core Based Statistical Area (OCBSA), which are counties that do not qualify for inclusion in a CBSA (rural). Thus, our data do not confirm that typically, the same DME suppliers are serving both the non-rural and the remaining non-CBAs. In addition, because assignment rates in the non-rural non-CBAs continue to be very high despite the full fee schedule adjustments, we believe the 50/50 blended rates are appropriate for DME items and services furnished in rural and non-contiguous areas, but not in other non-CBAs.

Comment: Some commenters mentioned studies that found beneficiaries had problems obtaining DME. For instance, some commenters mentioned an industry-funded survey done by Dobson DaVanzo & Associates, LLC that claimed that the Medicare competitive bidding program has negatively affected beneficiaries' access to DME services and supplies, adversely

[26] Morrison Informatics, Inc., A Comprehensive Cost Analysis of Medicare Home Oxygen Therapy (Mechanicsburg, Pa.: June 27, 2006).

impacted case managers' ability to coordinate DME for their patients, and placed additional strain on suppliers to deliver quality products without delay. Some commenters mentioned a survey done by the American Thoracic Society (ATC) that found that supplemental oxygen users experienced frequent and varied problems, particularly a lack of access to effective instruction and adequate portable systems, and that patients living in Competitive Bidding Program areas reported oxygen problems more often than those who did not.[27] [28]

Response: The GAO reviewed these and other studies mentioned by commenters that assessed the effect of the implementation of fee schedule adjustments on beneficiaries, DME suppliers, and others in a report titled ''Information on the First Year of Nationwide Reduced Payment Rates for Durable Medical Equipment'' (GAO–18–534). The GAO found that these studies did not provide persuasive evidence of substantial effects of fee schedule adjustments on DME access, primarily because of methodological issues with how the participants in the studies were recruited. Specifically, respondents were recruited on social media platforms or through targeted email notifications, raising concerns about selection bias. The GAO did note that some effects may take longer to appear, underscoring the importance of our continued monitoring activities, and we will continue to monitor the effects of the fee schedule adjustments on beneficiary access to DME items and services.

Comment: A few commenters recommended that CMS develop a mechanism to better understand why utilization has decreased in non-CBAs. Some commenters disagreed with CMS' determination that a decrease in utilization can be attributed to a reduction in waste, fraud, and abuse.

Response: We would like to note that while utilization of DME varies throughout area and by particular item, the number of total services increased from 2016 to 2017 (2.05 percent), and from 2017 to 2018 (3.08 percent) when looking at the number of total services furnished through week 34 of the respective year. There has been a persistent increase in total volume of services furnished in non-CBAs from 2016 to 2018, driven by an increase in CPAP/RADs. All other products exhibit either a continuous decline from 2016 through 2018, or at least a decline from 2017 to 2018. However, when looking at data through week 34 of the respective year, from 2016 to 2017, the services per supplier in non-rural non-CBAs increased by 11.33 percent, and from 2017 to 2018 it increased by 12.88 percent. Rural non-CBAs follow a similar trend, in that when looking at data through week 34 of the respective year, from 2016 to 2017, the services per supplier in rural non-CBAs increased by 10.91 percent, and from 2017 to 2018 it increased by 10.39 percent. Although we cannot be certain how much a decrease in utilization can be attributed to a reduction in waste, fraud, and abuse, the OIG has noted that services provided by DME suppliers have been consistent targets of Medicare fraud schemes, and the OIG has also previously noted that there have been reductions in Medicare billing and payments for certain services and geographic areas known for fraud risks.

Comment: Another commenter said that the geographic areas that CMS examines are too large and heterogeneous to detect access problems or other negative beneficiary outcome issues. The commenter asserted that even the size of the CBAs can be too large to detect access issues related to DMEPOS supplies. The commenter also said that these aggregate data mask important access issues to DMEPOS that may not ultimately result in negative outcomes — but only because hospitals or other stakeholders act to ensure that beneficiaries receive their DMEPOS and related supplies in a timely manner, despite suppliers' failure.

Response: We agree that individual problems with access to items and services may not be detected in the claims and health outcomes monitoring, but we do not agree that widespread issues exist that are undetected. The level of analysis performed would pick up any spikes in the data if they occurred. For example, an increase in the average length of stay in hospitals and nursing homes that might suggest a delay in receiving DME in the home would be detected and flagged for more detailed analysis. We believe the geographic areas that we examine are appropriate because they allow us to have an appropriately sized study population and that a smaller sized population might prevent us from drawing meaningful conclusions.

Comment: Some commenters, when commenting on ways to improve our fee schedule monitoring data, said that although CMS indicates no significant changes have been observed in assignment rates, nonassigned claims are not an option for dual eligible beneficiaries. This is because all Medicare providers must accept assignment (payment in full) for Part B services furnished to dual eligible beneficiaries. Therefore, the commenters concluded, using assignment rates for people with disabilities and who are eligible for Medicaid is not a valid monitor for access problems.

We also received many comments that focused on furnishing and billing for respiratory services, particularly oxygen. A few commenters said that the assignment rates are an interesting point, but it is not practical to assume that suppliers can seek additional payments from beneficiaries. The commenters said that suppliers take assignment because the beneficiaries cannot afford to pay suppliers directly for the services, and that even a monopoly supplier would take assignment because some payment is better than nothing, especially if there is some hope that policy-makers will reform the system. In addition, the commenters said that due to the rental nature of the equipment, and the compliance rules regarding monthly notification, and acknowledgement of non-assignment to the beneficiary, it is nearly impossible for reputable providers to compliantly bill for respiratory services on a non-assigned basis. Thus, the commenters asserted that assignment data do not really tell policy-makers anything about access. One commenter said that assignment provides no indication of a supplier's true willingness to accept the Medicare rate for products and services because assignment assumes suppliers can collect the difference in cost from beneficiaries. Another commenter said that any additional charges are highly unlikely to be recouped and will function as bad debt. The commenter also said that unlike other Medicare providers, home respiratory therapy suppliers are not required to report such bad debts and there is no policy to provide any bad debt relief to suppliers. Thus, even if Medicare payment amounts are too low, the commenter said suppliers are unlikely to seek the difference between the rates and the cost of providing equipment and services from beneficiaries, because the cost of seeking the additional payment coupled with the low likelihood of obtaining payment make the process impracticable.

Response: Our data shows that suppliers in the non-rural, non-CBAs

[27] Dobson DaVanzo & Associates, LLC. Access to Home Medical Equipment: Survey of Beneficiary, Case Manager, and Supplier Experiences. (October 9, 2017).

[28] American Thoracic Society. Patient Perceptions of the Adequacy of Supplemental Oxygen Therapy. Results of the American Thoracic Society Nursing Assembly Oxygen Working Group Survey. (January 1, 2018).

accept the fully adjusted fee schedule amounts as payment in full over 99 percent of the time, while allowed services in these areas continues to increase each year. We also would like to note that the assignment rate for suppliers furnishing oxygen in the non-rural non-CBAs was 99.96 percent in 2017, and remains unchanged at 99.96 percent in 2018, when looking at data through week 34 of 2018. Additionally, the number of services per supplier for suppliers furnishing oxygen in the non-rural non-CBAs is also increasing, for example, it increased 2.64 percent from 2016 to 2017, and increased 3.62 percent from 2017 to 2018, when looking at data through week 34 of 2018. We do not believe that a supplier can accept assignment if the payment amount is below their cost, certainly not on a sustained basis over several years. Even when we exclude claims for items and services furnished to beneficiaries dually enrolled in Medicare and Medicaid, which are cases in which suppliers must accept assignment of the claim, the rate of assignment remains extremely high. Table 35 shows the same data from Table 34 for non-rural non-CBAs, after excluding data for items and services furnished to beneficiaries dually enrolled in Medicare and Medicaid. Thus, the high overall assignment rates in the non-CBAs are not due to cases in which supplier must accept assignment. Rather, high assignment rates are prevalent throughout the non-CBAs. We believe that assignment rates are one effective method of determining whether Medicare payment rates are sufficient, and that these high assignment rates in the non-rural non-CBAs support our decision to apply the fully adjusted payment rates in these areas.

TABLE 35—ALLOWED SERVICES AND ASSIGNMENT RATES FOR CLAIMS FOR ITEMS SUBJECT TO THE FEE SCHEDULE ADJUSTMENTS FURNISHED IN NON-RURAL NON-CBAS

[Excluding claims for dual (Medicare/Medicaid)-eligible beneficiaries]

Year	Full year data		Claims paid through week 34	
	Allowed services	Assignment %	Allowed services	Assignment %
2015	8,809,268	99.87	4,639,097	99.87
2016	9,223,208	99.81	4,884,326	99.86
2017	9,487,963	99.77	5,067,065	99.76
2018	n/a	n/a	5,374,904	99.79

Comment: A few commenters recommended that CMS study the number of delivery/service calls a DME provider can make in a day in CBAs and non-CBAs. The commenters stated that the cost per delivery/service call will vary significantly in more densely populated areas than in less populated areas. For example, some commenters stated that in a CBA, a DME supplier can make multiple stops in a day, while a DME supplier in a non-CBA can make significantly fewer. Therefore, the cost per visit in non-CBAs is significantly higher. One commenter went on to explain that this means that DME suppliers in non-CBAs require more trucks, more employees, more fuel (and all the related overhead costs) to be able to serve the same number of beneficiaries. Another commenter disagreed with the way CMS measured its travel distance analysis, saying that CMS operated under the premise that DME suppliers use single round trips to deliver items to beneficiaries, when DME suppliers rely on the efficiency of routes and volume to deliver items to beneficiaries. The commenter asserted that had CMS started with this presumption of DME operations, they would have arrived at the conclusion that it is more costly to operate in non-CBAs.

Response: Since we do not have data on the number of stops a delivery truck makes and the distance between stops, we are not able to factor this variable into our data for average travel distance. However, our analysis was not based on a premise that DME suppliers use single round trips to deliver items to beneficiaries. We understand that this is not the case in practice and used other data besides the distance between the beneficiary address and the supplier address on claim forms to determine the service areas and delivery distances for suppliers. We looked at the differences in land areas for the CBAs compared to the land areas for non-CBAs (MSAs and micropolitan statistical areas not included in the CBP) and found that the areas served by the contract suppliers under the CBP are much larger than the non-CBA areas. The size of the CBAs are approximately double the size of the MSAs where competitive bidding has not yet been phased in. Data also show that 65 percent of the items furnished to beneficiaries in these MSAs are furnished from suppliers located within the MSA, meaning that the greatest distance the majority of suppliers serving these areas would have to travel to furnish items within these areas is half the distance that suppliers in CBAs would have to travel. We understand that suppliers serving larger, more densely populated areas will generally have more locations, trucks, drivers, and other employees to serve the larger populated areas, but as one commenter pointed out, travel time in heavily populated areas is affected by traffic and costs in larger, more densely populated areas metropolitan areas (wages, rent, utilities, tolls) is higher. Suppliers in CBAs will spend more money on rent and utilities, trucks, and wages to serve the larger, more densely populated urban areas than suppliers in smaller, less densely populated non-CBA urban areas. So, even though the supplier in the larger, more densely populated area may have more items to spread these costs over, the costs they spread over the items are considerably greater. We have not found that the total costs of suppliers in non-rural, non-CBAs are greater than or less than the total costs of suppliers in CBAs, nor have we seen data suggesting that the cost per visit in non-CBAs is significantly higher than in CBAs.

Comment: A few commenters stated that CMS should have compared the average travel distance and cost, the average volume of items and services furnished by suppliers, and the number of suppliers in CBAs to the average travel distance and cost, the average volume of items and services furnished by suppliers, and the number of suppliers in all non-CBAs, and not by any other geographic delineation (MSAs, micropolitan statistical areas, super rural areas, etc.). The commenter stated that the Cures Act mandated the Secretary to take into account a comparison of certain factors with

''respect to non-competitive acquisition areas and competitive acquisition areas'' when determining fee schedule adjustments for items and services furnished after January 1, 2019. The commenter also stated that as a result, CMS should make the same fee schedule adjustments for all non-CBAs, regardless of whether the area is rural or non-rural. Some commenters stated that because Congress passed Section 16007 of the Cures Act, which retroactively applied the 50/50 blended rates in all non-CBAs from June 30, 2016 to December 31, 2016, that it was the intent of Congress in passing section 16008 of the Cures Act for CMS to increase payment in all non-CBAs.

Response: We took into consideration the issues that stakeholders have raised for this analysis. Many stakeholders have claimed that the costs of furnishing items and services in rural areas are different than the cost of furnishing items and services in urban areas. Specifically, stakeholders have indicated that costs in rural areas are higher than costs in urban areas. All CBAs are currently located in MSAs or urban areas, whereas non-CBAs are a mixture of areas that are urban/MSAs (similar to CBAs) and other areas that are rural (not similar to CBAs). Based on stakeholder input, it is important to distinguish between urban and rural areas, and separately analyzing data for rural and urban non-CBAs and comparing this data and information to data and information for CBAs comports with this stakeholder input. Section 16008 of the Cures Act mandated that CMS take certain information into account when adjusting fee schedule amounts for items furnished on or after January 1, 2019. Section 16008 of the Cures Act does not require CMS to adjust fee schedule amounts any differently (upward or downward) based on this information. CMS conducted an analysis of the factors outlined in section 16008 of the Cures Act, and the results of the analysis are summarized in this final rule and in the proposed rule (83 FR 34380). Based on the stakeholder comments, and our data showing higher costs for non-contiguous areas, the increased average travel distance in certain rural areas, the significantly lower average volume per supplier in non-CBAs, especially in rural and non-contiguous areas, and the decrease in the number of non-CBA supplier locations, we believe the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in all areas that are currently rural or non-contiguous non-CBAs, should be based on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts in accordance with the current methodologies under § 414.210(g)(1) through (g)(8).

Comment: Some commenters recommended that CMS adopt add-on payment policies for the non-CBAs. For instance, a few commenters recommended that after the end of the blended rate extension, that CMS establish two percentage add-ons for the non-CBA areas: one for the non-rural non-CBAs and one for the rural non-CBAs. The commenters recommended setting the non-rural non-CBAs at the regional SPA + 16 percent, and the rural non-CBAs at the regional SPA + 22 percent. The commenters said that these amounts are based on data obtained from a survey of suppliers indicating that costs were 5 percent higher than the SPAs in CBAs and the cost differential they identified through their cost survey. As an example, a few commenters mentioned that Congress set the ambulance fee schedule urban and rural add-ons through statute, but left the calculation of the super rural add-on to CMS to determine. To make this calculation, CMS used existing GAO report data that ultimately supported the current super-rural add-on of 22.6 percent. One commenter said that this supports paying higher in these super-rural areas. Another commenter said that once CMS implements the next CBP, CMS should apply rural and super-rural add-on payments to all non-CBAs.

One commenter recommended that CMS establish a special payment policy for suppliers providing service to rural beneficiaries. The commenter mentioned how, currently, CMS uses a special rule for rural areas for items included in more than 10 CBAs. In addition, the commenter said CMS could supplement this special rule by making it more generous, and also applying the national ceiling prices in areas with a limited number of suppliers or low average volume of Medicare business. As an example, the commenter said the national ceiling amount could apply to areas with low volume of Medicare business or to suppliers meeting a low numerical threshold; for instance, the lowest quartile based on volume of a particular DMEPOS item or number of suppliers in an area. The commenter also said that this would help boost payment levels in other markets, and not just rural ones. In addition, the commenter also suggested CMS as another option, or in addition to the aforesaid policy, establish an add-on payment for these defined low volume or low supplier areas, based on its general approach used for rural areas in the ambulance fee schedule. The commenter also said that this could involve increasing the base payment by a percentage amount such as 10 percent.

One commenter recommended CMS conduct its own survey of costs to support the cost differential. The commenter also recommended that CMS extend the blended 50/50 payment rates in rural and non-rural non-CBAs until CMS can determine and implement the appropriate percentage add-on adjustments. Another commenter welcomed the opportunity to work with CMS to identify the specific data such a survey would collect and to work with other stakeholders.

One commenter recommended that CMS should add another percentage add-on to the current 50/50 blended rates in rural areas.

Another commenter said that CMS should create a formula to factor in costs due to distance and a lack of other patients. Similarly, another commenter said CMS should ensure there are a sufficient number of qualified suppliers within certain distances of rural and non-contiguous service areas to ensure products are available within acceptable time frames.

Response: We thank the commenters for their specific recommendations regarding adopting add-on payments for items and services furnished in non-CBAs. We did not propose any payments like those described by commenters. We will keep these recommendations in mind for future rulemaking.

We currently believe that finalizing the fee schedule adjustment policy of paying the 50/50 blended rates for items and services furnished in all rural and non-contiguous non-CBAs ensures access to DME in all of these areas and is administratively simpler than applying payments like those described by commenters only in certain areas. We recognize that there are certain supplier cost and volume differences in rural and non-contiguous non-CBAs, which is why this final rule distinguishes rural and non-contiguous non-CBAs from other non-CBAs and results in higher payments to suppliers furnishing items in the rural and non-contiguous non-CBAs. We also believe that paying an amount in addition to the blended 50/50 payment rates would be excessive and unnecessary, and not in line with what most commenters requested, as most commenters specifically requested the blended 50/50 payment rates in rural and non-contiguous non-CBAs. This indicates that such payment rates are sufficient, which is why we are also

not incorporating the ambulance fee schedule's concept of a super rural add-on into our payment. We do not believe that we need to conduct a survey of costs, as we have already analyzed several cost data variables as part of section 16008 of the Cures Act, as discussed in section VI.A.4 of the CY 2019 ESRD PPS DMEPOS proposed rule, and briefly described in section VI.A.1 in this final rule.

We will continue to monitor the effects of these adjustments. However, as discussed in section VI.A.7 of the CY 2019 ESRD PPS DMEPOS proposed rule, we have been monitoring the effects of the fee schedule adjustments since they took effect in 2016 in non-CBAs, and the data does not show any observable trends indicating an increase in adverse health outcomes such as mortality, hospital and nursing home admission rates, monthly hospital and nursing home days, physician visit rates, or emergency room visits in 2016, 2017, or 2018 compared to 2015 in the non-CBAs, overall. In addition, we have been monitoring data on the rate of assignment in non-CBAs and it remains high (over 99 percent) in most areas, which reflects when suppliers are accepting Medicare payment as payment in full and not balance billing beneficiaries for the cost of the DME.

Comment: A few commenters commented on our analysis of maximum winning bids for section 16008 of the Cures Act. One commenter said that CMS did not include in its analysis the bidding logic used by those who submitted bids, and the commenter went on to say that the factors that play a role in how one determines their bid amount are bid ceilings, median pricing, potential increased volumes, limited competition, out of area bid winners, how much of the service area is impacted by a bid area and the ability to remain in the Medicare business or not, logic, emotion, and financial impact. A few commenters said that they were not surprised that we found no discernable patterns in the maximum winning bids, given that, as the commenter says, the ability of suppliers to game the current methodology, a lack of transparency, and confusion around the bid ceiling, and that it is unlikely that the bids represent a true gauge of cost or reflect rationale and consistent behavior. The commenters went on to say that they believe that if the proposed changes to the CBP in section V of the CY 2019 ESRD PPS DMEPOS proposed rule are finalized, there will be more rational behavior among suppliers when determining their bids, which will lead suppliers to bid in a way that is more reflective of their costs and the markets they are serving.

Response: We agree that many factors influence what amount a supplier will submit as their bid amount, but there is no way to itemize all of the possible factors and which factors are more important to which types of suppliers. The circumstances surrounding the costs and efficiencies of every individual supplier as well as the bidding strategies they use can vary widely from supplier to supplier. We believe this reinforces the fact that this factor (the highest winning bid in an area is subjective and supplier-specific) provides little to no insight regarding supplier costs in general and how fee schedule amounts should be adjusted in non-CBAs.

Comment: A few commenters raised concerns with our proposal to adjust the fee schedule amounts for items and services furnished in rural and non-contiguous non-CBAs from January 1, 2019 through December 31, 2020 based on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts. The Medicare Payment Advisory Commission (MedPAC) did not support our proposal to pay the 50/50 blended rates for items and services furnished in rural and non-contiguous areas and said CMS should adopt a more limited, targeted, and less costly approach. MedPAC said that using 50/50 blended payment rates results in large payment increases, often of 50 percent or more. MedPAC also said that while CMS presents data indicating that some supplier costs are higher in rural and non-contiguous areas, the agency also found that other costs are lower in those areas, and the agency does not present data to justify the large magnitude of the proposed adjustment. MedPAC also said that the 50/50 blended payment rates in all rural and non-contiguous areas for all DMEPOS products included in the CBP is not well targeted. For example, MedPAC noted that micropolitan areas (which are considered rural for the purposes of fee schedule adjustments) likely face different challenges than remote, non-contiguous areas. Finally, MedPAC as well as another commenter, noted that the 50/50 blend rates creates a financial burden for the Medicare program and beneficiaries. Commenters noted that over 2 years, we estimate that the proposed fee schedule adjustments will cost more than $1.3 billion dollars—$1.05 billion for the Medicare program and $260 million in beneficiary cost sharing. MedPAC also noted the $360 million in additional costs incurred by the Medicare program and beneficiaries associated with using 50/50 blended rates in rural and non-contiguous areas for the last seven months of 2018, as a result of the interim final rule published in the **Federal Register** on May 11, 2018, titled ''Medicare Program; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas'' (83 FR 21912). MedPAC said that it continues to believe that CMS should use its current statutory authority (and seek additional legislative authority where necessary) to expand the CBP to offset these increased burdens. MedPAC said that expanding the CBP into new product categories, such as orthotics, would produce substantial savings and help prevent fraud and abuse.

Response: We thank the commenter for raising their concerns with us regarding our proposal to pay the 50/50 blended rates for items and services furnished in rural and non-contiguous non-CBAs. The extension of these blended rates is for a 2-year period and we will continue to monitor the effects of these rates. Based on the stakeholder comments, our data showing higher costs for non-contiguous areas, the increased average travel distance in certain rural areas, the significantly lower average volume per supplier in non-CBAs, especially in rural and non-contiguous areas, and the decrease in the number of non-CBA supplier locations, we believe the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020 in all areas that are currently rural or non-contiguous non-CBAs, should be based on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts in accordance with the current methodologies under § 414.210 (g)(1) through (g)(8).

Comment: MedPAC supported the proposal to continue to fully adjust the fee schedule amounts for items and services furnished in non-rural, contiguous non-CBAs based on information from the CBP. MedPAC believes CMS's analyses, which suggest that the travel distance and costs are lower in non-rural non-CBAs relative to CBAs, support fully adjusting the fee schedule amounts based on information from the CBP, instead of using a 50/50 blend of adjusted and unadjusted fee schedule amounts. In the long term, MedPAC said that CMS should use its current authority to expand the CBP to non-rural, non-CBAs to the extent any future concerns arise about the appropriateness of using CBP rates from

large non-rural areas to set payment rates in smaller non-rural areas.

Response: We thank MedPAC for their support of our proposal with respect to the fee schedule adjustments for items and services furnished in non-rural, contiguous non-CBAs. We agree that our analyses, which suggest that the travel distance and costs are lower in urban non-CBAs relative to CBAs, and support fully adjusting the fee schedule amounts for items and services furnished in non-rural, contiguous non-CBAs based on information from the CBP instead of using a 50/50 blend in such areas.

Comment: In the 2019 ESRD PPS DMEPOS proposed rule, we sought comments on ways to improve the fee schedule monitoring data that we use to monitor beneficiary health and access issues in the non-CBAs. These comments were outside the scope of the proposals. A few commenters suggested creating a position within CMS, such as an ombudsman, whose position would be to monitor and address access, quality, supplier availability, and other issues regarding the adequacy of payment levels in non-CBAs. One commenter said that because CMS already has an ombudsman focused on CBAs, an ombudsman focused on non-CBA issues would be able to better understand the impacts of payment rates in non-CBAs.

Some commenters said that it is impossible to track changes in the features and options available to Medicare beneficiaries within the CBP compared to those available to beneficiaries outside of the CBA due to the fact that the HCPCS codes contain heterogeneous products. The commenters recommended that CMS enable better monitoring of changes in product offerings as a result of the CBP and fee schedule adjustments through HCPCS coding. One commenter said that CMS has no measure of the access to services or the quality of services provided.

One commenter recommended that CMS examine the 2013 fee-for-service diabetic population that used insulin at the time, and track that population through 2017, with cohorts for those continuing use of diabetic testing supplies compared to those not using or discontinuing their use of diabetic testing supplies, and to assess the outcomes and costs for Part A and B for each subgroup by year.

A few commenters recommended that CMS compare the number of Medicare beneficiaries with chronic obstructive pulmonary disease (COPD) with the number of beneficiaries receiving home oxygen therapy. One commenter requested a standard benchmark to assess whether the percentage of patients who require the therapy because of their diagnosis actually receive it.

Another commenter said CMS should determine whether hospital data, admissions, or readmissions are specific enough to track admissions/readmissions related to complications associated with noncompliance with home respiratory therapy. The commenter also noted that the analysis should be sensitive to whether metrics of hospitalizations for other chronic conditions are improving but the metric for COPD patients is flat or declining, which could indicate that there is a problem with access to home therapies.

A few commenters said CMS should determine whether SNF/long-term care (LTC) beneficiaries using home respiratory therapies is increasing, and that an increase might suggest that patients are being institutionalized rather than being able to remain in their homes.

Other commenters said CMS should survey prescribers of home respiratory therapy to evaluate the difficulty of discharging patients who require such therapy.

Some commenters recommended that CMS support the ATC survey of patients and suggest modifications to target questions about services more specifically.

More commenters said CMS should enhance beneficiary awareness of the CMS complaint process and publicly report on the complaints it registers, and not just those that are ultimately resolved by a supplier.

They also said CMS should establish a patient satisfaction survey/patient-reported outcomes measure for home respiratory therapy that would capture issues like isolation, reduced services, reduced delivery areas, and other impacts that cannot be measured using claims data.

One commenter agreed that hospital and nursing home admission rates, monthly hospital and nursing home days, physician visit rates, and emergency room visits are all reasonable indicators for continued monitoring. The commenter encouraged CMS to also consider obtaining and monitoring information from discharge planners, prescribers and beneficiaries regarding delays and issues in obtaining DMEPOS services for their patients in impacted areas.

Another commenter said that the approach CMS currently uses to monitor access solely through review of claims data would not capture these, or similar, situations. In addition, the commenter then recommended a more refined and granular approach to detect meaningful differences that CMS can act on as part of an ongoing monitoring approach. The commenter also believed that a quantitative approach complemented by a qualitative approach, such as ongoing surveys or selective case studies of sites where issues have been reported, would improve CMS' efforts to monitor beneficiary access and health outcomes and provide more actionable data to resolve access-related issues.

Response: We thank the commenters for suggesting ways in which to improve our fee schedule monitoring data. We will take these comments into consideration going forward.

2. Proposed Fee Schedule Adjustments for Items and Services Furnished in Former Competitive Bidding Areas During a Gap in the DMEPOS CBP

In the event of a future gap in the CBP due to CMS being unable to timely recompete contracts under the program before the DMEPOS competitive bidding contract periods of performance end, we proposed a fee schedule adjustment methodology that would be used to adjust the fee schedules for items and services that are currently subject to and included in competitive bidding programs. We believe that a fee schedule adjustment methodology for items and services furnished during a gap in the CBP in areas that were included in the CBP should result in payment amounts that are comparable to the SPAs that would otherwise be established under the CBP in order to maintain the level of savings that would otherwise be achieved if the CBP was in effect. We proposed a specific fee schedule adjustment methodology for items and services furnished within former CBAs in accordance with sections 1834(a)(1)(F) and 1834(a)(1)(G) of the Act. Specifically, we proposed to add a new paragraph (10) under § 414.210(g) that would establish a methodology for adjusting fee schedule amounts paid in areas that were formerly CBAs during periods when there is a temporary lapse in the CBP. We proposed to adjust the fee schedule amounts for items and services furnished in former CBAs based on the SPAs in effect in the CBA on the last day before the CBP contract periods of performance ended, increased by the projected percentage change in the CPI for all Urban Consumers (CPI–U) for the 12-month period on the date after the contract periods ended (for example, January 1, 2019). If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day after the contract period

ended based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date.

We also proposed to revise § 414.210(g)(4), so that it does not conflict with the proposed new paragraph (g)(10), by revising the first sentence in paragraph (g)(4) to read: ''In the case where adjustments to fee schedule amounts are made using any of the methodologies described, other than paragraph (g)(10) of this section, if the adjustments are based solely on SPAs from competitive bidding programs that are no longer in effect, the SPAs are updated before being used to adjust the fee schedule amounts.''

With regard to payment for non-mail order diabetic testing supplies, section 1834(a)(1)(H) of the Act mandates that payment for non-mail order diabetic testing supplies be equal to the SPAs established under the national mail order competition for diabetic testing supplies. We believe that as of January 1, 2019, we must continue payment for non-mail order diabetic supplies at the current SPA rates. These SPA rates would not be updated by inflation adjustment factors and would remain in effect until new SPA rates are established under the national mail order program. We do not believe that this statutory provision would cease to apply in situations where there is a gap in the national mail order competitions for diabetic testing supplies; and therefore, we will continue to use the SPAs for mail order diabetic testing supplies as the payment amounts for non-mail order diabetic testing supplies in the event that there is a gap in the CBP.

We requested comments on these proposals.

The comments and our responses to the comments on our proposals for fee schedule adjustments for items and services furnished in former CBAs during a gap in the DMEPOS CBP are set forth below.

Comment: Several commenters endorsed increasing the payment levels in former CBAs beyond the proposal to adjust the fee schedule amounts in former CBAs based on the SPA increased by the projected percentage change in the CPI–U for the 12 month period ending January 2019. Some commenters raised a concern that the SPAs were based upon bids from suppliers who anticipated a larger volume of business as contract suppliers than what would occur starting January 1, 2019, in the former CBAs when any supplier can furnish the items and services. Some DME suppliers and industry associations said that without that greater volume, prices will have to increase to better ensure continuing beneficiary access. Other commenters stated that during the gap period in competitive bidding, CMS should recalculate SPAs based on the clearing price (maximum winning bids) and change the reimbursement rates for the non-CBAs and CBAs accordingly until the next round of competitive bidding begins. Some commenters recommended that CMS should apply the 50/50 blended rates to the former CBAs, until the next round of competitive bidding takes place. Other commenters recommended that CMS adjust the SPAs in the former CBAs by adding a CPI–U increase compounded from 2013 through 2018 or 2019 to generate the adjusted 2019 CBA SPA rate, as 2013 was when the CBP was expanded throughout the nation under Round 2. Another commenter said that previously contracted suppliers should not be penalized for providing service in CBAs during the contract terms, and that CMS should pay a premium to previously contracted suppliers to offset the reduction in the volume of patients, such as 15 percent.

Response: We thank the commenters for their recommendations for how to adjust the fee schedule amounts for items and services furnished in the former CBAs during the gap in the CBP. We believe that the CY 2019 ESRD PPS DMEPOS proposed rule, which we are finalizing, will result in adequate fee schedule amounts given that the SPAs that the adjusted fees are based on are the same amounts that have been used to adjust the fee schedule amounts for non-rural non-CBAs since January 1, 2017, and suppliers in these areas have accepted these rates as payment in full over 99 percent of the time. Stakeholders overwhelmingly have claimed that costs in non-rural non-CBAs are higher than costs in CBAs based on differences in population and volumes of items furnished. Thus, if fully adjusted fees based on SPAs are sufficient to cover the costs in the non-rural, non-CBAs, they should be sufficient to cover the costs in the higher populated, higher volume areas. As shown in Table 50 of the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34377), for items subject to the fee schedule adjustments, the 2016 allowed services in CBAs are approximately double the 2016 allowed services in non-rural, non-CBAs.

We believe that adjusting fees based on maximum winning bids would result in excessive payments based on this same logic.

Comment: Some commenters opposed the proposed rule, and specifically focused on the payment amounts for mail order diabetic supplies, requesting higher payments. They cited previous payment reductions for suppliers, a decline in the number of suppliers, claims that there are lower quality supplies due to the National Mail Order CBP, potential health and access issues during the gap in the National Mail Order, and the National Mail Order CBP contract periods of performance ending on December 31, 2018 as reasons why payments should be higher for mail order diabetic supplies during the gap in the CBP. Lastly, multiple commenters suggested ways CMS should pay higher amounts for diabetic testing supplies during the gap in the National Mail Order CBP. A few commenters said CMS should return to the unadjusted fee schedule reimbursement rate, or the lesser of the supplier's charge for an item. A few other commenters recommended that CMS apply an inherent reasonableness standard based on valid and reliable data, and reduce the unadjusted fee schedule price of a box of diabetic test strips by fifteen percent, for instance. A few commenters said that there was an average 45 percent reduction in the SPA for items in product categories other than diabetic testing supplies, and as a result, CMS should apply a 45 percent reduction in the price of diabetic testing supplies from the unadjusted fee schedule amount, which would result in a SPA of $18.70 per box. One commenter went on to say that if CMS decides to maintain the current reimbursement structure of SPA plus CPI–U for all former CBAs, CMS should set the SPA for diabetic testing supplies at the $18.70 amount plus the CPI–U for every 12 months since 2013, or set an amount that is above $20 per box for blood glucose test strips.

Response: We thank the commenters for their recommendations for how to adjust the fee schedule amounts used to pay for mail order diabetic testing supplies during the gap in the National Mail Order CBP. We believe that the proposed fee schedule adjustment methodology will result in payment amounts that will be adequate given the high rate of assignment of claims by suppliers for non-mail order diabetic testing supplies since July 2016, when fee schedule amounts adjusted based on the current SPAs from the National Mail Order CBP were implemented. We will continue our monitoring efforts during the gap in the CBP once contracts expire. With regard to the comment recommending that CMS apply an inherent reasonableness standard based on valid and reliable data in establishing the fee schedule amounts

for mail order diabetic testing supplies during the gap in the CBP, we note that the 15 percent threshold the commenters refer to is used to determine which of two processes outlined in section 1842(b)(8) of the Act CMS must follow when invoking the inherent reasonableness authority to adjust fee schedule amounts for items and services not subject to competitive bidding. This threshold has little bearing on what a reasonable payment amount is for diabetic testing supplies.

Comment: A few commenters said CMS did not have the authority to adjust fee schedule amounts for diabetic testing supplies by the current SPAs. For instance, one commenter stated section 1834(a)(1)(F)(ii) of the Act does not provide authority for fee schedule adjustments during a gap in the CBP because the commenter believed section 1834(a)(1)(F) only applies where there is an active CBP. The commenter went on to say that CMS did not follow the process required by section 1834(a)(1)(G), as amended by section 16008 of Cures Act, which as discussed in section VI of this final rule, requires that the Secretary in making any adjustments to the fee schedule amounts in accordance with sections 1834(a)(1)(F)(ii) and (iii), 1834(a)(1)(H)(ii), or 1842(s)(3)(B) of the Act, shall: (1) Solicit and take into account stakeholder input; and (2) take into account the highest bid by a winning supplier in a CBA and a comparison of each of the following factors with respect to non-CBAs and CBAs:

- The average travel distance and cost associated with furnishing items and services in the area.
- The average volume of items and services furnished by suppliers in the area.
- The number of suppliers in the area.

The commenter also said that section 1834(a)(1)(B) of the Act requires that, in the absence of a CBP, the Secretary make payments based on the unadjusted fee schedule, and that according to section 1834(a)(1)(F) of the Act, in these situations, the Congress established a reimbursement scheme for DMEPOS centered around a default payment of the lesser of the actual charge or the unadjusted fee schedule. The commenter asserted that reimbursing items based on the SPA is an exception to this more general rule and is only done for items and services included in, as section 1834(a)(1)(F) of the Act says, a ''competitive acquisition program in a competitive acquisition area.'' The commenter said that since there will be no competitive acquisition program for diabetic testing supplies beginning on January 1, 2019, this special rule does not apply, and the payment must be based on the unadjusted fee schedule.

The commenter also discussed how CMS has taken this approach on at least two occasions. The first being during a previous gap in the CBP, in which CMS paid for diabetic testing supplies based on the fee schedule, and contracts for bidding on mail order diabetic testing supplies were in place from January 1, 2011 through December 31, 2012, and then again from July 1, 2013 through June 30, 2016. For that gap period of January 1, 2013 to July 1, 2013, the commenter said that CMS paid based on the fee schedule rates across all regions.

The other occasion the commenter discussed was when CMS resorted to the fee schedule during the first round of competitive bidding when an auction was considered ''nonviable'' because beneficiary demand could not be met by qualified suppliers. In the seven Round 1 auctions that were considered nonviable, the commenter said that the DME items in that competitive bidding area were paid according to the ''fee schedule and all Medicare enrolled DME suppliers [were allowed to] continue . . . to submit DME claims for these items in that [competitive bidding area].''

The commenter also stated that if CMS determines that the payment amounts based on the fee schedule are not inherently reasonable, CMS can use its authority under section 1842(b)(8)(A)(i) of the Act to adjust the amounts. Under this section, the commenter said that CMS has the ability to deviate from the fee schedule and alter payment rates for items or services that are ''grossly excessive or grossly deficient'' and to determine an amount that is ''realistic and equitable.'' The commenter concluded by saying that it is this authority and not the authority in section 1834(a)(1)(F) of the Act that would allow CMS to adjust the fee schedule for diabetic testing supplies.

Response: We disagree with the commenters' assertions that we do not have the authority to adjust fee schedule amounts for mail order diabetic testing supplies furnished beginning January 1, 2019 by the current SPAs. In the Patient Protection and Affordable Care Act (the Affordable Care Act), Congress mandated fee schedule adjustments for items and services furnished in non-CBAs using the payment determined under the CBP. The relevant section of the Affordable Care Act (section 6410(b)) is titled ''Requirement to Either Competitively Bid Areas or Use Competitive Bid Prices by 2016.'' The intent of the CBP and fee schedule adjustments is to thus pay SPAs in CBAs and generate savings in other areas, either by bidding or by adjusting fee schedule amounts based on the payment determined under the CBP. In addition, in the final rule published in the **Federal Register** on November 6, 2014 titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies'' (79 FR 66120), we finalized § 414.210(g)(4), which describes fee schedule adjustments when the only information available is from a competitive bidding program no longer in effect. Thus, CMS has already promulgated a rule to address instances when items are no longer competitively bid. Consistent with that policy, we believe we should continue to adjust the fee schedule amounts for such items during a gap in competitive bidding rather than reverting to completely unadjusted fee schedules. We note that when promulgating this rule, we did take into account the relevant factors under section 16008 of the Cures Act for items furnished in former CBAs, including mail order diabetic testing supplies. With regard to mail order diabetic testing supplies, average travel distance is not applicable since these items are mail order items. Shipping and handling charges typically do not change based on the distance the item is mailed or shipped. The number of mail order suppliers during the gap should be higher and the average volume of mail order diabetic testing supplies furnished by suppliers during the gap will be somewhat lower than the average volume of mail order diabetic testing supplies furnished by suppliers under the CBP. We do not believe that this will have a significant impact on the overall cost of the diabetic testing supplies or the ability of the suppliers to furnish the items at approximately the same rate as suppliers of non-mail order diabetic testing supplies.

Lastly, we disagree with the commenter that the requirement to adjust fee schedule amounts does not apply if there is not an active CBP in place for an item, and that CMS should instead invoke its authority under section 1842(b)(8)(A)(i) of the Act to adjust the fee schedule amounts for diabetic testing supplies. Under section 1834(a)(1)(F) of the Act, if items furnished on or after January 1, 2011 are included in a CBP, the fee schedule amounts must be adjusted for those items if they are furnished on or after January 1, 2016 outside of CBAs. Diabetic testing supplies have been

included in the national mail order CBP from January 1, 2011 through December 31, 2018, and because the statute mandates the adjustment of the fee schedule amounts based on the payment determined under the CBP for items furnished on or after January 1, 2016, CMS must continue to adjust the fee schedule amounts for such items furnished on or after January 1, 2019.

Final Rule Action: After consideration of comments received on the proposed rule and for reasons we set forth previously in this final rule and in the proposed rule, we are finalizing the three fee schedule adjustment methodologies we proposed without change. Specifically, we are finalizing the proposed revisions to § 414.210(g)(9) to adjust the fee schedule amounts for items and services furnished in rural and noncontiguous non-CBAs by extending through December 31, 2020 the current fee schedule adjustment methodology which bases the fee schedule amounts on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts. We are also finalizing our proposal to continue fully adjusting the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in non-rural and contiguous non-CBAs in accordance with the current methodologies under § 414.210(g)(1) through (g)(8). We are also finalizing the proposed addition of paragraph (g)(10) to § 414.210 to establish a methodology for adjusting fee schedule amounts for items and services furnished in former CBAs during temporary gaps in the DMEPOS CBP.

VII. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

A. Background

The Medicare payment rules for durable medical equipment are set forth in section 1834(a) of the Act and 42 CFR part 414, subpart D of our regulations. In general, Medicare payment for DME items and services paid on a fee schedule basis is equal to 80 percent of the lower of either the actual charge or the fee schedule amount for the item. The beneficiary coinsurance is equal to 20 percent of the lower of either the actual charge or the fee schedule amount for the item. General payment rules for DME are set forth in section 1834(a)(1) of the Act and § 414.210 of our regulations, and § 414.210 also addresses maintenance and servicing of items and replacement of items. Specific payment rules for oxygen and oxygen equipment are set forth in section 1834(a)(5) of the Act and § 414.226 of our regulations. The average monthly payment to suppliers serving beneficiaries with a prescribed flow rate of greater than 4 liters per minute in 2006 was approximately $299.76. Before the enactment of the Deficit Reduction Act of 2005 (DRA) (Pub. Law No. 109–171), these monthly payments continued for the duration of use of the equipment, provided that Medicare Part B coverage and eligibility criteria were met. Medicare covers three types of oxygen delivery systems: (1) Stationary or portable oxygen concentrators, which concentrate oxygen in room air; (2) stationary or portable liquid oxygen systems, which use oxygen stored as a very cold liquid in cylinders and tanks; and (3) stationary or portable gaseous oxygen systems, which administer compressed oxygen directly from cylinders. There is also transfilling equipment that takes oxygen from concentrators and fills up small portable gaseous tanks. Both liquid and gaseous oxygen systems require delivery of oxygen contents. Concentrators and transfilling systems do not require delivery of oxygen contents. Medicare payment for furnishing oxygen and oxygen equipment is made on a monthly basis and the fee schedule amounts vary by state.

Effective January 1, 2006, section 5101(b) of the DRA amended section 1834(a)(5) of the Act, limiting the monthly payments for oxygen equipment to 36 months of continuous use. The limit of 36 months of payment also applies to cases where there is an oxygen flow rate of greater than 4 liters per minute. The DRA mandated that payment for the delivery of oxygen contents continue after the 36-month cap on payments for oxygen equipment. At this time, Medicare already had an established fee schedule amount or payment class for oxygen contents only for beneficiaries who owned the stationary and/or portable oxygen equipment. The monthly payment for oxygen contents for beneficiaries who purchased oxygen equipment prior to 1989 included payment for delivery of both stationary and portable contents and was approximately $156 on average in 2006. CMS implemented section 1834(a)(5) of the Act, as amended by section 5101 of the DRA, in the final rule published on November 9, 2006 in the **Federal Register**, titled ''Home Health Prospective Payment System Rule Update for Calendar Year 2007 and Deficit Reduction Act of 2005 Changes to Medicare Payment for Oxygen Equipment and Capped Rental Durable Medical Equipment'' (71 FR 65884). As part of this rule, we amended § 414.226 by adding a new paragraph (c) and separate payment classes for: oxygen generating portable equipment (OGPE) consisting of portable oxygen concentrators and transfilling equipment that met the patient's portable oxygen needs without relying on the delivery of oxygen contents; stationary oxygen contents after the 36-month rental period; and portable oxygen contents after the 36-month rental period. With the addition of the new class for OGPE, rather than paying the standard monthly add-on payment of $31.79 for portable oxygen equipment, we established a higher amount of $51.63 per month for this new technology while portable gaseous or liquid oxygen equipment continued to be paid at the lower add-on payment rate of $31.79 per month.

Section 1834(a)(9)(D) of the Act provides CMS the authority to create separate classes of oxygen and oxygen equipment. Section 1834(a)(9)(D)(ii) of the Act mandates that new, separate classes of oxygen and oxygen equipment be budget neutral; the Secretary may establish new classes for oxygen and oxygen equipment only if the establishment of such classes does not result in expenditures for any year that are less or more than the expenditures which would have been made had the classes not been established. It is important to stress that the budget neutrality requirement in section 1834(a)(9)(D)(ii) of the Act applies regardless of whether fee schedule amounts are adjusted based on information from the DMEPOS CBP. Since 2008, in accordance with our regulations at § 414.226(c), CMS has ensured budget neutrality each year by determining how much expenditures increased as a result of the higher paying OGPE class and reducing the monthly payment amount for stationary oxygen equipment and oxygen contents by a certain percentage to offset the increase in payments attributed to OGPE. Stakeholders have suggested that the budget neutrality requirement should not apply in situations where the fee schedule amounts for oxygen and oxygen equipment, including the fee schedule amounts for OGPE, are adjusted based on information from the DMEPOS CBP. We disagree. As long as the add-on payment amounts for OGPE are higher than the add-on payment amounts that would otherwise have been made if the OGPE class not been established, an offset is required to ensure budget neutrality.

As of January 1, 2018, the average adjusted monthly fee schedule add-on

amount was $40.08 for OGPE and $18.20 for portable gaseous and liquid oxygen equipment. Either of these monthly add-on amounts is added to the average adjusted fee schedule monthly payment for stationary oxygen equipment and oxygen contents, which was $72.95. We note that if the fee schedule amounts for oxygen and oxygen equipment are adjusted based on information from the DMEPOS CBP, and these adjustments result in the fees for OGPE being lower than the add-on payment amounts that would otherwise have been made if the OGPE class not been established, a positive rather than a negative budget neutrality offset would be needed to ensure that total expenditures for any year are not more or less than the expenditures which would have been made if the class had not been established.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

We received approximately 65 oxygen-related public comments on our proposals in the CY 2019 ESRD PPS proposed rule, including comments from suppliers and industry representative groups.

In this final rule, we provide a summary of the proposed provision, a summary of the public comments received and our responses to them, and the policies we are finalizing.

1. Adding a Portable Liquid Oxygen Equipment Class and a Liquid High-Flow Oxygen Contents Class and Applying Budget Neutrality Offset to All Oxygen and Oxygen Equipment Classes

We proposed in the CY 2019 ESRD PPS proposed rule (83 FR 34383 through 34386) to revise § 414.226(e) to add separate payment classes for portable gaseous oxygen equipment only and portable liquid oxygen equipment only. Instead of having one class for portable oxygen equipment only (gaseous and liquid tanks), we proposed splitting this class into two classes and increasing the add-on amount for portable liquid oxygen equipment. We proposed establishing the initial add-on amounts for portable liquid oxygen equipment so that they are equal to the add-on amounts for OGPE, thus reducing the incentive to furnish OGPE over portable liquid oxygen equipment. Thus, we believe that adding the portable liquid oxygen equipment class and adding a provision to the regulations that would ensure that the payment amount for portable liquid oxygen equipment is the same as OGPE would encourage suppliers to furnish this modality when it is requested by beneficiaries.

2. Adding a Liquid High-Flow Oxygen Contents Class

In § 414.226(e) we also proposed to add a separate payment class for portable liquid oxygen contents for prescribed flow rates of more than 4 liters per minute. We proposed to establish the initial fee schedule amounts for portable liquid oxygen contents for prescribed flow rates of more than 4 liters per minute by multiplying the fee schedule amounts for portable oxygen contents by 1.5 to increase the payment amount by 50 percent above the payment amount for portable oxygen contents. For patients with high flow needs who are also ambulatory, the liquid portable oxygen modality is the only one that allows use of the contents for more than a short period of time. We believe that adding this class and higher payment would encourage suppliers to furnish this modality when it is requested by beneficiaries. Table 36 compares the current classes of oxygen and oxygen equipment and the proposed classes of oxygen and oxygen equipment.

TABLE 36—CURRENT AND PROPOSED OXYGEN AND OXYGEN EQUIPMENT CLASSES

Current oxygen and oxygen equipment: 5 classes described in 414.226	Proposed oxygen and oxygen equipment, for years after 2018: 7 classes described in 414.226
Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).	Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).
Portable equipment only (gaseous or liquid tanks)	Portable gaseous equipment only.
	Portable liquid equipment only.
Oxygen generating portable equipment only	Oxygen generating portable equipment only.
Stationary oxygen contents only	Stationary oxygen contents only.
Portable oxygen contents only	Portable gaseous and liquid oxygen contents only, except for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute.
	Portable liquid oxygen contents only for prescribed flow rates greater than four liters per minute.

3. Applying Budget Neutrality Offset to All Oxygen and Oxygen Equipment Classes

We proposed to change § 414.226(c)(6) and the methodology for applying the budget neutrality offset in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34385 through 34386), in addition to adding the two new proposed oxygen and oxygen equipment classes. We proposed to apply the budget neutrality offset to all items of oxygen and oxygen equipment, rather than just stationary oxygen equipment. This proposed approach would lower the amount of the offset applied to stationary equipment. Table 37 is an example of the 2018 fee schedule amounts when the budget neutrality offset is applied only to the stationary oxygen equipment rate versus the proposed approach of applying the budget neutrality offset to all oxygen classes. This particular example depicts fully adjusted fee schedule amounts, including budget neutrality adjustments, for oxygen and oxygen equipment furnished in non-rural areas in the Southeast United States.

TABLE 37—JANUARY 1, 2018 FEES FOR CURRENT AND PROPOSED BUDGET NEUTRALITY METHODS

Current method	2018 rate	Proposed method	2018 rate
Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).	$70.23	Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).	$72.59
Portable equipment only (gaseous or liquid tanks)	17.29	Portable gaseous equipment only	16.04
		Portable liquid equipment only	34.73
Oxygen generating portable equipment only	37.44	..... Oxygen generating portable equipment only.	34.73
Stationary oxygen contents only	53.32	Stationary oxygen contents only	49.46
Portable oxygen contents only	53.32	Portable gaseous and liquid oxygen contents only with the exception of portable liquid contents greater than four liters per minute.	49.46
		Portable liquid contents only greater than four liters per minute.	74.19

For further detailed information, we refer readers to section VII.B of the CY 2019 ESRD PPS DMEPOS proposed rule.

We solicited comments on these proposals.

Comment: Some commenters simply stated that the payments for portable liquid oxygen equipment and high-flow liquid contents are too low given the high cost of furnishing these items.

Response: We agree that the cost of furnishing liquid oxygen and oxygen equipment is higher than the cost of furnishing other oxygen modalities. The proposals, which we are finalizing, will increase payment for portable liquid oxygen and oxygen equipment and portable oxygen contents for patients with high flow needs and therefore, will help to address the higher costs of these modalities. Although we could increase the rates by more than the amount we proposed, any increase to payment amounts would require a higher budget neutrality off-set. We believe the best course of action is to see what effect finalizing the proposed changes will have on access to liquid oxygen and oxygen equipment before deciding to increase the rates further and requiring a larger off-set to be applied to other items.

Comment: One commenter representing Medicare beneficiaries supported the proposed rule for establishing separate classes and higher payments for portable liquid oxygen equipment and high-flow liquid oxygen contents because of the unique nature of furnishing liquid oxygen and its higher cost.

Response: We agree and appreciate the support for the proposed provisions. For this and the reasons we set forth previously, we are finalizing the separate classes and higher payments for portable liquid oxygen equipment and high-flow liquid oxygen contents.

Comment: Many commenters stated that the budget neutrality adjustment should not apply to fee schedule amounts adjusted based on information on the payment determined under the CBP because they believe that the budget neutrality requirement no longer applies once fee schedule amounts have been adjusted based on information from the CBP.

Response: We do not agree. Section 1834(a)(1)(F)(ii) and (iii) of the Act mandates that the fee schedule amounts for DME be adjusted using information on the payment determined under the CBP and does not set aside the requirement of section 1834(a)(9)(D)(ii) of the Act. Section 1834(a)(9)(D)(ii) of the Act specifies that separate classes of oxygen and oxygen equipment may only be created to the extent that they do not result in expenditures for any year that are more or less than the expenditures which would have been made if such classes were not created. Even though the fee schedule amounts for oxygen and oxygen equipment have been reduced using information on the payment determined under the CBP, without a budget neutrality off-set, current expenditures for oxygen and oxygen equipment would be more than the expenditures which would have been made if the OGPE class was not created. Therefore, in order to ensure that expenditures are not more or less than they would have been without the introduction of higher payment oxygen classes, we must apply a budget neutrality off-set to the classes of oxygen and oxygen equipment even if we have already adjusted the fee schedules based on information from the CBP.

Comment: One commenter recommended spreading the budget neutrality offset over all items of DME rather than the proposed rule to spread the offset over all items of oxygen and oxygen equipment.

Response: We do not believe that payments should be reduced for DME items other than oxygen and oxygen equipment, since many suppliers who furnish such other items do not furnish oxygen and oxygen equipment and therefore are very unlikely to benefit from the higher payments resulting from the additional, separate classes of oxygen and oxygen equipment.

Final Rule Action: After consideration of comments and for reasons we set forth previously in this final rule and in the CY 2019 ESRD PPS DMEPOS proposed rule, we are finalizing the proposals as proposed. Specifically, we are finalizing the proposed revisions to § 414.226(e) to establish the following classes of items: Portable gaseous equipment only; portable liquid equipment only; portable oxygen contents only, except for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute; and portable liquid oxygen contents for prescribed flow rates greater than four liters per minute. We are also finalizing the proposed revision to § 414.226(e) to initially set the monthly payment rate for portable liquid equipment only, based on the monthly payment rate for OGPE and to subsequently adjust the monthly payment rates using the applicable methodologies in § 414.210(g) for items and services furnished beginning January 1, 2019. We are also finalizing the proposed revision to § 414.226(e) to initially set the monthly payment rate for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute based on 150 percent of the monthly payment rate for portable oxygen contents only, and to subsequently adjust the monthly payment rates using the applicable methodologies in § 414.210(g) for items and services furnished beginning January 1, 2019. We are finalizing the proposed revisions to § 414.226(e) to make annual adjustments beginning in 2019 to the monthly payment rates for all items of oxygen and oxygen equipment in order to ensure the annual

budget neutrality of all classes of oxygen and oxygen equipment. Further, we are finalizing the proposed revision to § 414.226(f) to explain the application of the monthly fee schedule amounts as listed in § 414.226(e). As proposed, we are to re-designating paragraphs § 414.226(e), (f) and (g) to § 414.226(g), (h), and (i), respectively. We are also finalizing a number of changes throughout § 414.226 and in § 414.230(h) due to the redesignation of paragraphs (e), (f) and (g) of § 414.226. For example, as proposed, we are finalizing a technical edit to § 414.230(h)—we are by removing the reference to ''§ 414.226(f)'' and adding in its place a reference to ''§ 414.226(h)''. In newly redesignated paragraph (g)(1)(i), we are removing the reference to ''paragraph (e)(2)'' and replacing it with ''paragraph (g)(2)''; and in newly redesignated paragraph (g)(2)(ii) by removing the reference ''paragraph (e)(2)(i)'' and adding in its place the reference ''paragraph (g)(2)(i).''

VIII. Payment for Multi-Function Ventilators

A. Background

Section 1834(a) of the Act governs payment for DME covered under Part B and under Part A for a home health agency and provides for the implementation of a fee schedule payment methodology for DME furnished on or after January 1, 1989. Sections 1834(a)(2) through (a)(7) of the Act set forth separate payment categories of DME and describe how the fee schedule amounts for items under each of the categories are established. Significantly, the payment rules for these categories are different and in some cases mutually exclusive. Table 38 provides a general summary of the payment categories, corresponding payment methodology, and statutory and regulatory provisions. The main payment categories are: Inexpensive or other routinely purchased items, items requiring frequent and substantial servicing, customized items, oxygen and oxygen equipment, and other items of DME (capped rental). There are some differences in the payment rules for the payment categories. For example, while sections 1834(a) (2), (4), (6), and (7) of the Act allow for the lump sum purchase of certain items classified under these categories, sections 1834(a)(3) and (5) of the Act do not allow for lump sum purchase of items in those categories. Also, sections 1834(a)(2), (5), and (7) of the Act cap or limit total rental payments for items in these categories, whereas section 1834(a)(3) does not. With regard to rented items, section 1834(a)(7) of the Act mandates beneficiary ownership of the item after 13 months of continuous rental, whereas sections 1834(a)(2), (3), and (5) do not require transfer of ownership to the beneficiary. Finally, section 1834(a)(3) of the Act mandates that payment for covered items such as ventilators and intermittent positive pressure breathing machines be made on a monthly basis for the rental of the item, whereas ventilators that are either continuous positive airway pressure devices or intermittent assist devices with continuous positive airway pressure devices are excluded from section 1834(a)(3) of the Act. Respiratory assist devices, suction pumps (aspirators), and nebulizers fall under section 1834(a)(7) of the Act (capped rental items).

TABLE 38—SUMMARY OF DME EQUIPMENT PAYMENT CATEGORIES AND RULES [1]

Payment category	Payment rules
Inexpensive or other routinely purchased items—section 1834(a)(2) of the Act.	Purchase price of $150 or less, OR were routinely purchased (75 percent of the time or more) under the rent/purchase program prior to 1989, OR are speech generating devices, OR are accessories used in conjunction with nebulizers, aspirators, continuous positive airway pressure devices, respiratory assist devices, or speech generating devices. If covered, these items can be purchased new or used and can be rented; however, total payments cannot exceed the purchase new fee for the item. See 42 CFR 414.220.
Items requiring frequent and substantial servicing—section 1834(a)(3) of the Act.	Items, such as ventilators, requiring frequent and substantial servicing, in order to avoid risk to the patient's health. If covered, these items can be rented as long as they are medically necessary with the supplier retaining ownership of the equipment. Payment is generally made on a monthly rental basis with no cap on the number of rental payments made as long as medically necessary. Excludes CPAP devices, respiratory assist devices, suction pumps/aspirators, and nebulizers. See 42 CFR 414.222.
Customized items—section 1834(a)(4) of the Act.	Payment amounts are not calculated for a customized DME item. Customized DME is defined at 42 CFR 414.224, including customized wheelchairs. If covered, payment is made in a lump-sum amount for the purchase of the item based on the DME Medicare Administrative Contractor (MAC), Part A MAC, or Part B MAC's individual determination. See 42 CFR 414.224.
Oxygen and oxygen equipment—section 1834(a)(5) of the Act.	One bundled monthly rental payment amount is made, not to exceed a 36 month cap, for all covered stationary equipment, stationary and portable contents, and all accessories used in conjunction with the oxygen equipment. An add-on payment may also be made for portable oxygen. After 36 months, payment can continue to be made on a monthly basis for oxygen contents for liquid or gaseous oxygen equipment. Payment for in-home maintenance and servicing of supplier-owned oxygen concentrators and transfilling equipment may be made every 6 months, beginning 6 months after the 36 month rental cap, for any period of medical need for the remainder of the reasonable useful lifetime of the equipment (5 years). See 42 CFR 414.226.
Other Covered Items (Other than DME)—section 1834(a)(6) of the Act.	Payment under a lump sum purchase.
Other items of DME (capped rental items)—section 1834(a)(7) of the Act.	Monthly rental payment amount is made not to exceed a 13 month cap at which point the beneficiary takes over ownership of the equipment. Complex rehabilitative power wheelchairs can be purchased in the first month of use. For capped rental items other than power wheelchairs, the payment amount is calculated based on 10 percent of the base year purchase price for months 1 through 3. Beginning with the fourth month, the payment amount is equal to 7.5 percent of the purchase price. For power wheelchairs, the rental payment amount is calculated based on 15 percent of the base year purchase price for months 1 through 3. Beginning with the fourth month, the fee schedule amount is equal to 6 percent of the purchase price. See 42 CFR 414.229.

[1] This is a general summary of the DME payment rules. The reader should refer to the statute and regulations for the full payment rules.

The Medicare allowed amount for DMEPOS items and services paid under the DMEPOS fee schedule in accordance with section 1834 of the Act (outside of the CBP) is equal to the lower of the supplier's actual charge or the fee schedule amount. The Medicare payment amount for a DME item is generally equal to 80 percent of the lesser of the actual charge or the fee schedule amount for the item, less any unmet Part B deductible. The beneficiary coinsurance for such items is generally equal to 20 percent of the lesser of the actual charge or the fee schedule amount for the item once the deductible is met.

Concerns have been raised by the manufacturer of a multi-function ventilator about how the separate payment categories set forth at sections 1834(a)(2) through (a)(7) of the Act would apply to a new type of ventilator, which consists of a ventilator base item classified under section 1834(a)(3) of the Act, but can also perform the function of portable oxygen equipment classified under the payment category in section 1834(a)(5) of the Act, and the functions of a nebulizer, a suction pump, and a cough stimulator classified under section 1834(a)(7) of the Act. In particular, a new product was recently cleared by the Food and Drug Administration (FDA) as a ventilator, but can also function as a portable oxygen concentrator, nebulizer, suction pump (aspirator), and cough stimulator. The multi-function ventilator assists with serving multiple, different medical needs of beneficiaries with diagnoses such as chronic lung disease, cystic fibrosis, ALS, and muscular dystrophy. As shown in Table 39, separate DME items perform each of these functions, and the DME items that perform these functions have already been assigned separate HCPCS codes and payment amounts under the DMEPOS fee schedule. Currently, HCPCS codes E0465 and E0466 denote home ventilator item, any type, used with either an invasive interface (for example, tracheostomy tube) or non-invasive interface (for example, mask, chest shell). Portable oxygen concentrators are identified using a combination of codes E1390 plus E1392.

TABLE 39—FUNCTIONS, PAYMENT CATEGORY, AND HCPCS CODES FOR DME ITEMS THAT PERFORM FUNCTIONS OF A MULTI-FUNCTION VENTILATOR

HCPCS code	Function	Payment category
E0465 or E0466	Ventilator	Items requiring frequent and substantial servicing.
E1390 and E1392	Portable Oxygen Concentrator	Oxygen and oxygen equipment.
E0570	Nebulizer	Capped rental items.
E0600	Suction Pump	Capped rental items.
E0482	Cough Stimulator	Capped rental items.

In the CY 2019 ESRD PPS DMEPOS proposed rule, we noted additional concerns in considering how to categorize and pay for the multi-function ventilator. One concern is that a patient may not need all of the functions that the new multi-function ventilator performs, and there are different Medicare medical necessity coverage criteria for each of the five different functions typically performed by five different pieces of equipment. In addition, another concern we have is while section 1847(a)(2)(A) of the Act mandates the implementation of competitive bidding for covered items, the only items that comprise the multi-function ventilator that have been phased into the DMEPOS CBP at this time are portable oxygen concentrators and nebulizers. As a result, in CBAs, only contract suppliers can furnish portable oxygen concentrators or nebulizers to beneficiaries in these areas, whereas non-contract suppliers can furnish ventilators, suction pumps, and cough stimulators in these same areas. The current competitive bid product categories do not include a single item, furnished by one supplier, which performs the functions of five separate items, as the multi-function ventilator does. Even so, upon determination that the multi-function ventilator is a covered item within the meaning of section 1834(a)(13) of the Act and its payment category under section 1834(a)(3) of the Act, the multi-function ventilator item can be eligible for inclusion in a CBP in the future along with other ventilator items.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on Payment for Multi-Function Ventilators

In the CY 2019 ESRD PPS DMEPOS proposed rule, we proposed to add a provision to the regulation at § 414.222(f) to establish a payment methodology for multi-function ventilators effective for dates of service on or after January 1, 2019 (83 FR 34386). As we noted, we believe that our proposal complies with the Medicare payment rules for DME in section 1834(a) of the Act, while recognizing and encouraging innovations in technology such as multi-function ventilators. We proposed that multi-function ventilators be classified under section 1834(a)(3) of the Act because the statute specifically mandates that ventilators other than continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices be classified under this section. Items classified under section 1834(a)(3) of the Act are paid on a continuous monthly rental basis.

We proposed to establish the monthly rental fee schedule amounts for a multi-function ventilator based on the existing monthly rental fee schedule amounts for ventilators plus payment for the average cost of the additional functions. Under this proposal, a single monthly rental fee schedule amount would be paid to encompass the base ventilator item and its additional functional components as follows.

- The monthly rental fee schedule amount for a multi-function ventilator is equal to the monthly rental fee schedule amount for a ventilator established in § 414.222(c) and (d) plus the average of the lowest monthly cost for one additional function and the monthly cost of all additional functions, increased by the annual coverage item updates of section 1834(a)(14) of the Act.
- The monthly cost for additional functions shall be determined as follows:

++ For functions performed by items classified under § 414.222 prior to 1994 the monthly cost is equal to the monthly rental fee schedule amount established in paragraphs (c) and (d) of this section increased by the covered item update of section 1834(a)(14) of the Act.

++ For functions performed by items classified under § 414.220, the monthly cost is equal to the fee schedule amount for purchased equipment established in

§ 414.220 (c), (d), (e), and (f), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment. There are currently no multi-function ventilators on the market that perform the function for items classified under § 414.220.

++ For functions performed by items classified under § 414.226 for oxygen equipment, the monthly cost is equal to the monthly payment amount established in § 414.226(e), and (f), adjusted in accordance with § 414.210(g), multiplied by 36 and divided by 60 months or total number of months of the reasonable useful lifetime of the oxygen equipment.

++ For functions performed by items classified under § 414.229 for cough stimulator, the monthly cost is equal to the purchase price established in § 414.229(c), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

TABLE 40—PROPOSED PAYMENT METHOD FOR MULTI-FUNCTION VENTILATORS

[Example]

Step	Method	HCPCS codes
(1)	Base amount = ventilator monthly rental fee schedule amount	E0465 or E0466.
(2)	Determine monthly rental fee schedule amount for each additional function:	
(a)	(Portable Oxygen Concentrator monthly fee schedule amount × 36 months)/60 months *	E1392 + E1390.
(b)	CY 1993 Nebulizer monthly rental fee schedule amount × covered item update factor for DME to CY 2019 **.	E0570.
(c)	CY 1993 Suction Pump monthly rental fee schedule amount × covered item update factor for DME to CY 2019 **.	E0600.
(d)	(Cough Stimulator newly purchased fee schedule amount)/60 months *	E0482.
(3)	Base amount from Step 1 + lowest cost function amount from Step 2.	
(4)	Base amount from Step 1 + all function amounts from Step 2.	
(5)	Determine Payment for Multi-function ventilator (average of step 3 and 4).	

* 5 year (60 months) reasonable useful lifetime of the equipment.

** The monthly rental amounts paid prior to 1994 included payment for the equipment and all related accessories.

Medicare coverage and payment would be available for multi-function ventilators furnished to beneficiaries who are prescribed a multi-function ventilator and meet the Medicare medical necessity coverage criteria for a ventilator and at least one of the four additional functions of the device. The fee schedule amount for the multi-function ventilator would be determined in advance for each calendar year and would not vary regardless of how many additional functions the beneficiary needs in addition to the ventilator function. We proposed that the payment amount would be established for CY 2019 and then updated each year after 2019 using the covered item update factors mandated by section 1834(a)(14) of the Act. In the event that a patient is furnished a multi-function ventilator and only meets the Medicare medical necessity coverage criteria for a ventilator, Medicare coverage and monthly rental payments would be for the ventilator only, and payment could not be made for the other functions of the device.

We proposed a payment method that we believe ensures an integration of the functions of the multi-function ventilator with a bundled corresponding payment amount that addresses additional functions of the items that are necessary for patient care. If a beneficiary is furnished a multi-function ventilator, payment would be denied for any separate claims for oxygen and oxygen equipment, nebulizers and related accessories, suction pumps and related accessories, and cough stimulators and any related accessories if these separate items are furnished on or after the date that the multi-function ventilator is furnished. Thus, we noted our proposal would prevent division of the multi-function item into separate parts with separate fee schedule amounts for each function of the item, some of which have conflicting payment rules (83 FR 34389). Also, this proposed payment method would lessen confusion for the supplier which could occur if the supplier were to receive varying monthly rental amounts for a multi-function item and instead permits a supplier to receive predictable monthly payments over the 60 month reasonable useful lifetime of the multi-function ventilator.

We note, we did not propose to apply proposed § 414.222(f) to other DME items. Subsequent rulemaking would be necessary to address other multi-function items in the future. For further detailed information, we refer readers to section VIII.C of the CY 2019 ESRD PPS DMEPOS proposed rule.

We received approximately 23 public comments on our proposal from manufacturers, suppliers, beneficiary advocacy groups, and industry representative groups including respiratory associations. The comments on the proposed rule and our responses to the comments are set forth below. We also provide a summary of several comments that were outside the scope of this rulemaking.

Comment: Most commenters supported our proposal to establish a payment methodology for the new technology multi-function ventilator. Commenters support reimbursement for this integrated item that is innovative and improves care for complex beneficiaries and their caregivers in the home and permits improved patient mobility.

Response: We appreciate the support for our proposal. We are finalizing § 414.222(f) to establish a payment method for multi-function ventilators.

Comment: Two commenters recommended that CMS monitor this new payment method to ensure that patients who require all five functions and have a short life expectancy maintain access to the multi-function device. The commenters were concerned that the proposed rule spreads payments for the additional functions performed by the ventilator over 60 months (the reasonable useful lifetime of equipment performing these functions). The commenters explain that certain patients with a life expectancy of 1 or 2 years may require all five therapies, but would not benefit from payment spread over 60 months. The commenters are concerned this shorter life expectancy may not coincide with the payment structure spread over 60 months.

Response: In the CY 2019 ESRD PPS DMEPOS proposed rule, we proposed to

establish a monthly rental fee schedule amount for the equipment that does not cap consistent with the mandated payment rule for ventilators and other items classified under section 1834(a)(3) of the Act. Moreover, the supplier never loses title to the equipment, and the supplier can rent the equipment to other beneficiaries once one beneficiary has rented the item for one or two years. As a result, the supplier can receive payment for each rental month and over the duration that the equipment is medically necessary even in cases when the supplier rents the equipment to a beneficiary with a short term need for the equipment. We believe the ability to re-rent the multi-function ventilator to another beneficiary permits a supplier to furnish the item in instances where a beneficiary might only have a short term need and receive payment for the number of months rented.

Comment: Some commenters did not support our proposal for payment of a multi-function ventilator under a methodology which establishes a fee schedule amount. The commenters recommended the item be paid based on the reasonable charge payment method (42 CFR 405.502). The commenters recommended the item be paid under reasonable charge method as use of the item's functions may change based on the beneficiary's medical needs and the commenters recommend that suppliers should bill additional charges for each function utilized on the multi-function ventilator item.

Response: We appreciate this comment. However, as discussed in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34387), the information we gathered during our review supported our proposal to classify the multi-function ventilator item under the frequent and substantial servicing payment category at section 1834(a)(3) of the Act, which is the statutory payment category for ventilators other than continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices. Also, section 1834(a)(1)(C) of the Act mandates that payment for DME be based on the lesser of the actual charge for the item or the payment amount recognized under sections 1834(a)(2) through 1834(a)(7) of the Act (the fee schedule). In coordination with our review of the item and the statutory payment requirements, we believe a monthly rental fee schedule amount can be established for a multi-function ventilator based on the cost of the ventilator function and the average costs of the various additional functions or features for oxygen concentration, drug nebulization, respiratory airway suction, and cough stimulation. This payment method permits a supplier to receive a predictable monthly payment amount from the start of the rental period for a multi-function ventilator. Also, the item will only be covered for beneficiaries that have a medical need for a ventilator and additional function(s).

Final Rule Action: After consideration of comments received and for the reasons we articulated above and in the CY 2019 ESRD PPS DMEPOS proposed rule, we are finalizing § 414.222(f) similar to our proposal to establish a payment methodology for multi-function ventilators effective for dates of service on or after January 1, 2019. However, we are finalizing three minor technical edits to § 414.222(f) to correct for typos. Specifically, we are deleting the extraneous word ''of'' in two places where it appeared in the proposed regulation text in § 414.222(f)(3)(iii) and (iv) and we are deleting the cross reference to subparagraph ''(g)'' in § 414.226, as it does not apply.

IX. Northern Mariana Islands in Future National Mail Order CBPs

A. Background

In our CY 2015 ESRD PPS DMEPOS final rule (79 FR 66223 through 66265), we said that while section 1847(a)(1)(A) of the Act provides that CBPs be established throughout the U.S., the definition of U.S. at section 210(i) of the Act does not include the Northern Mariana Islands. Therefore, at the time we did not consider the Northern Mariana Islands to be an area eligible for inclusion under a national mail order CBP. We also finalized a fee schedule adjustment methodology based on information from the national mail order program for items and services furnished in the Northern Mariana Islands at § 414.210(g)(7) to provide that the fee schedule amounts for mail order items furnished in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the SPAs established under a national mail order program.

The national mail order program for diabetic testing supplies is currently in effect in all areas of the U.S., except for the Northern Mariana Islands. Thus, the Northern Mariana Islands are currently the only non-CBA for mail order diabetic testing supplies. However, even though the Northern Mariana Islands are currently not included in the national mail order program, per § 414.210(g)(7), CMS currently pays for mail order items furnished in the Northern Mariana Islands at 100 percent of the SPAs established under the national mail order CBP. After further examining this issue, it is now our view that the Northern Mariana Islands are an area eligible for inclusion under a national mail order CBP. A Joint Resolution addressing the Northern Mariana Islands titled ''Covenant to Establish a Commonwealth of the Northern Mariana Islands in Political Union with the United States of America'' was approved in 1976 (Pub. L. 94–241 (HJRes 549), 90 Stat 263, March 24, 1976). The Joint Resolution addresses the applicability of certain federal laws to the Northern Mariana Islands. Article V (''Applicability of Laws''), section 502(a) specifies:

''The following laws of the United States in existence as of the effective date of this Section and subsequent amendments to such laws will apply to the Northern Mariana Islands, except as otherwise noted in this Covenant: (1) Those laws which provide federal services and financial assistance programs and the federal banking laws as they apply to Guam;''

Thus, under the Joint Resolution, laws which provide federal services and financial assistance apply to the Northern Mariana Islands to the same extent as they do to Guam. CMS has recognized the Joint Resolution and taken the position that the Northern Mariana Islands fall within the definition of U.S. under Medicare in 42 CFR 411.9(a). In a proposed rule published on April 25, 2006, in the **Federal Register** titled ''Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates'', we discussed the Joint Resolution and defined the U.S. to include the 50 States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands (71 FR 23996). The Northern Mariana Islands are also included in the definition of U.S. at 42 CFR 400.200. Thus, even though the Northern Mariana Islands are not explicitly referenced in sections 1861(x) and 210(h) and (i) (which notably do reference Guam) of the Act, we believe that we can consider the Northern Mariana Islands to be part of the U.S. for the purposes of the national mail order program as well.

B. Summary of the Proposed Provisions, Public Comments, and Responses to Comments on Including the Northern Mariana Islands in Future National Mail Order CBPs

In the CY 2019 ESRD PPS DMEPOS proposed rule, we proposed to amend § 414.210(g)(7) to say that beginning on or after the date that the Northern

Mariana Islands are included under a national mail order CBP, the fee schedule adjustment methodology under this paragraph would no longer apply (83 FR 34389). Section 414.210(g)(7) currently states that the fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the single payment amounts established under a national mail order competitive bidding program. Once the Northern Mariana Islands are included under a national mail order CBP, this part of § 414.210(g)(7) would be confusing and unnecessary, which is why we proposed to amend § 414.210(g)(7) to say that beginning on or after the date that the Northern Mariana Islands are included under a national mail order CBP, the fee schedule adjustment methodology under this paragraph would no longer apply (83 FR 34389). We are finalizing this amendment to § 414.210(g)(7) because we intend to include the Northern Mariana Islands in the CBA for all competitions under the national mail order CBP beginning on or after January 1, 2019.

We received approximately four public comments on our proposal from suppliers, and industry representative groups; however, none of the suppliers were located in the Northern Mariana Islands. The comments and our responses to those comments are set forth below.

Comment: The commenters recommended that the Northern Mariana Islands not be included in future National Mail Order CBPs, saying that including the Northern Mariana Islands in future National Mail Order CBPs will create access issues due to increased shipping times, and causing what they believed to be an already at-risk population to face an increased risk.

Response: We do not believe that including the Northern Mariana Islands in a future National Mail Order CBP will limit access. On the contrary, we believe it will help ensure access for the beneficiaries in this area. Including the Northern Mariana Islands under the National Mail Order CBP ensures access to mail order diabetic supplies since suppliers awarded contracts under the program must make the supplies available to any beneficiary in the area who requests the items from the supplier. Because there are a limited number of pharmacies in the Northern Mariana Islands, we believe that adding the Northern Mariana Islands to a future National Mail Order CBP will help ensure access for beneficiaries in Northern Mariana Islands who need diabetic testing supplies. We also do not have any evidence to suggest that implementing the National Mail Order CBP in the Northern Mariana Islands will increase shipping times. Beneficiaries will also still be able to obtain their diabetic testing supplies from pharmacy storefronts as well, if they so choose. As with all CBPs, we will continue to monitor the National Mail Order CBP for any access issues, including any negative beneficiary health outcomes.

Final Rule Action: After consideration of comments received and for reasons we set forth previously in this final rule and in the CY 2019 ESRD PPS DMEPOS proposed rule, we are finalizing the proposed revision to § 414.210(g)(7) with a minor technical change to the language to denote that beginning on or after the date that the Northern Mariana Islands are included under a national mail order competitive bidding program, the fee schedule adjustment methodology under § 414.210(g)(7) no longer applies. Thus, beginning on or after the date that the Northern Mariana Islands are included under a National Mail Order CBP, the fee schedule adjustment methodology under § 414.210(g)(7) will no longer apply to mail order items furnished to beneficiaries in the Northern Mariana Islands.

X. Summary of the Request for Information on the Gap-Filling Process for Establishing Fees for New DMEPOS Items

In general, the statute mandates that fee schedule amounts established for DME, prosthetics and orthotics and other items be based on average payments made previously under the reasonable charge payment methodology. The criteria for determining reasonable charges are at 42 CFR 405.502. For example, the exclusive payment rule at sections 1834(a)(2), (3), (8), and (9) of the Act mandates that the fee schedule amounts for DME generally be based on average reasonable charges from 1986 and/or 1987, increased by annual covered item update factors. Since section 1834(a)(1)(C) of the Act mandates that this be the exclusive payment rule for DME, as section 1834(h)(1)(D) of the Act does for prosthetic devices, prosthetics and orthotics, CMS is required to establish fee schedule amounts for these items based on the amounts and levels established under the reasonable charge payment periods set forth in the statute (that is, July 1, 1986 through June 30, 1987, for prosthetic devices, prosthetics and orthotics, therapeutic shoes, and most DME items).

Because there may be DMEPOS items that come on the market that were not paid for by Medicare during the reasonable charge payment periods that the statute mandates be used for establishing the fee schedule amounts for these items, we establish the fee schedule amounts for newly covered items using a ''gap-filling'' process. The gap-filling process allows Medicare to establish fee schedule amounts that align with the statutory basis for the DMEPOS fee schedule. We essentially fill the gap in the data due to the lack of historic reasonable charge payments from 1986 and 1987 by estimating what the historic reasonable charge payments would have been for the items. As described in section 60.3 of chapter 23 of the Medicare Claims Processing Manual (Pub. L. 100–04), CMS gap-fills by using fees for comparable equipment or prices from supplier price lists, such as mail order catalogs. The gap-filling process only applies to items not assigned existing HCPCS codes that are also not items that previously were paid for under a HCPCS code that was either deleted or revised, in other words truly new items or technology as opposed to recoded/reclassified or technologically refined items or technology. This gap-filling process can result in fee schedule amounts that greatly exceed the cost to suppliers of the new technology items (such as when inflated prices from a manufacturer were used as a proxy for supplier price lists under past gap-filling exercises) or do not cover the costs of furnishing the technology if the comparable items used for gap-filling purposes are less expensive than the new item.

We are considering if changes should be made to the gap-filling process for establishing fees for newly covered DMEPOS items paid on a fee schedule basis. We solicited comments for information on how the gap-filling process could be revised in terms of what data sources or methods could be used to estimate historic allowed charges for new technologies in a way that satisfies the exclusive payment rules for DMEPOS items and services, while preventing excessive overpayments or underpayments for new technology items and services.

We received approximately 25 public comments from manufacturers, suppliers, beneficiary advocacy groups, and industry representative groups. The comments received in response to the Request for Information on the Gap-filling Process for Establishing Fees for New DMEPOS Items are set forth below.

Comments: Overall the commenters recommended that CMS increase transparency for stakeholders during the

gap-filling process for establishing fees for new DMEPOS items and revise the process for filling the gap in the data due to the lack of historic reasonable charge payments by estimating what the historic reasonable charge payments would have been for the items from a base year of 1986 and 1987 and inflating to the current year. Many commenters recommended discontinuing the application of past Consumer Price Index (CPI) freezes and reductions when establishing new fee schedule amounts for new HCPCS codes. Some commenters recommended that CMS include in its next budget proposal a provision to amend the statute at 42 U.S.C. 1395 to eliminate or modify the 1987 base year requirement for payment for DMEPOS items and 1992 base year requirement for payment for surgical dressing items. Also, some commenters recommended against CMS including internet or catalog pricing in the gap-filling process unless there is evidence that the price meets all Medicare criterion and includes all Medicare required services. The commenters elaborated that internet and catalog prices do not reflect the costs of the many Medicare supplier requirements such as supplier accreditation, in-the-home assessment, beneficiary training, and documentation, and therefore, do not contribute to a reasonable payment level. Several commenters suggested developing additional guidelines and definitions for determining whether an item is comparable for the purpose of assigning a fee schedule amount to a new item. The commenters elaborated that in order for an item to be comparable to another item, both should have similar features and function, should be intended for the same patient population, for the same clinical indicators, and to fill the same medical need. In addition, some commenters endorsed the addition of a weighting calculation to apply to a median price to factor in the existing market share of the item. The commenters expressed concern that the current gap-filling methodology assumes that all products within a given HCPCS code have equal characteristics, minimum specifications, and the gap-filling method does not account for relative quality, durability, clinical preference, and overall market demand. Thus, the commenters are concerned that the calculation of a gap-fill amount for a new item does not reflect the utilization experience of an existing item. Two commenters recommended that CMS develop an appeals process in situations where the manufacturer or supplier disagrees with the recommendation of a contractor or a final payment decision by CMS and there is data to support the opposition. One commenter recommended that CMS develop a separate gap-filling process for orthotics and prosthetics items. The commenter described that most orthotic and prosthetic care requires a significant, ongoing patient-clinician relationship which is different from the furnishing of DME, which the commenter stated is typically a one-time or short-term encounter between the home health agency or DME supplier. Finally, two commenters stated changes to the HCPCS coding process are required to establish more codes for new technology DMEPOS items before applying the gap-filling process.

We appreciate the range of the comments we received. We will consider these comments carefully as we contemplate future policies. We recognize exploring ways to accommodate new technology, accessibility and affordability are important goals while satisfying the exclusive payment rules for DMEPOS items and services.

XI. DMEPOS CBP Technical Amendments

A. Background

Medicare pays for certain DMEPOS items and services furnished within competitive bidding areas based on the payment rules that are set forth in section 1847 of the Social Security Act (the Act) and 42 CFR part 414, subpart F. We proposed to make two minor technical amendments to correct the existing DMEPOS CBP regulations in 42 CFR 414.422 published in the **Federal Register** on November 6, 2014, titled ''Medicare Program; End–Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Final Rule'' (79 FR 66120) and in § 414.423 in a final rule published in the **Federal Register** on November 29, 2010, titled ''Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Final Rule'' (75 FR 73169).

B. Proposed Technical Amendments

We proposed to make minor technical amendments as follows:

- In § 414.422, we proposed to correct the numbering in paragraph (d)(4), which contains subsections (i) through (vi), but omits (ii) in the numbering sequence. This error was made when the regulation was promulgated. The proposed new numbering in paragraph (d)(4) contains subsections (i) through (v), including (ii). The content of paragraph (d)(4) would remain the same.
- In § 414.423(i)(8), we proposed to remove the reference to ''42 U.S.C.'' before Title 18. This statutory citation was inadvertently included when the regulation was promulgated.

We solicited public comments on these technical amendments. We did not receive any comments, and therefore, we are finalizing as proposed without change. We are finalizing the technical amendments to § 414.422 to correct the numbering so that paragraph (d)(4) contains subsections (i) through (v), including (ii). The content of paragraph (d)(4) would remain the same. We are also finalizing the removal of the reference to ''42 U.S.C.'' in § 414.423.

XII. Burden Reduction on Comorbidities

A. Background

In the CY 2011 ESRD PPS final rule (75 FR 49094), we finalized six comorbidity categories that are eligible for a comorbidity payment adjustment, each with associated International Classification of Diseases (ICD) Clinical Modification diagnosis codes (75 FR 49100). Beginning January 1, 2011, these categories included three acute, short-term diagnostic categories (pericarditis, bacterial pneumonia, and gastrointestinal tract bleeding with hemorrhage) and three chronic diagnostic categories (hereditary hemolytic anemia (including sickle cell anemia), myelodysplastic syndrome, and monoclonal gammopathy).

We stated in the same rule (75 FR 49099) that we would require ESRD facilities to have documentation in the patient's medical/clinical record to support any diagnosis recognized for a payment adjustment, utilizing specific criteria that we issued in sub-regulatory guidance, specifically the Medicare Benefit Policy Manual, Pub. 100–02, Chapter 11, Section 60.A.5 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c11.pdf*). For example, to qualify for the pericarditis comorbidity adjustment, at least two of the four following criteria must be met: Atypical chest pain; pericardial friction rub; suggestive electrocardiogram changes (for example, widespread ST segment elevation with reciprocal ST segment depressions and PR depressions) not previously reported; and new or worsening pericardial effusion. In response to such requirements, stakeholders have suggested it would require additional

testing or procedures to document a comorbidity, which was not our intent. Rather, our assumption was that the patient's diagnosing physician would provide the documentation. In the CY 2011 ESRD PPS final rule (75 FR 49105), we stated that ESRD facilities will obtain diagnostic information through increased communication with their patients, their patient's nephrologists and their patient's families. If there is no documentation in the medical record, the ESRD facility would be unable to claim a comorbidity payment adjustment for that patient, but could seek payment through the outlier mechanism.

In the CY 2012 ESRD PPS final rule (76 FR 70252), we clarified that the ICD–9–CM codes eligible for the comorbidity payment adjustment are subject to the annual ICD–9–CM coding updates that occur in the hospital Inpatient Prospective Payment System final rule and are effective October 1st of each year. We explained that any updates to the ICD–9–CM codes that affect the categories of comorbidities and the diagnoses within the comorbidity categories that are eligible for a comorbidity payment adjustment would be communicated to ESRD facilities through sub-regulatory guidance. We update the list of eligible diagnosis codes on an annual basis and communicate these changes through the CMS.gov website.

In the CY 2016 ESRD PPS final rule (80 FR 68989 through 68990), in consideration of stakeholder concerns about the burden associated with meeting the documentation requirements for bacterial pneumonia, we finalized the elimination of the case-mix payment adjustment for the comorbidity categories of bacterial pneumonia and monoclonal gammopathy beginning in CY 2016.

B. Final Documentation Requirements

In the CY 2018 ESRD PPS proposed rule (82 FR 31224), we published a request for information (RFI) related to improvements to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families, and we invited the public to submit their ideas for regulatory, sub-regulatory, policy, practice, and procedural changes to better accomplish these goals. The aim of the RFI was to request information that would lead to increased quality of care, lower costs, improved program integrity, and to make the health care system more effective, simple and accessible.

As we discussed in the CY 2019 ESRD PPS proposed rule (83 FR 34390), after reviewing the comments received in response to the RFI, we have determined that the documentation requirements associated with the conditions that are eligible for the comorbidity payment adjustment should be revisited. We have heard from stakeholders that they continue to face challenges in obtaining the required documentation in order to report specific diagnosis codes and obtain the comorbidity payment adjustments. Additionally, we have determined that the ESRD PPS documentation requirements are more rigorous than the documentation requirements under other CMS payment systems that generally rely on the ICD Official Guidelines.

In order to reduce burden on ESRD facilities and provide consistent policy across Medicare payment systems, we proposed to reduce the documentation requirements necessary for justification of the comorbidity payment adjustment. Specifically, we would no longer require that ESRD facilities obtain results from specific diagnostic tests in order to qualify for a comorbidity payment adjustment. Instead, we proposed to rely on the guidelines established by the Official ICD Guidelines for Coding and Reporting. This proposal did not preclude the requirement for ESRD facilities to maintain clear documentation in the beneficiary's medical record used to justify the reporting of diagnosis codes, which is also necessary for adherence to ICD Guidelines. Documentation required to meet ICD guidelines continues to be required for purposes of the adjustment.

We solicited comment on this proposal. The comments and our responses to the comments on the comorbidity documentation burden reduction proposal are set forth below.

Comment: A national dialysis organization thanked CMS for acknowledging its concerns regarding comorbidity documentation, but indicated the use of ICD Official Guidelines will not sufficiently address this problem. The organization stated the proposed rule is silent on what documentation will be required to support the reporting of comorbid condition ICD–10 codes and pointed out the dialysis facilities do not diagnose patients with these conditions, which means they will continue to have to rely upon documentation from other providers to support the claim. An LDO stated that the use of the ICD Official Guidelines will have no material effect on the root problem dialysis facilities encounter in receiving payments under the comorbidity adjustment.

A dialysis provider organization stated the use of ICD–10 codes to document comorbidities is an improvement over the current documentation requirements, since both pericarditis and hemolytic anemia (including sickle cell anemia) are more likely to be captured as a routine matter by ESRD providers than the current requirements. However, the commenter pointed out gastrointestinal tract bleeding with hemorrhage is not a diagnosis for which a dialysis clinic has ready access to the necessary documentation and when a hospital admission is involved, gathering the required supporting documentation such as from a colonoscopy or endoscopy, can be difficult, if not impossible. The commenter questioned whether these comorbidities are appropriate to begin with from both clinical, as well as cost vantage points. The commenter stated that from a clinical vantage point, cardiovascular disease, which is not among the current comorbidities is a, if not the, leading cause of death in the ESRD population. The commenter stated the ESRD PPS outlier policy can help address disproportionate costs associated with comorbidities and, since the Secretary has discretion as to what may be included in the case mix adjustment, CMS should consider suspending use of comorbidities.

An LDO expressed appreciation for the proposal to no longer require ESRD facilities obtain results from specific diagnostic tests in order to qualify for a comorbidity payment adjustment and to rely on the guidelines established by the Official ICD Guidelines for Coding and Reporting. The LDO stated CMS's assumption that the patient's diagnosing physician would provide the documentation is not accurate. In the majority of the cases, the LDO asserted, coding for the comorbidities is performed by hospital system professional coders at the time of a hospital discharge by reading though a patient's chart. In most cases the treating physicians are hospitalists, and they are unfamiliar with ESRD policies about comorbidities and payment. Furthermore, the LDO sees no reason to obtain more results to get to the granularity of the ICD–10 code currently required to support ESRD comorbidity reporting, because the LDO believes that in many or most cases, this diagnostic information will not change the treatment course.

Response: We appreciate the feedback from commenters on our proposal to rely on ICD Official Guidelines. We continue to believe it is important for ESRD facilities to be aware of patients'

conditions. The CfCs for ESRD facilities at § 494.80(a)(1) indicates a patient's comprehensive assessment must include evaluation of current health status and medical condition, including co-morbid conditions. For the purpose of receiving a payment adjustment, the appropriate ICD–10–CM codes are required to be present on the claim with the appropriate documentation as required by ICD official guidelines in the patient's medical record.

We also continue to believe obtaining the medical documentation necessary to receive payments should not be complicated or burdensome, and is important for care coordination purposes. In situations where the patient's medical record is incomplete and the ESRD facility is unable to obtain the documentation needed to report the comorbidity diagnosis, we would expect the facility to include the cost for all outlier-eligible services on the claim and qualify for an outlier payment when the cost exceeds the outlier fixed dollar loss threshold. This approach supports access to dialysis for high cost patients. We will continue to monitor the extent to which the comorbidities are reported.

Comment: Several commenters expressed concern regarding the availability of the documentation needed to support the reporting of the diagnosis code describing the comorbidity eligible for the adjustment and provided suggestions on how to streamline the process.

Some commenters indicated that the documentation is rarely, if ever, available because CMS does not require the other providers to disclose the information to dialysis facilities. An LDO stated that that despite its best attempts in following up with other providers, the organization has encountered challenges in receiving discharge instructions/summaries, pending laboratory results, and other relevant information on their patients. The LDO asserted that to ensure effective care delivery, patient safety, and the application of a revised, valid and reliable comorbidity adjuster, CMS should require hospitals, particularly those using certified health information technology, to send the following information to other providers involved in an ESRD patient's care: (1) Discharge instructions and discharge summary within 48 hours; (2) pending test results within 72 hours of their availability; and (3) all other necessary information specified in the ''transfer to another facility'' requirements.

One health plan encouraged CMS to reduce documentation burden by automatically incorporating diagnosis codes from all claims (that is, hospital and physician claims in addition to ESRD claims) when determining if a comorbidity adjustment applies. The health plan explained that ESRD facilities struggle to obtain documentation from other providers in order to include the diagnosis on the ESRD claim, even when the ESRD facility has a common electronic health record with the hospital and physician practice. The health plan noted that because the diagnosis coding does not automatically transfer to the ESRD medical record the hospital medical record has to be thoroughly reviewed to determine the appropriate diagnosis codes to enter on the ESRD claim. The health plan believes automation within CMS's system would create a more seamless and accurate application of the comorbidity adjustment.

One dialysis provider organization requested that CMS use claims data in addition to the ICD Guidelines for Coding and Reporting to identify comorbidities present in patients eligible for payment adjustments. The organization believes the supplementing of ICD coding information with claims data will ensure more accurate payment to providers, as well as further ease administrative burden. As part of this effort, the organization would welcome the opportunity to work with CMS to help educate dialysis providers on how to code patient comorbidities on their claims.

Response: We appreciate the requests for interoperability with other care settings either through electronic health records or claims data and agree that it could reduce the burden related to comorbidity documentation. We will consider these for future updates and will coordinate with other federal partners, as feasible.

Comment: MedPAC commented CMS should consider removing all comorbidity payment adjustments used in the current ESRD PPS because these adjustment factors may not be estimated accurately. A MedPAC analysis showed the comorbid conditions are poorly identified on dialysis claims and reflect only differences in the cost of dialysis services formerly separately billable. MedPAC further stated that to the extent unreported comorbid conditions increase the cost of treatment above the ESRD PPS base rate, those costs are currently borne by the facility and the outlier payment pool.

An LDO stated CMS's proposal to have facilities document different criteria does not change the fundamental challenge with claiming case mix adjusters. The LDO recommended CMS follow the long-standing recommendations of the kidney community and MedPAC and eliminate the comorbid case mix adjusters from the ESRD PPS in the CY 2019 ESRD PPS final rule.

A national dialysis organization, in its comment on the outlier expansion solicitation, recommended CMS address the comorbidity documentation burden by relying upon the outlier payments for the higher costs it assumes are addressed through the comorbid case-mix adjusters. The organization expressed concern that these adjusters do not actually reflect higher cost patients and that money is being taken out of the system that is never returned to support patient care. Additionally, the organization stated outlier payments would be sufficient to address the higher costs related to patients with these conditions. Instead, the organization recommended that CMS eliminate the comorbid case-mix adjusters for CY 2019 and recognize any patient with one of the remaining conditions would use more of the drugs currently eligible for the outlier payment.

A national provider organization also urged CMS to eliminate comorbidity adjustments from the payment system until CMS develops appropriate adjusters that accurately capture variance in costs of care for particularly high-cost, high-acuity patients. The organization agrees with CMS that the cost of dialysis treatment varies depending on the volume of services provided at the facility, its location and the adult and pediatric patients it serves, and thus appreciates appropriate adjustments in the payment system that account for these differences in cost of care. However, the organization stated the existing comorbidity adjustments in the ESRD PPS do not correspond well with the significant variance in costs facilities experience in treating patients with certain particularly complex and costly comorbidities and other acute illness or trauma events. As a result, the organization believes the current comorbidity adjustments inappropriately take away funding from the ESRD base rate that otherwise could support provision of high-quality care. An LDO recommended removing the remaining comorbid adjustors; and if not removed, they should be adjusted. Another LDO advised CMS to add more generic codes to the list including:

K29.51 Unspecified chronic gastritis with bleeding
K29.61 Other gastritis with bleeding
K29.71 Gastritis, unspecified, with bleeding
K29.91 Gastroduodenitis, unspecified, with bleeding

K92.2 Gastrointestinal hemorrhage, unspecified

A professional association expressed concern that, without a clear, simple process to obtain detailed comorbid condition data and the ability to document these data for submission to CMS, comorbid conditions impacting the ESRD PPS bundled payment will continue to be insufficiently documented. Consequentially, funds set aside for care of dialysis patients will not be expended. The association expressed that it is inappropriate to have funds set aside to improve care for the most complex patients remain unused due to a documentation hurdle, ultimately missing an opportunity to improve the lives of dialysis patients.

Response: We acknowledge that some commenters would prefer comorbidity adjusters be removed from the payment system with the dollars returned to the base rate and allow more expensive care for certain patients be addressed through the outlier policy. As we discussed in the CY 2016 ESRD PPS final rule (80 FR 68981 through 68982), the comorbidity adjusters have economically meaningful multipliers so we will continue to include them in the payment system. We will, however, consider this feedback.

With regard to the commenter's suggestion on adding more generic diagnosis codes to the list of comorbidities eligible for the payment adjustment, we would like to refer the commenter to the CY 2011 ESRD PPS final rule (75 FR 49095) where we discuss the exclusion criteria used when determining the eligible diagnosis codes. Specifically, we explained that based on various issues and concerns raised in public comments regarding the proposed co-morbidity categories recognized for a payment adjustment, we further evaluated the co-morbidity categories with regard to: (1) Inability to create accurate clinical definitions; (2) potential for adverse incentives regarding care; and (3) potential for ESRD facilities to directly influence the prevalence of the co-morbidity either by altering dialysis care, diagnostic testing patterns, or liberalizing the diagnostic criteria. We believe that unspecified codes would meet the first criteria since the code would not provide an accurate description of the active condition. Additionally, in that rule (75 FR 49108), we finalized eliminating diagnostic codes identified in Table 16 of the CY 2011 ESRD PPS proposed rule (74 FR 49956) described as unspecified, not otherwise specified, or not elsewhere specified, since these codes are general and do not provide meaningful identification of a disease. With this information in mind, we believe the diagnosis codes suggested by the commenter would meet the exclusion criteria and would exclude them from being eligible for a payment adjustment.

We remain concerned eliminating the comorbidity categories may result in access to care issues. We continue to believe the payment model aligns with our goals for the PPS in establishing accurate payments and safeguarding access for Medicare beneficiaries. We plan to continue to monitor the reporting of diagnosis codes and are conducting research on potential future refinements. Additionally, we are undertaking a new research effort and plan to engage with stakeholders further on this issue

Final Rule Action: After considering the public comments, we are finalizing the proposal to rely on ICD Official Guidelines and general documentation requirements to receive the comorbidity payment adjustment without change.

XIII. Requests for Information

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

In the CY 2019 ESRD PPS proposed rule (83 FR 34304 through 34415), we included a Request for Information (RFI) related to promoting interoperability and electronic health care information exchange. We received approximately 9 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Provider and Supplier Charge Information

In the CY 2019 ESRD PPS proposed rule (83 FR 34304 through 34415), we included a Request for Information (RFI) related to price transparency and improving beneficiary access to provider and supplier charge information. We received approximately 8 timely pieces of correspondence on this RFI. We appreciate the input provided by commenters.

XIV. Collection of Information Requirements

A. Legislative Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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. We solicited comments in the notice of proposed rulemaking that published in the **Federal Register** on July 19, 2018 (83 FR 34304 through 34415). For the purpose of transparency, we are republishing the discussion of the information collection requirements. All of the requirements discussed in this section are already accounted for in OMB approved information collection requests.

B. Requirements in Regulation Text

In sections II.B.1 and II.B.2.b of this final rule, we are finalizing changes to regulatory text for the ESRD PPS in CY 2019. We are also finalizing changes to regulatory text for the ESRD QIP in section IV.A.3 of this final rule. However, the changes that are being finalized do not impose any new information collection requirements.

C. Additional Information Collection Requirements

This final rule does not impose any new information collection requirements in the regulation text, as specified above. However, this final rule does make reference to several associated information collections that are not discussed in the regulation text contained in this document. The following is a discussion of these information collections.

1. ESRD QIP—Wage Estimates

To derive wage estimates, we used data from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates. In the CY 2016 ESRD PPS final rule (80 FR 69069), we stated that it was reasonable to assume that Medical Records and Health Information Technicians, who are responsible for organizing and managing health information data,[29] are the individuals tasked with submitting measure data to CROWNWeb and NHSN, as well as compiling and submitting patient records for purposes of the data validation studies rather than a Registered Nurse, whose duties are centered on providing and coordinating care for patients.[30] The mean hourly wage of a Medical Records and Health Information Technician is $20.59 per hour. Fringe benefit and overhead are calculated at 100 percent. Therefore, using these assumptions, we estimate an

[29] *https://www.bls.gov.oes/current/oes292071.htm.*

[30] *https://www.bls.gov.oes/current/oes291141.htm.*

hourly labor cost of $41.18 as the basis of the wage estimates for all collection of information calculations in the ESRD QIP. We have adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. These are necessarily rough adjustments, both because fringe benefits and overhead costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that these are reasonable estimation methods.

We used these updated wage estimates along with updated facility counts and patient counts to re-estimate the total information collection burden under the ESRD QIP. We estimate the total information collection burden for the PY 2021 ESRD QIP to be $181 million, and for PY 2022, to be $202 million for a net incremental burden of $21 million.

a. Estimated Time Required To Submit Data Based on Reporting Requirements

In the CY 2016 ESRD PPS final rule (80 FR 69070), we estimated that the time required to submit measure data using CROWNWeb is 2.5 minutes per data element submitted, which takes into account the small percentage of data that is manually reported, as well as the human interventions required to modify batch submission files to ensure that they meet CROWNWeb's internal data format requirements.

b. Estimated Burden Associated With the Data Validation Requirements for PY 2021 and PY 2022

Section IV.B.6 of this final rule outlines the new data validation policies that we are finalizing for the ESRD QIP. Specifically, for the CROWNWeb validation, we are finalizing a policy to adopt the CROWNWeb data validation methodology that we previously adopted for the PY 2016 ESRD QIP as the methodology we will use to validate CROWNWeb data for all payment years, beginning with PY 2021. Under this methodology, 300 facilities will be selected each year to submit to CMS not more than 10 records, and we will reimburse these facilities for the costs associated with copying and mailing the requested records. The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it will take each facility approximately 2.5 hours to comply with this requirement. If 300 facilities are asked to submit records, we estimate that the total combined annual burden for these facilities will be 750 hours (300 facilities × 2.5 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff will submit these data, we estimate that the aggregate cost of the CROWNWeb data validation each year will be approximately $30,885 (750 hours × $41.18), or an annual total of approximately $103 ($30,885/300 facilities) per facility in the sample. The burden associated with these requirements is captured in an information collection request (OMB control number 0938–1289).

Under the continued study for validating data reported to the NHSN Dialysis Event Module, we are finalizing a modification of the sampling methodology that we previously finalized in the CY 2018 ESRD PPS final rule (82 FR 50766 through 50767). Under the finalized modifications, we will select 150 facilities for participation in the PY 2021 validation study and 300 facilities for participation in the PY 2022 validation study. A CMS contractor will send these facilities requests for 20 patient records for each of 2 quarters of data reported in CY 2018 (for a total of 40 patient records per facility). The burden associated with these validation requirements is the time and effort necessary to submit the requested records to a CMS contractor. We estimate that it will take each facility approximately 10 hours to comply with this requirement. We also estimate that in PY 2021, the total combined annual burden for the 150 facilities asked to submit records will be 1,500 hours (150 facilities × 10 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff will submit these data, we estimate that the aggregate cost of the NHSN data validation in PY 2021 will be $61,770 (1,500 hours × $41.18), or a total of approximately $412 ($61,770/150 facilities) per facility in the sample in PY 2021. We finalized a policy to ask 300 facilities to submit records for PY 2022, and we estimate that the total combined annual burden for these facilities will be 3,000 hours (300 facilities × 10 hours). Since we anticipate that Medical Records and Health Information Technicians or similar administrative staff will submit these data, we estimate that the aggregate cost of the NHSN data validation in PY 2022 would be $123,540 (3,000 hours × $41.18), or a total of approximately $412 ($123,540/300 facilities) per facility in the sample for PY 2022. The information collection request (OMB control number 0938–1340) will be revised and sent to OMB for approval.

2. New CROWNWeb Reporting Requirements for PY 2021 and PY 2022

To determine the burden associated with the new collection of information requirements, we look at the total number of patients nationally, the number of data elements per patient-year that the facility will be required to submit to CROWNWeb for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into CROWNWeb, and the number of facilities submitting data to CROWNWeb. In section IV.B.1.c of this final rule, we are finalizing a policy to modify our data collection requirements for PY 2021 by removing four reporting measures from the ESRD QIP measure set. These changes will result in a burden collection savings of approximately $12 million for PY 2021 (from an estimated $193 million in total ESRD QIP burden for PY 2021 to an estimated $181 million). Approximately $2 million of that reduction is attributable to the removal of the Pain Assessment and Follow-Up reporting measure and the remaining $10 million of that reduction is attributable to the removal of the Serum Phosphorus reporting measure. The total reduction in burden hours is approximately 300,000 hours (from an estimated 4.7 million burden hours for PY 2021 to an estimated 4.4 million burden hours). Approximately 40,000 hours of that reduction is attributable to the removal of the Pain Assessment and Follow-Up reporting measure and the remaining 260,000 hours of that reduction is attributable to the removal of the Serum Phosphorus reporting measure. The removal of the other two reporting measures (Healthcare Personnel Influenza Vaccination and Anemia Management) will not affect our burden calculations because data on those measures are not reported through CROWNWeb.

In section IV.C.1 of this final rule, we are finalizing policies to adopt two new measures beginning with PY 2022. We estimate that the burden associated with this new data collection requirement will be approximately $21 million, or an estimated 510,000 burden hours, and that this burden will be attributable entirely to the reporting of data on the proposed MedRec measure. Since facilities are not required to submit data

to CROWNWeb for the PPPW measure, we estimate that there will be no additional burden on facilities related to the PPPW measure. We estimate that the total burden increase associated with reporting data on the two new measures finalized for PY 2022 is $21 million. The information collection request under OMB control number 0938–1289 will be revised and sent to OMB.

In section IV.D.1 of the CY 2019 ESRD PPS proposed rule, we proposed to adopt one new measure beginning in PY 2024. We estimated that the burden associated with the proposed measure will be zero. Since facilities would not have been required to submit data to CROWNWeb for the SWR measure, we estimated that there would be no burden in connection with this measure in PY 2024. We are not finalizing this proposal.

3. DMEPOS Competitive Bidding Program

a. Bidding Forms A and B

Section V.D.1 of this final rule outlines our changes to the DMEPOS CBP. DMEPOS suppliers submit bids in order to compete to become a contract supplier to furnish competitively bid items to Medicare beneficiaries who live in a CBA. CMS publishes Request for Bids instructions to describe DMEPOS CBP requirements and to instruct bidders through the bid submission process. Bids are submitted electronically via the DMEPOS Bidding System (DBidS), which is the DMEPOS CBP online bidding system. The bids submitted before the close of the bid window are evaluated to determine which bidders will be offered contracts. Form A collects key business information to identify a bidder, the areas and products where the bidder chooses to bid, and pertinent information to indicate whether the bidder meets all eligibility requirements. A thorough analysis is performed of all information submitted to determine that the bidder has met all requirements, including licensure, financial, and quality standards. Form B contains key bid information including the bid amount for each item, historical experience providing each item, and specific manufacturer and model information for each item. The manufacturer and model information is utilized to populate the Medicare Supplier Directory during the contract period for bidders that are awarded a contract. CMS utilizes the combined information from Forms A and B to select winning bidders and establish single payment amounts for competitively bid items and services. The previously approved information collection request is under OMB control number 0938–1016.

All bidders must submit their information and signature(s) electronically into Forms A and B using DBidS. This system allows bidders to efficiently and consistently provide the necessary information contained on Forms A and B for CMS to review. Bidders are allowed to make changes to their bids at any time prior to the close of the bid window, at which time bidders are required to complete, approve, and certify their bids. The Competitive Bidding Implementation Contractor (CBIC) will use the appropriate technology to obtain and secure the bidding information that is transmitted. Assistance and technical support is available to bidders throughout the competitive bidding process. Bidders will be required to submit supporting documentation, such as required financial documents, proof of a bid surety bond(s), and any network agreement(s) to the CBIC.

b. Burden Estimates (Hours and Wages) for Bidding Forms A and B

Form A is used to identify the bidder. This form includes information for all locations that would be included with the bid(s). In preparation for the next round of bidding, CMS has incorporated an update to this form that would also provide new instructions in accordance with § 414.412(h), allowing the bidder to attest that they have obtained a bid surety bond for each CBA for which they are submitting a bid.

We have estimated the time to obtain a bid surety bond from a surety company (including contacting the company, filling out forms, submitting forms, filing paperwork, etc.) to be 11 minutes. Additionally, we estimated that the time to assemble and complete the new bid surety bond section of Form A to be 5 minutes. The time to submit the bid surety bond documentation is estimated to take an additional 5 minutes. Therefore, the total time to complete Form A has changed from 8 hours to 8 hours and 21 minutes. Based on the number of bidders from prior rounds of competition, we estimated the number of respondents (bidders) to be 1,500 for the next round. Each bidder would be required to complete one Form A for each round in which it bids. We anticipated that this form would be completed by the equivalent of an Administrative Services Manager with a mean hourly wage of $49.70, plus fringe benefits and overhead of $49.70, for a total of $99.40. This wage is based on the May 2017 Occupational Employment Statistics from the Bureau of Labor Statistics, plus fringe benefits and overhead, *https://www.bls.gov/oes/current/oes113011.htm.* It is anticipated that an Administrative Services Manager would have the requisite knowledge, access to information, and decision making authority related to a bidder's business operations necessary to formulate a bid. We sought comments on this assumption and we did not receive any comments. We estimated, based on information from previous rounds of competition, the burden for each bidder to complete Form A is 8 hours and 21 minutes, and $829.99 ($99.40 × 8 hours and 21 minutes). This estimate is based on the time it takes a bidder to develop their business strategy on which CBAs and product categories to bid; obtain their bid surety bond(s); gather the required documents; and enter and review their information.

We do not know the exact number of bidders who would bid in the next round; however, for purposes of this estimate, we assumed that the number of bidders would be roughly the same as in previous rounds of competition. We estimated there would be approximately 1,500 bidders in the next round and each bidder would complete Form A once for a total of 12,525 hours and a total cost of $1,244,985.

Bidders will use Form B to submit bids for items included in the DMEPOS CBP. This form would be completed once for each CBA and product category combination with an estimated completion time of 3 hours. Total completion time assumes the time it takes a bidder to familiarize itself on how to complete Form B, develop its bid amount and enter the applicable information into Form B. For the next round, we do not know how many bids will be submitted; however, for purposes of this estimate, we assumed the average bidder would bid in 5 CBAs in 7 product categories for an average total of 35 Form Bs. We expected the number of hours to complete Form B to decrease from previous rounds based on the removal of the expansion plan section, as well as the change in bidding methodology to move to lead item pricing as described in section V.D.1 of this final rule. Specifically, the expansion plan section is being removed from Form B to reduce the burden for bidders as we have learned from past rounds that this information is no longer necessary. The change in bidding methodology to move to lead item pricing would require bidders to only submit a single bid for an entire product category, instead of multiple bids (which can be over 100 for some product categories). We anticipated that this form would be completed by the

equivalent of an Administrative Services Manager with a mean hourly wage of $49.70, plus fringe benefits and overhead of $49.70, for a total of $99.40. It is anticipated that an Administrative Services Manager would have the requisite knowledge, access to information, and decision making authority related to a bidder's business operations necessary to formulate the bid. As a result, we estimated it would require the average bidder 105 hours to complete all 35 Form Bs with a cost of $10,437 ($99.40 × 105 hours). Assuming 1,500 bidders participate in the next round of the DMEPOS CBP, and each bidder completes 35 Form Bs, there would be an estimated 52,500 Form Bs submitted taking an estimated 157,500 hours for a total estimated cost of $15,655,500 ($99.40 × 157,500 hours).

The information collection request associated with the DMEPOS CBP will be revised and submitted to OMB under control number 0938–1016. The requirement to use Forms A and B when bidding in the next round of the DMEPOS CBP will not be effective until the two forms are approved by OMB.

XV. Economic Analyses

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a regulatory impact analysis that to the best of our ability presents the costs and benefits of the rulemaking. We solicited comments on the regulatory impact analysis provided, and we received 1 comment, which we discuss in section XVI of this final rule.

2. Statement of Need

a. ESRD PPS

This rule finalizes a number of routine updates and several policy changes to the ESRD PPS in CY 2019. The finalized routine updates include the CY 2019 wage index values, the wage index budget-neutrality adjustment factor, and outlier payment threshold amounts. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2019 for renal dialysis services furnished to ESRD beneficiaries.

b. AKI

This rule also finalizes routine updates to the payment for renal dialysis services furnished by ESRD facilities to individuals with AKI. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2019 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

c. ESRD QIP

This rule finalized policies to implement requirements for the ESRD QIP, including the adoption of two new measures beginning with PY 2022. Failure to finalize requirements for the PY 2022 ESRD QIP would prevent continuation of the ESRD QIP beyond PY 2021. In addition, finalizing requirements for the PY 2022 ESRD QIP provides facilities with more time to review and fully understand new measures before their implementation in the ESRD QIP.

d. DMEPOS

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

The final revisions include implementation of lead item pricing and determination of SPAs based on maximum winning bids submitted for a lead item in each product category. This rule also finalizes revisions to the definitions of ''bid'' and ''composite bid'' and establishes a new definition for ''lead item.''

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

We are finalizing transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019, in areas that are currently CBAs and in areas that are currently not CBAs. Altogether, we are finalizing three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous U.S.; and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

The estimated impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are made consistent with the rules in place as of January 1, 2018.

The impacts are expected to cost $1.05 billion in Medicare benefit payments and $260 million in Medicare beneficiary cost sharing for the 2-year period beginning January 1, 2019, and ending December 31, 2020. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be $45 million and $30 million, respectively.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

This final rule amends our regulations at § 414.226 by revising the payment rules for oxygen and oxygen equipment and adding a new paragraph that establishes some new oxygen and oxygen equipment payment classes effective January 1, 2019. Instead of having one class for portable oxygen equipment only (gaseous and liquid tanks), we are establishing two classes for portable oxygen equipment: (1) One class for gaseous tanks, and (2) another class for liquid tanks. We are also finalizing an additional class for liquid oxygen contents for prescribed flow rates greater than 4 liters per minute and used with portable equipment. We are also finalizing a new budget neutrality offset to ensure the budget neutrality of all oxygen and oxygen equipment classes added after 2006.

iv. Payment for Multi-Function Ventilators

We are finalizing a payment rule in § 414.222(f) for multi-function ventilators that establishes payment in accordance with section 1834(a)(3) of the Act for ventilators that also perform the functions of other items of durable medical equipment subject to payment rules under paragraphs (2), (5), and (7) of section 1834(a) of the Act.

v. Northern Mariana Islands in Future National Mail Order CBPs

We are finalizing an amendment to § 414.210(g)(7) to say that beginning on or after the date that the Northern Mariana Islands are included under a national mail order competitive bidding program, the fee schedule adjustment methodology under this paragraph no longer applies.

3. Overall Impact

a. ESRD PPS

We estimate that the finalized revisions to the ESRD PPS will result in an increase of approximately $210 million in payments to ESRD facilities in CY 2019, which includes the amount associated with updates to the outlier thresholds, and updates to the wage index. These payments represent transfers from the Federal Government to ESRD providers ($160 million) and transfers from the beneficiaries to ESRD providers ($50 million).

b. AKI

We are estimating approximately $40 million will be paid to ESRD facilities for dialysis treatments provided to AKI beneficiaries.

c. ESRD QIP

For PY 2021, we have re-estimated the costs associated with information collection requirements under the Program for this final rule with updated wage estimates, facility counts, and patient counts, as well as the policy changes described earlier in the preamble of this final rule, including the measure removals and measure weighting changes. We also re-estimated the payment reductions under the ESRD QIP in accordance with the policy changes described earlier, including the domain restructuring and reweighting. We estimate that these updates will result in an overall impact of $213 million associated with quality reporting burden and payment reductions, which includes a $12 million incremental reduction in burden in collection of information requirements and $32 million in estimated payment reductions across all facilities. PY 2021 ESRD QIP payment reductions represent transfers from the federal government to ESRD providers of −$32 million, and total ESRD provider costs under the ESRD QIP for PY 2021 total $181 million.

For PY 2022, we estimate that the proposed revisions to the ESRD QIP will result in an increase in overall impact to $234 million, which includes a $21 million incremental increase associated with the collection of information requirements and $32 million in estimated payment reductions across all facilities. PY 2022 ESRD QIP payment reductions represent transfers from the federal government to ESRD providers of −$32 million, and total ESRD provider costs under the ESRD QIP for PY 2022 total $202 million.

d. DMEPOS

Impacts are generally considered against the Medicare, Medicaid and beneficiary cost sharing. A special consideration of impacts is made in Table 50 wherein impacts are considered as transfer amounts based on annualized value against two different interest rates.

i. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

We estimate that the finalized revisions to base SPAs on the maximum winning bid and to implement lead item pricing in the Medicare DMEPOS CBP, (which we expect could potentially be delayed until January 1, 2021) will cost about $10 million in Medicare benefit payments and roughly $3 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019, and ending September 30, 2023. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be $0 million.

ii. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

We are finalizing transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019, in areas that are currently CBAs and in areas that are currently not CBAs. Altogether, we are finalizing three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous U.S.; and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

The estimated impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are made consistent with the rules in place as of January 1, 2018.

The impacts are expected to cost $1.05 billion in Medicare benefit payments and $260 million in Medicare beneficiary cost sharing for the 2-year period beginning January 1, 2019, and ending December 31, 2020. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be $45 million and $30 million, respectively.

iii. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

This rule finalizes new payment classes for oxygen and oxygen equipment and is estimated to be budget neutral to the Medicare program. However, the new payment classes may result in overall slightly increased beneficiary cost-sharing.

iv. Payment for Multi-Function Ventilators

This final rule establishes payment rules for multi-function ventilators. The impacts are estimated by rounding to the nearer 5 million dollars and are expected to cost $15 million in Medicare benefit payments and $3 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019, and ending September 30, 2023. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to both be $0 million.

v. Northern Mariana Islands in Future National Mail Order CBPs

This change will not have a fiscal impact.

4. Regulatory Review Cost Estimation

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 final rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this 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 final rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcomed comments on the approach in estimating the number of entities which will review this final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption. We did not receive any comments on this section of the rule.

Using the wage information from the BLS (*https://www.bls.gov/oes/2017/may/naics4_621100.htm*) for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $110.00 per hour, including overhead and fringe benefits. Assuming an average reading speed, we estimate that it would take approximately 6.25 hours for the staff to review half of this final rule. For each ESRD facility that reviews the rule, the estimated cost is $687.50 (6.25 hours × $110.00). Therefore, we estimate that the total cost of reviewing this regulation rounds to $39,875. ($687.50 × 58 reviewers).

For DME suppliers, we calculate a different cost of reviewing this rule. Assuming an average reading speed, we estimate that it would take approximately 2 hours for the staff to review this final rule. For each entity that reviews this final rule, the estimated cost is $220.00 (2 hours × $110.00). Therefore, we estimate that the total cost of reviewing this final rule is $143,000 ($220.00 × 650 reviewers).

B. Detailed Economic Analysis

1. CY 2019 End-Stage Renal Disease Prospective Payment System

a. Effects on ESRD Facilities

To understand the impact of the changes affecting payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2018 to estimated payments in CY 2019. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of payments in CY 2018 and CY 2019 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used CY 2017 data from the Part A and Part B Common Working Files, as of August 3, 2018, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2017 claims to 2018 and 2019 using various updates. The updates to the ESRD PPS base rate are described in section II.B.3 of this final rule. Table 41 shows the impact of the estimated CY 2019 ESRD payments compared to estimated payments to ESRD facilities in CY 2018.

TABLE 41—IMPACT OF FINALIZED CHANGES IN PAYMENT TO ESRD FACILITIES FOR CY 2019 [1]

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2019 changes in outlier policy (%)	Effect of 2019 changes in wage index, wage floor, and labor-related share (%)	Effect of 2019 changes in payment rate update (%)	Effect of total 2019 final changes (%)
	A	B	C	D	E	F
All Facilities	7,099	45.1	0.3	0.0	1.3	1.6
Type:						
Freestanding	6,681	43.0	0.3	0.0	1.3	1.6
Hospital based	418	2.2	0.6	−0.1	1.3	1.7
Ownership Type:						
Large dialysis organization	5,400	34.9	0.3	−0.1	1.3	1.6
Regional chain	881	5.7	0.4	0.1	1.3	1.9
Independent	485	2.9	0.4	0.2	1.3	1.9
Hospital based [2]	327	1.7	0.6	−0.1	1.3	1.8
Unknown	6	0.0	0.2	0.4	1.2	1.8
Geographic Location:						
Rural	1,271	6.5	0.3	−0.3	1.3	1.3
Urban	5,828	38.6	0.3	0.1	1.3	1.7
Census Region:						

TABLE 41—IMPACT OF FINALIZED CHANGES IN PAYMENT TO ESRD FACILITIES FOR CY 2019 [1]—Continued

Facility type	Number of facilities	Number of treatments (in millions)	Effect of 2019 changes in outlier policy (%)	Effect of 2019 changes in wage index, wage floor, and labor-related share (%)	Effect of 2019 changes in payment rate update (%)	Effect of total 2019 final changes (%)
	A	B	C	D	E	F
East North Central	1,145	6.3	0.3	−0.4	1.3	1.3
East South Central	572	3.3	0.3	−0.7	1.3	1.0
Middle Atlantic	777	5.5	0.4	0.1	1.3	1.7
Mountain	400	2.3	0.2	−0.4	1.3	1.1
New England	191	1.5	0.3	−0.4	1.3	1.2
Pacific [3]	845	6.5	0.3	1.1	1.3	2.7
Puerto Rico and Virgin Islands	51	0.3	0.1	4.5	1.3	6.0
South Atlantic	1,622	10.6	0.4	−0.3	1.3	1.4
West North Central	497	2.3	0.4	−0.3	1.3	1.3
West South Central	999	6.6	0.3	0.0	1.3	1.6
Facility Size:						
Less than 4,000 treatments	1,246	2.1	0.3	−0.2	1.3	1.5
4,000 to 9,999 treatments	2,666	11.9	0.4	−0.2	1.3	1.5
10,000 or more treatments	3,147	31.0	0.3	0.1	1.3	1.7
Unknown	40	0.2	0.6	0.3	1.3	2.2
Percentage of Pediatric Patients:						
Less than 2	6,993	44.8	0.3	0.0	1.3	1.6
Between 2 and 19	41	0.3	0.4	0.1	1.3	1.8
Between 20 and 49	11	0.0	0.1	−0.2	1.3	1.2
More than 50	54	0.0	−0.1	0.1	1.3	1.4

[1] Calcimimetics will be paid under the transitional drug add-on payment adjustment for CY 2019. In CY 2016 there was approximately $840 million in spending for Sensipar under Part D.
[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.
Note: Totals do not necessarily equal the sum of rounded parts, as percentages are multiplicative, not additive.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final changes to the outlier payment policy described in section II.B of this final rule is shown in column C. For CY 2019, the impact on all ESRD facilities as a result of the changes to the outlier payment policy would be a 0.3 percent increase in estimated payments. Nearly all ESRD facilities are anticipated to experience a positive effect in their estimated CY 2019 payments as a result of the proposed outlier policy changes.

Column D shows the effect of the finalized CY 2019 wage indices, the wage index floor of 0.50, and the updated labor-related share. The categories of types of facilities in the impact table show changes in estimated payments ranging from a −0.7 percent to a 4.5 percent increase due to these final updates.

Column E shows the effect of the finalized CY 2019 ESRD PPS payment rate update. The final ESRD PPS payment rate update is 1.3 percent, which reflects the final ESRDB market basket percentage increase factor for CY 2019 of 2.1 percent and the final MFP adjustment of 0.8 percent.

Column F reflects the overall impact, that is, the effects of the finalized outlier policy changes, wage index floor, labor-related share, and payment rate update. We expect that overall ESRD facilities will experience a 1.6 percent increase in estimated payments in CY 2019. The categories of types of facilities in the impact table show impacts ranging from an increase of 1.0 percent to 6.0 percent in their CY 2019 estimated payments.

b. Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services, which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2019, we estimate that the finalized ESRD PPS payment rate will have zero impact on these other providers.

c. Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2019 will be

approximately $10.5 billion. This estimate takes into account a projected increase in fee-for-service Medicare dialysis beneficiary enrollment of 2.0 percent in CY 2019.

d. Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 1.6 percent overall increase in the proposed CY 2019 ESRD PPS payment amounts, we estimate that there will be an increase in beneficiary co-insurance payments of 1.6 percent in CY 2019, which translates to approximately $50 million.

e. Alternatives Considered

In section II.B.3 of this final rule, we finalized a new wage index floor of 0.50. In establishing the new wage index floor, we considered maintaining the existing wage index floor of 0.40 and also considered increasing the wage floor to 0.51 and 0.55. However, based on the analyses we have conducted, we no longer believe a wage index floor value of 0.40 is appropriate and we are concerned about the impact a higher floor value than .50 would have on the base rate.

2. Proposed Payment for Renal Dialysis Services Furnished to Individuals with AKI

To understand the impact of the changes affecting payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated payments in CY 2018 to estimated payments in CY 2019. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the estimates of payments in CY 2018 and CY 2019 contain similar inputs. Therefore, we simulated payments only for those ESRD facilities for which we are able to calculate both current payments and new payments.

For this final rule, we used CY 2017 data from the Part A and Part B Common Working Files, as of August 3, 2018, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2017 claims to 2018 and 2019 using various updates. The updates to the AKI payment amount are described in section III of this final rule. Table 42 shows the impact of the estimated CY 2019 payments for renal dialysis services furnished to individuals with AKI compared to estimated payments for renal dialysis services furnished to individuals with AKI in CY 2018.

TABLE 42—IMPACT OF FINALIZED CHANGES IN PAYMENT FOR RENAL DIALYSIS SERVICES FURNISHED TO INDIVIDUALS WITH AKI FOR CY 2019

Facility type	Number of facilities	Number of treatments (in thousands)	Effect of 2019 changes in wage index, wage floor, and labor-related share (%)	Effect of 2019 changes in payment rate update (%)	Effect of total 2019 final changes (%)
	A	B	C	D	E
All Facilities	3,930	163.7	0.0	1.3	1.3
Type:					
Freestanding	3,837	160.3	0.0	1.3	1.3
Hospital based	93	3.4	-0.1	1.3	1.2
Ownership Type:					
Large dialysis organization	3,318	139.7	0.0	1.3	1.3
Regional chain	426	16.6	-0.0	1.3	1.3
Independent	125	4.8	0.0	1.3	1.4
Hospital based [1]	61	2.7	-0.1	1.3	1.2
Unknown	0	0.0	0.0	0.0	0.0
Geographic Location:					
Rural	703	26.6	-0.3	1.3	1.0
Urban	3,227	137.1	0.1	1.3	1.4
Census Region:					
East North Central	718	31.2	-0.3	1.3	1.0
East South Central	315	11.3	-0.6	1.3	0.8
Middle Atlantic	406	17.4	0.0	1.3	1.3
Mountain	248	11.3	-0.4	1.3	0.9
New England	126	4.9	-0.4	1.3	1.0
Pacific [2]	486	27.7	1.1	1.3	2.5
Puerto Rico and Virgin Islands	2	0.0	5.9	1.3	7.3
South Atlantic	889	35.7	-0.4	1.3	1.0
West North Central	255	7.8	-0.3	1.3	1.0
West South Central	485	16.3	-0.1	1.3	1.2
Facility Size:					
Less than 4,000 treatments	394	11.4	0.0	1.3	1.4
4,000 to 9,999 treatments	1,538	58.0	-0.1	1.3	1.2
10,000 or more treatments	1,990	93.9	0.1	1.3	1.4
Unknown	8	0.4	0.6	1.3	1.9
Percentage of Pediatric Patients:					
Less than 2	3,929	163.5	0.0	1.3	1.3
Between 2 and 19	0	0.0	0.0	0.0	0.0
Between 20 and 49	0	0.0	0.0	0.0	0.0
More than 50	1	0.2	0.6	1.3	1.9

[1] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.
[2] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands
Note: Totals do not necessarily equal the sum of rounded parts, as percentages are multiplicative, not additive.

Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of AKI dialysis treatments (in thousands).

Column C shows the effect of the final CY 2019 wage indices, the wage index floor of 0.50, and the updated labor-related share. The categories of types of facilities in the impact table show changes in estimated payments ranging from a 0.0 percent to a 5.9 percent increase due to these final updates.

Column D shows the effect of the final CY 2019 ESRD PPS payment rate update. The final ESRD PPS payment rate update is 1.3 percent, which reflects the final ESRDB market basket percentage increase factor for CY 2019 of 2.1 percent and the final MFP adjustment of 0.8 percent.

Column E reflects the overall impact, that is, the effects of the final wage index floor, labor-related share, and payment rate update. We expect that overall ESRD facilities would experience a 1.3 percent increase in estimated payments in CY 2019. The categories of types of facilities in the impact table show impacts ranging from an increase of 0.0 percent to 7.3 percent in their CY 2019 estimated payments.

b. Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are updating the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The decision about where the renal dialysis services are furnished is made by the patient and his or her physician. Therefore, this proposal will have zero impact on other Medicare providers.

c. Effects on the Medicare Program

We estimate approximately $40.0 million would be paid to ESRD facilities in CY 2019 as a result of AKI patients receiving renal dialysis services in the ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

d. Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent co-insurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients will continue to be responsible for a 20 percent co-insurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we will expect beneficiaries to pay less co-insurance when AKI dialysis is furnished by ESRD facilities.

e. Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients and as such, including those policies and adjustment would be inappropriate. We continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring would assist us in developing knowledgeable, data-driven proposals.

3. ESRD QIP

a. Effects of the PY 2021 ESRD QIP on ESRD Facilities

The ESRD QIP provisions are intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries. The methodology that we are finalizing to use to determine a facility's TPS for the PY 2021 ESRD QIP is described in section IV.C of this final rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2021 ESRD QIP will apply to ESRD PPS payments made to the facility for services furnished in CY 2021.

For the PY 2021 ESRD QIP, we estimate that of the 7,042 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 46.01 percent or 3,240 of the facilities would receive a payment reduction for PY 2021. The total payment reduction for all of the 3,240 facilities expected to receive a reduction is approximately $32,196,724. Facilities that do not receive a TPS do not receive a payment reduction. Additionally, we estimate that the proposed removal of four reporting measures beginning with PY 2021 will reduce the information collection burden by $12 million.

Table 43 shows the overall estimated distribution of payment reductions resulting from the PY 2021 ESRD QIP.

TABLE 43—ESTIMATED DISTRIBUTION OF PY 2021 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities
0.0%	3,802	56.10
0.5%	1,532	22.61
1.0%	896	13.22
1.5%	359	5.30
2.0%	188	2.77

Note: This table excludes 256 facilities that we estimate will not receive a payment reduction because they will not report enough data to receive a TPS.

To estimate whether a facility would receive a payment reduction in PY 2021, we scored each facility on achievement and improvement on several measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Measures used for the simulation are shown in Table 44.

TABLE 44—DATA USED TO ESTIMATE PY 2021 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance period
VAT:		
Standardized Fistula Rate	Jan 2015–Dec 2015	Jan 2016–Dec 2016
Long Term Catheter Rate	Jan 2015–Dec 2015	Jan 2016–Dec 2016
Kt/V Dialysis Adequacy Comprehensive	Jan 2016–Dec 2016	Jan 2017–Dec 2017
Hypercalcemia	Jan 2016–Dec 2016	Jan 2017–Dec 2017
STrR	Jan 2015–Dec 2015	Jan 2016–Dec 2016
ICH CAHPS Survey	Jan 2016–Dec 2016	Jan 2017–Dec 2017
SRR	Jan 2016–Dec 2016	Jan 2017–Dec 2017
NHSN BSI	Jan 2016–Dec 2016	Jan 2017–Dec 2017

TABLE 44—DATA USED TO ESTIMATE PY 2021 ESRD QIP PAYMENT REDUCTIONS—Continued

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance period
SHR	Jan 2015–Dec 2015	Jan 2016–Dec 2016

For all measures except STrR and SHR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPS. For SHR and STrR, facilities were required to have at least 5 and 10 patient-years at risk, respectively, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated minimum TPS and an estimated payment reduction table that were consistent with the proposals outlined in section IV.B.3.b of this final rule. Facility reporting measure scores were estimated using available data from CY 2016 and 2017. Facilities were required to have a score on at least one measure in any two out of the four domains to receive a TPS.

To estimate the total payment reductions in PY 2021 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2017 and December 2017 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: Total ESRD payment in January 2017 through December 2017 times the estimated payment reduction percentage.

Table 45 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2021. The table also details the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities). Given that the performance periods used for these calculations will differ from those we are finalizing to use for the PY 2021 ESRD QIP, the actual impact of the PY 2021 ESRD QIP may vary significantly from the values provided here.

TABLE 45—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2021

	Number of facilities	Number of treatments 2017 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	7,042	44.5	6,777	2,975	−0.38
Facility Type:					
Freestanding	6,626	42.4	6,415	2,728	−0.35
Hospital-based	416	2.1	362	247	−0.79
Ownership Type:					
Large Dialysis	5,355	34.4	5,208	2,096	−0.32
Regional Chain	871	5.7	841	388	−0.38
Independent	479	2.9	447	286	−0.68
Hospital-based (non-chain)	325	1.6	280	204	−0.88
Unknown	12	0.0	1	1	−0.50
Facility Size:					
Large Entities	6,226	40.0	6,049	2,484	−0.33
Small Entities [1]	804	4.5	727	490	−0.75
Unknown	12	0.0	1	1	−0.50
Rural Status:					
(1) Yes	1,263	6.4	1,221	350	−0.23
(2) No	5,779	38.1	5,556	2,625	−0.41
Census Region:					
Northeast	960	6.9	917	427	−0.42
Midwest	1,628	8.5	1,559	625	−0.34
South	3,168	20.2	3,048	1,491	−0.42
West	1,228	8.5	1,195	381	−0.26
US Territories [2]	58	0.4	58	51	−1.03
Census Division:					
Unknown	7	0.1	7	5	−1.00
East North Central	1,136	6.2	1,089	475	−0.37
East South Central	569	3.3	553	225	−0.31
Middle Atlantic	769	5.4	733	372	−0.46
Mountain	398	2.3	386	101	−0.21
New England	191	1.5	184	55	−0.23
Pacific	830	6.3	809	280	−0.28
South Atlantic	1,612	10.4	1,551	822	−0.46
West North Central	492	2.3	470	150	−0.27
West South Central	987	6.5	944	444	−0.40
US Territories [2]	51	0.3	51	46	−1.03
Facility Size (number of total treatments):					
Less than 4,000 treatments	1,689	5.9	1,478	731	−0.49
4,000–9,999 treatments	2,502	11.8	2,493	920	−0.29

TABLE 45—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2021—Continued

	Number of facilities	Number of treatments 2017 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
Over 10,000 treatments	2,776	26.7	2,773	1,294	−0.38
Unknown	75	0.2	33	30	−1.22

[1] Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.
[2] Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

b. Effects of the PY 2022 ESRD QIP on ESRD Facilities

The ESRD QIP provisions are intended to prevent possible reductions in the quality of ESRD dialysis facility services provided to beneficiaries. The methodology that we are finalizing to use to determine a facility's TPS for the PY 2022 ESRD QIP is described in section IV.C of this final rule. Any reductions in ESRD PPS payments as a result of a facility's performance under the PY 2022 ESRD QIP will apply to ESRD PPS payments made to the facility for services furnished in CY 2022.

For the PY 20co22 ESRD QIP, we estimate that of the 7,042 dialysis facilities (including those not receiving a TPS) enrolled in Medicare, approximately 43.34 percent or 2,937 of the facilities would receive a payment reduction for PY 2022. The total payment reduction for all of the 2,937facilities expected to receive a reduction is approximately $31,624,158.67. Facilities that do not receive a TPS do not receive a payment reduction.

Table 46 shows the overall estimated distribution of payment reductions resulting from the PY 2022 ESRD QIP.

TABLE 46—ESTIMATED DISTRIBUTION OF PY 2022 ESRD QIP PAYMENT REDUCTIONS

Payment reduction	Number of facilities	Percent of facilities
0.0%	3,840	56.66
0.5%	1,535	22.65
1.0%	872	12.87
1.5%	352	5.19
2.0%	178	2.63

Note: This table excludes 265 facilities that we estimate will not receive a payment reduction because they will not report enough data to receive a TPS.

To estimate whether a facility would receive a payment reduction in PY 2022, we scored each facility on achievement and improvement on several measures we have previously finalized and for which there were available data from CROWNWeb and Medicare claims. Measures used for the simulation are shown in Table 47.

TABLE 47—DATA USED TO ESTIMATE PY 2022 ESRD QIP PAYMENT REDUCTIONS

Measure	Period of time used to calculate achievement thresholds, performance standards, benchmarks, and improvement thresholds	Performance period
VAT:		
Standardized Fistula Rate	Jan 2015–Dec 2015	Jan 2016–Dec 2016
Long Term Catheter Rate	Jan 2015–Dec 2015	Jan 2016–Dec 2016
Kt/V Dialysis Adequacy Comprehensive	Jan 2016–Dec 2016	Jan 2017–Dec 2017
Hypercalcemia	Jan 2016–Dec 2016	Jan 2017–Dec 2017
STrR	Jan 2015–Dec 2015	Jan 2016–Dec 2016
ICH CAHPS Survey	Jan 2016–Dec 2016	Jan 2017–Dec 2017
SRR	Jan 2016–Dec 2016	Jan 2017–Dec 2017
NHSN BSI	Jan 2016–Dec 2016	Jan 2017–Dec 2017
SHR	Jan 2015–Dec 2015	Jan 2016–Dec 2016

For all measures except STrR and SHR, clinical measure topic areas with less than 11 cases for a facility were not included in that facility's TPS. For SHR and STrR, facilities were required to have at least 5 and 10 patient-years at risk, respectively, in order to be included in the facility's TPS. Each facility's TPS was compared to an estimated minimum TPS and an estimated payment reduction table that were consistent with the proposals outlined in section IV.B.3.b of this final rule. Facility reporting measure scores were estimated using available data from CY 2016 and 2017. Facilities were required to have a score on at least one measure in any two out of the four domains to receive a TPS.

To estimate the total payment reductions in PY 2022 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2017 and December 2017 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility: Total ESRD payment in January 2017 through December 2017 times the estimated payment reduction percentage.

Table 48 shows the estimated impact of the finalized ESRD QIP payment reductions to all ESRD facilities for PY 2022. The table details the distribution of ESRD facilities by facility size (both among facilities considered to be small entities and by number of treatments per facility), geography (both urban/rural and by region), and by facility type (hospital based/freestanding facilities). Given that the performance periods used for these calculations will differ from those we are finalizing to use for the PY 2022 ESRD QIP, the actual impact of the PY 2022 ESRD QIP may

vary significantly from the values provided here.

TABLE 48—IMPACT OF PROPOSED QIP PAYMENT REDUCTIONS TO ESRD FACILITIES FOR PY 2022

	Number of facilities	Number of treatments 2017 (in millions)	Number of facilities with QIP score	Number of facilities expected to receive a payment reduction	Payment reduction (percent change in total ESRD payments)
All Facilities	7,042	44.5	6,777	2,937	−0.37
Facility Type:					
Freestanding	6,626	42.4	6,415	2,691	−0.34
Hospital-based	416	2.1	362	246	−0.78
Ownership Type:					
Large Dialysis	5,355	34.4	5,208	2,065	−0.31
Regional Chain	871	5.7	841	383	−0.37
Independent	479	2.9	447	285	−0.66
Hospital-based (non-chain)	325	1.6	280	203	−0.87
Unknown	12	0.0	1	1	−0.50
Facility Size:					
Large Entities	6,226	40.0	6,049	2,448	−0.32
Small Entities [1]	804	4.5	727	488	−0.74
Unknown	12	0.0	1	1	−0.50
Rural Status:					
(1) Yes	1,263	6.4	1,221	346	−0.22
(2) No	5,779	38.1	5,556	2,591	−0.40
Census Region:					
Northeast	960	6.9	917	421	−0.40
Midwest	1,628	8.5	1,559	614	−0.33
South	3,168	20.2	3,048	1,481	−0.41
West	1,228	8.5	1,195	369	−0.25
US Territories [2]	58	0.4	58	52	−1.03
Census Division:					
Unknown	7	0.1	7	5	−0.92
East North Central	1,136	6.2	1,089	465	−0.36
East South Central	569	3.3	553	221	−0.30
Middle Atlantic	769	5.4	733	369	−0.45
Mountain	398	2.3	386	98	−0.20
New England	191	1.5	184	52	−0.22
Pacific	830	6.3	809	271	−0.27
South Atlantic	1,612	10.4	1,551	822	−0.46
West North Central	492	2.3	470	149	−0.27
West South Central	987	6.5	944	438	−0.40
US Territories [2]	51	0.3	51	47	−1.04
Facility Size (number of total treatments):					
Less than 4,000 treatments	1,689	5.9	1,478	718	−0.48
4,000–9,999 treatments	2,502	11.8	2,493	907	−0.29
Over 10,000 treatments	2,776	26.7	2,773	1,282	−0.37
Unknown	75	0.2	33	30	−1.22

[1] Small Entities include hospital-based and satellite facilities, and non-chain facilities based on DFC self-reported status.
[2] Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

c. Effects on Other Providers

The ESRD QIP is applicable to dialysis facilities. We are aware that several of our measures impact other providers. For example, with the introduction of the SRR clinical measure in PY 2017 and the SHR clinical measure in PY 2020, we anticipate that hospitals may experience financial savings as dialysis facilities work to reduce the number of unplanned readmissions and hospitalizations. We are exploring various methods to assess the impact these measures have on hospitals and other outpatient facilities, such as through the impacts of the Hospital Readmissions Reduction Program and the Hospital-Acquired Conditions Reduction Program, and we intend to continue examining the interactions between our quality programs to the greatest extent feasible.

d. Effects on the Medicare Program

For PY 2022, we estimate that ESRD QIP will contribute approximately $31,624,159 in Medicare savings. For comparison, Table 49 shows the payment reductions that we estimate will be achieved by the ESRD QIP from PY 2017 through PY 2022. We note that we have updated the PY 2021 payment reduction estimate that we published in the CY 2018 ESRD PPS final rule (82 FR 50795).

TABLE 49—ESTIMATED PAYMENT REDUCTIONS PAYMENT YEAR 2017 THROUGH 2022

Payment year	Estimated payment :reductions (citation)
PY 2022	$31,624,159.
PY 2021	32,196,724.
PY 2020	31,581,441 (81 FR 77960).
PY 2019	15,470,309 (80 FR 69074).
PY 2018	11,576,214 (79 FR 66257).
PY 2017	11,954,631 (79 FR 66255).

e. Effects on Medicare Beneficiaries

The ESRD QIP is applicable to dialysis facilities. Since the Program's inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. To date we have been unable to examine the impact of the ESRD QIP on Medicare beneficiaries including the financial impact of the Program or the impact on the health outcomes of beneficiaries. However, in future years we are interested in examining these impacts through the addition of new measures to the Program and through the analysis of available data from our existing measures.

Additionally, in this final rule, we are finalizing changes to the ESRD QIP to reflect the Meaningful Measures Initiative's priorities, including focusing our quality measure set on more outcome-oriented, less burdensome quality measures. We believe that the changes we are finalizing will help focus the Program's measurements on the most clinically appropriate topics while ensuring that facilities are not unduly burdened by quality reporting requirements.

f. Alternatives Considered

As discussed in the CY 2019 ESRD PPS proposed rule (83 FR 34405) and in section IV.B.3.b of this final rule, we proposed two alternatives for reassigning measure weights in situations where a facility does not receive a score on at least one measure but is still eligible to receive a TPS score: (1) Redistribute the weight of missing measures evenly across the remaining measures (that is, we would divide up the missing measure's weight equally across the remaining measures), (2) redistribute the weight of missing measures proportionately across the remaining measures, based on their weight as a percentage of TPS (that is, when dividing up a missing measure's weight, we would shift a larger share of that weight to measures with a higher assigned weight; measures with a lower weight would gain a smaller portion of the missing measure's weight.

We had proposed the second alternative in the CY 2019 ERD PPS proposed rule as our weighting redistribution policy. However, in response to concerns raised by public commenters that the STrR measure's weight will comprise a significant share of the TPS for some facilities, and that facilities that predominantly or exclusively care for patients that dialyze at home will be scored predominantly on only a handful of measures, we are not finalizing our proposed weight redistribution policy. Instead, we are finalizing that if a facility does not receive a score on any of the measures in a domain, then that domain's weight will be redistributed evenly across the remaining domains, and then evenly across the measures within each of those domains on which the facility receives a score. Additionally, if a facility receives a score on some, but not all, of the measures within a domain, the weight of the measure(s) for which a score is missing will be redistributed evenly across the other measures in that domain.

The weighting redistribution policy we are finalizing differs from the two policy alternatives discussed in the CY 2019 ESRD PPS proposed rule (83 FR 34342). We are not finalizing our proposed weight redistribution policy because we agree with commenters' concerns that certain facilities could receive a TPS that is dominated by the scores of only a few measures. We also reconsidered the policy alternative discussed in the CY 2019 ESRD PPS proposed rule but believe that this policy alternative would not maintain the Meaningful Measures Initiative priorities in measure weights as effectively as we prefer.

We then considered how best to address commenters' concerns while maintaining the Meaningful Measures Initiative priorities and determined that the policy we are finalizing accomplishes this objective. Our finalized policy maintains the Meaningful Measures Initiative priorities and our preferred emphasis on those topic areas because when a facility is not scored on a measure, the domain weights will be the same as the domain weights of a complete measure set (unless an entire domain's worth of measures is missing, in which case the domain's weight would be redistributed across the remaining domains; for example, if a facility did not receive an ICH CAHPS score, one-third of the Patient & Family Engagement Domain's weight of 15 percent would be distributed to each of the three remaining domains). Our finalized policy also addresses commenters concerns that certain facilities could receive a TPS that is dominated by the scores of only a few measures because the weight of measures for which a facility does not receive a score is redistributed evenly within its domain rather than proportionately across the entire measure set; measures with high weights will not receive the largest share of redistributed weights.

4. DMEPOS

a. Changes to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP)

i. Effects on Other Providers

We believe that using the maximum winning bid amount and lead item pricing to establish the SPAs and paying most contract suppliers more than they bid helps to ensure beneficiary access to DMEPOS and long term sustainability of the CBP. This methodology has the advantage of being easily understood by bidding suppliers. Further, lead item pricing simplifies the supplier's bidding process. We anticipate that more suppliers would compete given the simpler rules and the fact that all winning bidders would be paid at least as much as they bid for the lead item. Therefore, we believe that this final rule will have a positive economic impact on bidding suppliers.

ii. Effects on the Medicare Program

The effect of this rule, which finalizes our proposal to base SPAs on the maximum winning bid and to implement lead item pricing in the Medicare DMEPOS CBP, is estimated by rounding to the nearer 5 million dollars and is expected to cost $10 million in Medicare benefit payments for the 5-year period beginning January 1, 2019, and ending September 30, 2023. The estimate uses the current baseline which bases the SPAs on the median of winning bids. The cost of the rule is the sum of yearly impacts. Each year's impact is the product of the projected spending on items subject to competitive bidding furnished in former CBAs for that year multiplied by the percentage increase in aggregate spending due to the change in the payment rules, in this case 0.2 percent.

As noted in the CY 2019 ESRD PPS DMEPOS proposed rule (83 FR 34358), median bid levels have trended lower with each successive round of competition. To the extent that factors impacting the competition are still developing, the impacts of this final rule may be underestimated.

iii. Effects on Medicare Beneficiaries

This final rule will base SPAs on the maximum winning bid and implement lead item pricing in the Medicare DMEPOS CBP. The effects are estimated by rounding to the nearer 5 million dollars and to cost roughly $3 million in Medicare beneficiary cost sharing for the 5-year period beginning January 1, 2019, and ending September 30, 2023. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be $0 million. Section 503 of the Consolidated Appropriations Act of 2016 and section 5002 of the Cures Act, added section 1903(i)(27) to the Act, which prohibits federal Medicaid reimbursement to states for certain DME expenditures that are, in the aggregate, in excess of what Medicare would have paid for such items. The requirement took effect January 1, 2018. Many states have started limiting payment for DME based on the Medicare rates, but the majority of the states do not currently have the ability to use rates that apply to only parts of the state, such as rates paid in CBAs or rural areas of the state.

iv. Alternatives Considered

One alternative we considered was to continue the Medicare DMEPOS CBP with no changes. This would have no economic impact on the Medicare program or its beneficiaries.

Another alternative we considered but did not propose was to implement lead item pricing based on maximum winning bids as proposed, but offer contracts based on overall demand for items and services and unadjusted supplier capacity. We believe that currently more contracts are offered under the program than are needed to meet overall demand for items and services, so this is potentially an option we could consider. For example, we currently limit a supplier's capacity to 20 percent of projected demand. We could eliminate this limit which could result in less winning contracts being offered. However, the risk is that the number of contract suppliers could be reduced too much and could lead to access problems.

b. Adjustments to DMEPOS Fee Schedule Amounts Based on Information From the DMEPOS CBP

In the event of a gap in the CBP beginning January 1, 2019, any enrolled supplier can furnish the items currently subject to competitive bidding in former CBAs and non-CBAs. The suppliers furnishing items in former CBAs would be paid slightly more than the current SPAs based on the median of winning bids because the finalized fee schedule adjustment methodology for items and services furnished in former CBAs will adjust the fee schedule amounts for such items and services based on the current SPAs plus a CPI–U update. We understand this final rule to be consistent with the requirements of section 1834(a)(1)(F) of the Act. The suppliers furnishing items in areas that are currently non-CBAs will be paid based on adjusted fee schedule amounts.

i. Effects on the Medicare Program

This rule finalizes transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019, for areas that are currently CBAs and for areas that are currently not CBAs. Altogether, this rule finalizes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous U.S.; and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas. The impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are done consistent with the rules in place as of January 1, 2018. The impacts are expected to cost $1.05 billion dollars in Medicare benefit payments for the 2-year period beginning January 1, 2019 and ending December 31, 2020.

ii. Effects on Medicare Beneficiaries

This rule finalizes transitional fee schedule adjustments for DMEPOS items and services furnished on or after January 1, 2019, in areas that are currently CBAs and for areas that are currently not CBAs. Altogether, this rule finalizes three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous U.S.; and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

The estimated impacts for this part of the rule are calculated against a baseline that assumes payments for items furnished in CBAs and non-CBAs are made consistent with the rules in place as of January 1, 2018. The impacts are expected to cost $260 million in Medicare beneficiary cost sharing beginning January 1, 2019. The Medicaid impacts for cost sharing for the beneficiaries enrolled in the Medicare Part B and Medicaid programs for the federal and state portions are assumed to be $45 million and $30 million, respectively.

iii. Alternatives Considered

After consideration of comments received on the proposed rule and for reasons we set forth previously and in the proposed rule, we are finalizing the three fee schedule adjustment methodologies we proposed without change. Specifically, we are finalizing the proposed revisions to § 414.210(g)(9) to adjust the fee schedule amounts for items and services furnished in rural and noncontiguous non-CBAs by extending through December 31, 2020 the current fee schedule adjustment methodology which bases the fee schedule amounts on a blend of 50 percent of the unadjusted fee schedule amounts and 50 percent of the adjusted fee schedule amounts. We are also finalizing our proposal to continue fully adjusting the fee schedule amounts for items and services furnished from January 1, 2019 through December 31, 2020, in non-rural and contiguous non-CBAs in accordance with the current methodologies under paragraphs (1) through (8) of § 414.210(g). We are also finalizing the proposed addition of paragraph (g)(10) to § 414.210 to establish a methodology for adjusting fee schedule amounts for items and services furnished in former CBAs during temporary gaps in the DMEPOS CBP.

One alternative we considered but did not propose was to establish a fee schedule adjustment methodology that uses the blended (75 unadjusted/25 adjusted) rates in all super rural and non-contiguous areas, and the blended (25 unadjusted/75 adjusted) rates in all other non-CBAs. In this alternative, the

fee schedule amount for items furnished in current CBAs would be based on the current SPAs updated by the projected change in the CPI–U. This alternative is estimated by rounding to the nearer 5 million dollars and is expected to cost $30 million in Medicare benefit payments and $5 million in Medicare beneficiary cost sharing beginning January 1, 2019. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be $0 million and $0 million, respectively.

Another alternative we considered but did not propose was to maintain the current SPA determination methodology and maintain the current fee schedule adjustment methodologies. This alternative is estimated by rounding to the nearer 5 million dollars and to save $1.14 billion in Medicare benefit payments and $280 million in Medicare beneficiary cost sharing beginning January 1, 2019. The Medicaid impacts for cost sharing for the dual eligibles for the federal and state portions are assumed to be $50 million and $40 million, respectively.

We requested public comments on these alternatives.

Altogether, we proposed, and are finalizing three different fee schedule adjustment methodologies depending on the area in which the items and services are furnished: (1) One fee schedule adjustment methodology for DME items and services furnished on or after January 1, 2019, in areas that are currently CBAs, in the event of a gap in the CBP; (2) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs, are not rural areas, and are located in the contiguous U.S.; and (3) another fee schedule adjustment methodology for items and services furnished from January 1, 2019 through December 31, 2020, in areas that are currently not CBAs and are either rural areas or non-contiguous areas.

c. New Payment Classes for Oxygen and Oxygen Equipment and Methodology for Ensuring Annual Budget Neutrality of the New Classes

i. Effects on Other Providers

Suppliers of high-flow oxygen equipment and oxygen contents will get paid more when furnishing oxygen to the high-risk beneficiaries who have been prescribed high-flow oxygen. The budget neutrality offset applied to all oxygen classes will lessen the offset applied to the stationary oxygen equipment fee schedule amount, which will be to the advantage of suppliers that furnish only stationary oxygen equipment.

ii. Effects on the Medicare Program

No fiscal impact due to the annual budget neutrality calculation.

iii. Effects on Medicare Beneficiaries

No fiscal impact due to the annual budget neutrality calculation. Note that certain beneficiaries will have increased cost sharing expenses depending on the type of equipment furnished.

iv. Alternatives Considered

One alternative we considered but did not propose was to apply the budget neutrality offset to all DME, not just to the oxygen classes as proposed. This would have no fiscal impact because it would be budget neutral.

Another alternative we considered but did not propose was to eliminate OGPE classes added in 2006 and resort back to modality neutral payments for both stationary and portable equipment. This alternative would have no fiscal impact, either.

d. Payment for Multi-Function Ventilators

i. Effects on Other Providers

We expect that the impact of classifying the multi-function ventilator item in the frequent and substantial servicing payment category and this final rule establishing payment rules for multi-function ventilators will overall result in a slight increase in payments to suppliers since the suppliers will continue to receive the monthly rental amount for the base ventilator item plus an additional average amount for the integrated functions. In addition, the supplier will retain ownership of the multi-function ventilator and can furnish the equipment for additional separate rental periods to other beneficiaries.

ii. Effects on the Medicare Program

We expect the final rule for multi-function ventilators to be a 5-year cost of $15 million to the Medicare program as the payment method we are finalizing will result in suppliers continuing to receive the monthly rental amount for the base ventilator item plus an additional average amount for the integrated functions.

iii. Effects on Medicare Beneficiaries

We expect the final rule will have an overall effect of increasing cost sharing by $3 million for Medicare beneficiaries.

iv. Alternatives Considered

We considered two alternatives for our proposed payment rule for multi-function ventilators. One alternative payment approach is to pay a ventilator base item monthly rental amount and also pay separate, add-on monthly rental payments for each of the four additional functions of the item. This alternative is expected to have no cost to the beneficiaries or the Medicare program because the beneficiary cost share amount for the item would be the same amount as the total of that paid for each of the five items separately. Another alternative payment approach is to establish a monthly rental payment amount for a ventilator plus the monthly cost of all four additional functions. However, this payment alternative would only be allowed if the patient requires all five functions of the multi-function ventilator. This alternative is expected to have no cost to the beneficiaries or the Medicare program because the beneficiaries will end up paying the same amount as they would if they paid for five separate items together. Each of these alternatives did not approach the new multi-function ventilator as an integrated item that encompasses efficiencies for the suppliers, beneficiaries and the program. Also, neither of these two alternatives would address payment for multi-function ventilators in a different manner than paying for five separate items that perform the same functions. Thus, we did not elect to pursue these alternatives.

e. Northern Mariana Islands in Future National Mail Order CBPs

Because the proposal we are finalizing will not have a fiscal impact, no detailed economic analysis is necessary.

C. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars_a004_a-4*), in Table 50, we have prepared an accounting statement showing the classification of the transfers and costs associated with the various provisions of these final rules.

TABLE 50—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS AND COSTS/SAVINGS

ESRD PPS and AKI	
Category	Transfers
Annualized Monetized Transfers	$160 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Transfers
Increased Beneficiary Co-insurance Payments	$50 million.
From Whom to Whom	Beneficiaries to ESRD providers.

ESRD QIP for PY 2021	
Category	Transfers
Annualized Monetized Transfers	−32 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs	181 million. The PY 2021 policy changes will result in an estimated $12 million in savings.

ESRD QIP for PY 2022	
Category	Transfers
Annualized Monetized Transfers	−32 million.
From Whom to Whom	Federal government to ESRD providers.
Category	Costs
Annualized Monetized ESRD Provider Costs	202 million. The PY 2022 policy changes will result in an estimated $21 million increase.

DME Provisions: Competitive Bidding Reforms Annualization Period 2019 to 2023			
Category	Transfer		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer on Beneficiary Cost Sharing (in $Millions)	$2 $2	2019 2019	7% 3%
From Whom to Whom	Beneficiaries to Medicare providers.		
	Transfers		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer Payments (in $Millions)	$0.6 $0.6	2019 2019	7% 3%
From Whom to Whom	Federal government to Medicare providers.		

DME Provisions: Transitional Fee Adjustments Annualization Period 2019 to 2020			
Category	Transfer		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer on Beneficiary Cost Sharing (in $Millions)	$506 $516	2019 2019	7% 3%
From Whom to Whom	Beneficiaries to Medicare providers.		
	Transfers		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer Payments (in $Millions)	$128	2019	7%

	$130	2019	3%
From Whom to Whom	Federal government to Medicare providers.		

DME Provisions: Multi-function Ventilator Annualization Period 2019 to 2023

Category	Transfer		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer on Beneficiary Cost Sharing (in $Millions)	$3 $3	2019 2019	7% 3%
From Whom to Whom	Beneficiaries to Medicare providers.		
	Transfers		
	Estimates	Year dollar	Discount rate
Annualized Monetized Transfer Payments (in $Millions)	$0.6 $0.6	2019 2019	7% 3%
From Whom to Whom	Federal government to Medicare providers.		

In accordance with the provisions of Executive Order 12866, these final rules were reviewed by the Office of Management and Budget.

XVI. Regulatory Flexibility Act Analysis

The Regulatory Flexibility Act (September 19, 1980, Pub. L. 96–354) (RFA) requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 11 percent of ESRD dialysis facilities are considered small entities according to the Small Business Administration's (SBA) size standards, which classifies small businesses as those dialysis facilities having total revenues of less than $38.5 million in any 1 year. Individuals and states are not included in the definitions of a small entity. For more information on SBA's size standards, see the Small Business Administration's website at *http://www.sba.gov/content/small-business-size-standards* (Kidney Dialysis Centers are listed as 621492 with a size standard of $38.5 million).

We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity.

For purposes of the RFA, we estimate that approximately 11 percent of ESRD facilities are small entities as that term is used in the RFA (which includes small businesses, nonprofit organizations, and small governmental jurisdictions). This amount is based on the number of ESRD facilities shown in the ownership category in Table 42. Using the definitions in this ownership category, we consider 485 facilities that are independent and 327 facilities that are shown as hospital-based to be small entities. The ESRD facilities that are owned and operated by Large Dialysis Organizations (LDOs) and regional chains would have total revenues of more than $38.5 million in any year when the total revenues for all locations are combined for each business (individual LDO or regional chain), and are not, therefore, included as small entities.

For the ESRD PPS updates finalized in this rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of dialysis facility) is estimated to receive a 1.8 percent increase in payments for CY 2019. An independent facility (as defined by ownership type) is also estimated to receive a 1.9 percent increase in payments for CY 2019.

For AKI dialysis, we are unable to estimate whether patients will go to ESRD facilities, however, we have estimated there is a potential for $37.5 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

For the PY 2021 ESRD QIP, we estimate that of the 3,240 ESRD facilities expected to receive a payment reduction in the PY 2021 ESRD QIP, 490 are ESRD small entity facilities. We present these findings in Table 43 (''Estimated Distribution of PY 2021 ESRD QIP Payment Reductions'') and Table 45 (''Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2021''). We estimate that the payment reductions will average approximately $10,822.43 per facility across the 3,240 facilities receiving a payment reduction, and $13,055.63 for each small entity facility. We also estimate that there are 804 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities will decrease 0.75 percent in PY 2021.

For the PY 2022 ESRD QIP, we estimate that of the 2,937 ESRD facilities expected to receive a payment reduction in the PY 2022 ESRD QIP, 488 are ESRD small entity facilities. We present these findings in Table 46 (''Estimated Distribution of PY 2022 ESRD QIP Payment Reductions'') and Table 48 (''Impact of Proposed QIP Payment Reductions to ESRD Facilities for PY 2022''). We estimate that the payment reductions will average approximately $10,767.50 per facility across the 2,937 facilities receiving a payment reduction, and $12,929.28 for each small entity facility. We also estimate that there are 804 small entity facilities in total, and that the aggregate ESRD PPS payments to these facilities will decrease 0.37 percent in PY 2022.

For DMEPOS, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Approximately 85 percent of the DME industry are considered small businesses according to the Small Business Administration's size standards with total revenues of $6.5 million or less in any 1 year and a small percentage are nonprofit organizations. Individuals and states are not included in the definition of a small entity. For Section V of this final rule, we believe that using the maximum winning bid amount and lead item pricing to establish the SPAs and paying most contract suppliers more than they bid

helps to ensure long term sustainability of the CBP. This methodology has the advantage of being easily understood by bidding suppliers. Further, lead item pricing simplifies the supplier's bidding process. We anticipate that more suppliers would compete given the simpler rules and the fact that all winning bidders would be paid at least as much as they bid for the lead item. Therefore, we believe that this final rule will have a positive economic impact on bidding suppliers. As discussed in section VI of this final rule, this rule will provide additional revenue to a substantial number of small rural entities, especially for certain items furnished outside of the former competitively bid areas.

Therefore, the Secretary has determined that only sections V and VI of the final rule will have a significant economic impact on a substantial number of small entities.

The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs.

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. Any such regulatory impact analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We do not believe this final rule will have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 132 rural hospital-based dialysis facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 132 rural hospital-based dialysis facilities will experience an estimated 1.6 percent increase in payments. With regard to the DME provisions of the rule, our data indicates that only around 6.9 percent of small rural hospitals are organizationally linked to a DME supplier with paid claims in 2017. Thus, we do not believe the DME provisions of the rule will have a significant impact on operations of a substantial number of small rural hospitals. As a result, this final rule is not estimated to have a significant impact on small rural hospitals.

Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

We solicited comment on the RFA analysis provided. We received 1 comment on this section. The comment and our response on our detailed economic analysis are set forth below.

Comment: One commenter said that although CMS estimated that the proposed rule would create significant costs for Medicare beneficiaries via cost sharing, the commenter believed that the increased access to quality DME and supplier/brand name choice is a beneficial trade-off. The commenter said that the true impact of this forecasted cost-sharing is unclear due to the widespread existence of secondary insurance, and that for beneficiaries who are dually eligible for both Medicare and Medicaid, Medicaid will typically pay the cost sharing, offsetting this total amount. The commenter also said that many beneficiaries who do not qualify for Medicaid, but cannot afford secondary insurance, do not end up paying for DME cost sharing out of pocket, and that it is common practice for suppliers to write off co-payments when beneficiaries cannot afford to pay after the supplier has made reasonable attempts to collect the balance. The commenter encouraged CMS to monitor how this cost increase impacts beneficiaries, but they believed the increase in access, quality, and choice will offset the legitimate concerns of increased beneficiary cost-sharing.

Response: While we appreciate the support for our proposal, we intend to carefully monitor of the impact of the final rule on access to DME and the quality of items and services furnished in areas that are currently CBAs and areas that are currently non-CBAs.

XVII. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. These final rules do not include any mandates that would impose spending costs on state, local, or Tribal governments in the aggregate, or by the private sector, of $150 million. Moreover, HHS interprets UMRA as applying only to unfunded mandates. We do not interpret Medicare payment rules as being unfunded mandates, but simply as conditions for the receipt of payments from the Federal government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, state, local, or tribal.

XVIII. Federalism Analysis

Executive Order 13132 on Federalism (August 4, 1999) establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have reviewed these final rules under the threshold criteria of Executive Order 13132 on Federalism, and have determined that it will have substantial direct effects on the rights, roles, and responsibilities of states, local or Tribal governments. It is estimated that these policies contained in section VI of this final rule will add $30 million dollars of additional expense to state governments because of the added cost sharing expense for Medicare and Medicaid dual eligible beneficiaries.

XIX. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' The Department believes that this final rule is a significant regulatory action as defined by Executive Order 12866, which imposes costs, and therefore, is considered a regulatory action under Executive Order 13771. The estimated impact will be $0.182875 million in costs in 2019, $12 million in savings in 2021, and $9 million in cost in 2022, and thereafter. Annualizing these costs and cost savings in perpetuity and discounting at 7 percent back to 2016, we estimate that this rule will generate $5.45 million in annualized net costs for Executive Order 13771 accounting purposes.

XX. Congressional Review Act

These final rules are 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.

XXI. Files Available to the Public via the Internet

The Addenda for the annual ESRD PPS proposed and final rules will no

longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet on the CMS website at *http://www.cms.gov/ESRDPayment/PAY/list.asp*. In addition to the Addenda, limited data set (LDS) files are available for purchase at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile.html*. Readers who experience any problems accessing the Addenda or LDS files, should contact *ESRDPayment@cms.hhs.gov.*

List of Subjects

42 CFR Part 413

Health facilities, Kidney diseases, Medicare Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, 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 follows:

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 1. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 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.

■ 2. Section 413.177(a) is revised to read as follows:

§ 413.177 Quality incentive program payment.

(a) With respect to renal dialysis services as defined under § 413.171, in the case of an ESRD facility that does not earn enough points under the program described at § 413.178 to meet or exceed the minimum total performance score (as defined at § 413.178(a)(8)) established by CMS for a payment year (as defined at § 413.178(a)(10)), payments otherwise made to the facility under § 413.230 for renal dialysis services during the payment year will be reduced by up to 2 percent as follows:

(1) For every 10 points that the total performance score (as defined at § 413.178(a)(14)) earned by the ESRD facility falls below the minimum total performance score, the payments otherwise made will be reduced by 0.5 percent.

(2) [Reserved]

* * * * *

■ 3. Section 413.178 is added to read as follows:

§ 413.178 ESRD quality incentive program.

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

(1) *Achievement threshold* means the 15th percentile of national ESRD facility performance on a clinical measure during the baseline period for a payment year.

(2) *Baseline period* means, with respect to a payment year, the time period used to calculate the performance standards, benchmark, improvement threshold and achievement threshold that apply to each clinical measure for that payment year.

(3) *Benchmark* means, with respect to a payment year, the 90th percentile of national ESRD facility performance on a clinical measure during the baseline period that applies to the measure for that payment year.

(4) *Clinical measure* means a measure that is scored for a payment year using the methodology described in paragraphs (d)(1)(i) through (v) of this section.

(5) *End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)* means the program authorized under section 1881(h) of the Social Security Act.

(6) *ESRD facility* means an ESRD facility as defined in § 413.171.

(7) *Improvement threshold* means an ESRD facility's performance on a clinical measure during the baseline period that applies to the measure for a payment year.

(8) *Minimum total performance score (mTPS)* means, with respect to a payment year, the total performance score that an ESRD facility would receive if, during the baseline period, it performed at the 50th percentile of national ESRD facility performance on all clinical measures and the median of national ESRD facility performance on all reporting measures.

(9) *Payment reduction* means the reduction, as specified by CMS, to each payment that would otherwise be made to an ESRD facility under § 413.230 for a calendar year based on the TPS earned by the ESRD facility for the corresponding payment year that is lower than the mTPS score established for that payment year.

(10) *Payment year* means the calendar year for which a payment reduction, if applicable, is applied to the payments otherwise made to an ESRD facility under § 413.230.

(11) *Performance period* means the time period during which data are collected for the purpose of calculating an ESRD facility's performance on measures with respect to a payment year.

(12) *Performance standards* are, for a clinical measure, the performance levels used to award points to an ESRD facility based on its performance on the measure, and are, for a reporting measure, the levels of data submission and completion of other actions specified by CMS that are used to award points to an ESRD facility on the measure.

(13) *Reporting measure* means a measure that is scored for a payment year using the methodology described in paragraph (d)(1)(vi) of this section.

(14) *Total performance score (TPS)* means the numeric score ranging from 0 to 100 awarded to each ESRD facility based on its performance under the ESRD QIP with respect to a payment year.

(b) *Applicability of the ESRD QIP.* The ESRD QIP applies to ESRD facilities as defined at § 413.171 beginning the first day of the month that is 4 months after the facility CMS Certification Number (CCN) effective date.

(c) *ESRD QIP measure selection.* CMS specifies measures for the ESRD QIP for a payment year and groups the measures into domains. The measures for a payment year include, but are not limited to:

(1) Measures on anemia management that reflect the labeling approved by the Food and Drug Administration for such management.

(2) Measures on dialysis adequacy.

(3) To the extent feasible, a measure (or measures) of patient satisfaction.

(4) To the extent feasible, measures on iron management, bone mineral metabolism, and vascular access (including for maximizing the placement of arterial venous fistula).

(5) Beginning with the 2016 payment year, measures specific to the conditions treated with oral-only drugs and that are, to the extent feasible, outcomes-based.

(d) *Performance scoring under the ESRD QIP.* (1) CMS will award points to an ESRD facility based on its

performance on each clinical measure for which the ESRD facility reports the applicable minimum number of cases during the performance period for a payment year, and based on the degree to which the ESRD facility submits data and completes other actions specified by CMS for a reporting measure during the performance period for a payment year.

(i) CMS will award from 1 to 9 points for achievement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds the achievement threshold but is less than the benchmark specified for that measure.

(ii) CMS will award 0 points for achievement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period falls below the achievement threshold specified for that measure.

(iii) CMS will award from 0 to 9 points for improvement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period meets or exceeds the improvement threshold but is less than the benchmark specified for that measure.

(iv) CMS will award 0 points for improvement on a clinical measure to each ESRD facility whose performance on that measure during the applicable performance period is below the improvement threshold specified for that measure.

(v) CMS will award 10 points to each ESRD facility whose performance on a clinical measure during the applicable performance period meets or exceeds the benchmark specified for that measure.

(vi) CMS will award from 0 to 10 points to each ESRD facility on a reporting measure based on the degree to which, during the applicable performance period, the ESRD facility reports data and completes other actions specified by CMS with respect to that measure.

(2) CMS calculates the TPS for an ESRD facility for a payment year as follows:

(i) CMS calculates a domain score for each domain based on the total number of points the ESRD facility has earned under paragraph (d)(1) of this section for each measure in the domain and the weight that CMS has assigned to each measure.

(ii) CMS weights each domain score in accordance with the domain weight that CMS has established for the payment year.

(iii) The sum of the weighted domain scores is the ESRD facility's TPS for the payment year.

(e) *Public availability of ESRD QIP performance information.* (1) CMS will make information available to the public regarding the performance of each ESRD facility under the ESRD QIP on the Dialysis Facility Compare website, including the facility's TPS and scores on individual measures.

(2) Prior to making the information described in paragraph (e)(1) of this section available to the public, CMS will provide ESRD facilities with an opportunity to review that information, technical assistance to help them understand how their performance under the ESRD QIP was scored, and an opportunity to request and receive responses to questions that they have about the ESRD QIP.

(3) CMS will provide each ESRD facility with a performance score certificate on an annual basis that describes the TPS achieved by the facility with respect to a payment year. The performance score certificate must be posted by the ESRD facility within 15 business days of the date that CMS issues the certificate to the ESRD facility, with the content unaltered, in an area of the facility accessible to patients.

(f) *Limitation on review.* There is no administrative or judicial review of the following:

(1) The determination of the amount of the payment reduction under section 1881(h)(1) of the Act.

(2) The specification of measures under section 1881(h)(2) of the Act.

(3) The methodology developed under section 1881(h)(3) of the Act that is used to calculate TPSs and performance scores for individual measures.

(4) The establishment of the performance standards and the performance period under section 1881(h)(4) of the Act.

■ 4. Section 413.232 is amended by—

■ a. Revising paragraphs (b) introductory text and (b)(2);

■ b. Revising paragraph (c)(2);

■ c. Revising paragraph (e);

■ d. Revising paragraph (g)(2); and

■ e. Adding paragraph (g)(3).

The revisions and addition read as follows:

§ 413.232 Low-volume adjustment.

* * * * *

(b) *Definition of low-volume facility.* A low-volume facility is an ESRD facility that, as determined based on the documentation submitted pursuant to paragraph (g) of this section:

* * * * *

(2) Has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

(c) * * *

(2) Five (5) road miles or less from the ESRD facility in question.

* * * * *

(e) Except as provided in paragraph (f) of this section and unless extraordinary circumstances justify an exception, to receive the low-volume adjustment an ESRD facility must provide an attestation statement, by November 1st of each year preceding the payment year, to its Medicare Administrative Contractor that the facility meets all the criteria established in this section, except that, for calendar year 2012, the attestation must be provided by January 3, 2012, for calendar year 2015, the attestation must be provided by December 31, 2014, and for calendar year 2016, the attestation must be provided by December 31, 2015.

* * * * *

(g) * * *

(2) In the case of an ESRD facility that has undergone a change of ownership wherein the ESRD facility's Medicare billing number does not change or changes due to a reclassification of facility type, the MAC relies upon the attestation and if the change results in two non-standard cost reporting periods (less than or greater than 12 consecutive months) does one of the following for the 3 cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorates the data to equal a full 12-consecutive month period.

(3) In the case of an ESRD facility that has changed its cost reporting period, the MAC relies on the attestation and does one or both of the following for the 3-cost reporting years preceding the payment year to verify the number of treatments:

(i) Combines the two non-standard cost reporting periods of less than 12 months to equal a full 12-consecutive month period; and/or

(ii) Combines the two non-standard cost reporting periods that in combination may exceed 12-consecutive

months and prorates the data to equal a full 12-consecutive month period.

■ 5. Section 413.234 is amended (effective January 1, 2020)—

■ a. In paragraph (a) by removing the definition of ''New injectable or intravenous product'' and adding the definition of ''New renal dialysis drug or biological product'' in alphabetical order; and

■ b. By revising paragraphs (b) and (c).

The addition and revisions read as follows:

§ 413.234 Drug designation process.

(a) * * *

New renal dialysis drug or biological product. An injectable, intravenous, oral or other form or route of administration drug or biological product that is used to treat or manage a condition(s) associated with ESRD. It must be approved by the Food and Drug Administration (FDA) on or after January 1, 2020, under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, have an HCPCS application submitted in accordance with the official Level II HCPCS coding procedures, and designated by CMS as a renal dialysis service under § 413.171. Oral-only drugs are excluded until January 1, 2025.

* * * * *

(b) *Drug designation process.* New renal dialysis drugs or biological products are included in the ESRD PPS bundled payment using the following drug designation process:

(1) If the new renal dialysis drug or biological product is used to treat or manage a condition for which there is an ESRD PPS functional category, the new renal dialysis drug or biological product is considered included in the ESRD PPS bundled payment and the following steps occur:

(i) The new renal dialysis drug or biological product is added to an existing ESRD PPS functional category.

(ii) The new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(1) of this section.

(2) If the new renal dialysis drug or biological product is used to treat or manage a condition for which there is not an ESRD PPS functional category, the new renal dialysis drug or biological product is not considered included in the ESRD PPS bundled payment and the following steps occur:

(i) An existing ESRD PPS functional category is revised or a new ESRD PPS functional category is added for the condition that the new renal dialysis drug or biological product is used to treat or manage;

(ii) The new renal dialysis drug or biological product is paid for using the transitional drug add-on payment adjustment described in paragraph (c)(2) of this section; and

(iii) The new renal dialysis drug or biological product is added to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

(c) *Transitional drug add-on payment adjustment.* A new renal dialysis drug or biological product is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of Average Sales Price (ASP), except that for calcimimetics it is based on the pricing methodologies under section 1847A of the Social Security Act. If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of Wholesale Acquisition Cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

(1) A new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment for 2 years.

(i) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will not be modified.

(ii) [Reserved]

(2) A new renal dialysis drug or biological product that is not considered included in the ESRD PPS base rate is paid the transitional drug add-on payment adjustment until sufficient claims data for rate setting analysis for the new renal dialysis drug or biological product is available, but not for less than 2 years.

(i) Following payment of the transitional drug add-on payment adjustment the ESRD PPS base rate will be modified, if appropriate, to account for the new renal dialysis drug or biological in the ESRD PPS bundled payment.

(ii) [Reserved]

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 6. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(l) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(l)).

■ 7. Section 414.210 is amended by—

■ a. Revising paragraphs (g)(4), (7) and (9); and

■ b. Adding paragraph (g)(10).

The revisions and addition read as follows:

§ 414.210 General payment rules.

* * * * *

(g) * * *

(4) *Payment adjustments using data on items and services included in competitive bidding programs no longer in effect.* In the case where adjustments to fee schedule amounts are made using any of the methodologies described, other than paragraph (g)(10) of this section, if the adjustments are based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts are updated before being used to adjust the fee schedule amounts. The single payment amounts are updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) from the mid-point of the last year the single payment amounts were in effect to the month ending 6 months prior to the date the initial fee schedule reductions go into effect. Following the initial adjustments to the fee schedule amounts, if the adjustments continue to be based solely on single payment amounts from competitive bidding programs that are no longer in effect, the single payment amounts used to reduce the fee schedule amounts are updated every 12 months using the percentage change in the CPI–U for the 12-month period ending 6 months prior to the date the updated payment adjustments would go into effect.

* * * * *

(7) *Payment adjustments for mail order items furnished in the Northern Mariana Islands.* The fee schedule amounts for mail order items furnished to beneficiaries in the Northern Mariana Islands are adjusted so that they are equal to 100 percent of the single payment amounts established under a national mail order competitive bidding program. Beginning on or after the date that the Northern Mariana Islands are included under a national mail order competitive bidding program, the fee schedule adjustment methodology under this paragraph no longer applies.

* * * * *

(9) *Transition rules.* The payment adjustments described above are phased in as follows:

(i) For applicable items and services furnished with dates of service from January 1, 2016 through December 31, 2016, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(ii) For items and services furnished with dates of service from January 1, 2017, through May 31, 2018, the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

(iii) For items and services furnished in rural areas and non-contiguous areas (Alaska, Hawaii, and U.S. territories) with dates of service from June 1, 2018 through December 31, 2020, based on the fee schedule amount for the area is equal to 50 percent of the adjusted payment amount established under this section and 50 percent of the unadjusted fee schedule amount.

(iv) For items and services furnished in areas other than rural or noncontiguous areas with dates of service from June 1, 2018 through December 31, 2020, based on the fee schedule amount for the area is equal to 100 percent of the adjusted payment amount established under this section.

(10) *Payment adjustments for items and services furnished in former competitive bidding areas during temporary gaps in the DMEPOS CBP.* During a temporary gap in the entire DMEPOS CBP and/or National Mail Order CBP, the fee schedule amounts for items and services that were competitively bid and furnished in areas that were competitive bidding areas at the time the program(s) was in effect are adjusted based on the SPAs in effect in the competitive bidding areas on the last day before the CBP contract period of performance ended, increased by the projected percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) for the 12-month period ending on the date after the contract periods ended. If the gap in the CBP lasts for more than 12 months, the fee schedule amounts are increased once every 12 months on the anniversary date of the first day of the gap period based on the projected percentage change in the CPI–U for the 12-month period ending on the anniversary date.

■ 8. Section 414.222 is amended by adding paragraph (f) to read as follows:

§ 414.222 Items requiring frequent and substantial servicing.

* * * * *

(f) *Multi-function ventilators*—(1) Definition. For the purpose of this paragraph (f), a multi-function ventilator is a ventilator as defined in paragraph (a)(1) of this section that also performs medically necessary functions for the patient at the same time that would otherwise be performed by one or more different items classified under § 414.220, § 414.226, or § 414.229.

(2) *Payment rule.* Effective for dates of service on or after January 1, 2019, the monthly rental fee schedule amount for a multi-function ventilator described in paragraph (f)(1) of this section is equal to the monthly rental fee schedule amount for the ventilator established in paragraph (c) and paragraph (d) of this section plus the average of the lowest monthly cost for one additional function determined under paragraph (f)(3) of this section and the monthly cost of all additional functions determined under paragraph (f)(3) of this section, increased by the annual covered item updates of section 1834(a)(14) of the Act.

(3) *Monthly cost for additional functions.* (i) For functions performed by items classified under this section prior to 1994, the monthly cost is equal to the monthly rental fee schedule amount established in paragraphs (c) and (d) of this section increased by the covered item update of section 1834(a)(14) of the Act.

(ii) For functions performed by items classified under § 414.220, the monthly cost is equal to the fee schedule amount for purchased equipment established in § 414.220(c), (d), (e), and (f), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

(iii) For functions performed by items classified under § 414.226, the monthly cost is equal to the monthly payment amount established in § 414.226(e) and (f), adjusted in accordance with § 414.210(g), multiplied by 36 and divided by 60 months or total number of months of the reasonable useful lifetime of the oxygen equipment.

(iv) For functions performed by items classified under § 414.229, the monthly cost is equal to the purchase price established in § 414.229(c), adjusted in accordance with § 414.210(g), divided by 60 months or total number of months of the reasonable useful lifetime of the equipment.

■ 9. Section 414.226 is amended—

■ a. By revising the heading of paragraph (c);

■ b. By revising paragraph (c)(6);

■ c. By revising the heading of paragraph (d);

■ d. In paragraph (d)(2) by removing the reference ''paragraph (e)(2)'' and adding in its place the reference ''paragraph (g)(2)'';

■ e. By redesignating paragraphs (e), (f) and (g) as paragraphs (g), (h), and (i);

■ f. By adding new paragraphs (e) and (f).

■ g. In newly redesignated paragraph (g)(1)(i), by removing the reference ''paragraph (e)(2)'' and adding in its place the reference ''paragraph (g)(2)''; and

■ h. In newly redesignated paragraph (g)(2)(ii), by removing the reference ''paragraph (e)(2)(i)'' and adding in its place the reference ''paragraph (g)(2)(i)''.

The revisions and additions read as follows:

§ 414.226 Oxygen and oxygen equipment.

* * * * *

(c) *Monthly fee schedule amount for items furnished from 2007 through 2018.* * * *

* * * * *

(6) For 2008 through 2018, CMS makes an annual adjustment to the national limited monthly payment rate for items described in paragraph (c)(1)(i) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(d) *Application of monthly fee schedule amounts for items furnished from 2007 through 2018.* * * *

* * * * *

(e) *Monthly fee schedule amount for items furnished for years after 2018.* (1) For 2019, national limited monthly payment rates are calculated and paid as the monthly fee schedule amounts for the following classes of items:

(i) Stationary oxygen equipment (including stationary concentrators) and oxygen contents (stationary and portable).

(ii) Portable gaseous equipment only.

(iii) Portable liquid equipment only.

(iv) Oxygen generating portable equipment only.

(v) Stationary oxygen contents only.

(vi) Portable oxygen contents only, except for portable liquid oxygen contents for prescribed flow rates greater than four liters per minute.

(vii) Portable liquid oxygen contents only for prescribed flow rates of more than 4 liters per minute.

(2) The monthly payment rate for items described in paragraphs (e)(1)(i), (ii), (iv), (v), and (vi) of this section are determined using the applicable methodologies contained in § 414.210(g).

(3) The monthly payment rate for items described in paragraph (e)(1)(iii) of this section is determined initially based on the monthly payment rate for items described in paragraph (e)(1)(iv) of this section and is subsequently adjusted using the applicable methodologies contained in § 414.210(g).

(4) The monthly payment rate for items described in paragraph (e)(1)(vii)

of this section is determined initially based on 150 percent of the monthly payment rate for items described in paragraph (e)(1)(vi) of this section and is subsequently adjusted using the applicable methodologies contained in § 414.210(g).

(5) Beginning in 2019, CMS makes an annual adjustment to the monthly payment rate for items described in paragraphs (e)(1)(i) through (e)(1)(vii) of this section to ensure that such payment rates do not result in expenditures for any year that are more or less than the expenditures that would have been made if such classes had not been established.

(f) *Application of monthly fee schedule amounts for items furnished for years after 2018.* (1) The fee schedule amount for items described in paragraph (e)(1)(i) of this section is paid when the beneficiary rents stationary oxygen equipment.

(2) Subject to the limitation set forth in paragraph (g)(2) of this section, the fee schedule amount for items described in paragraphs (e)(1)(ii), (iii), and (iv) of this section is paid when the beneficiary rents portable oxygen equipment.

(3) The fee schedule amount for items described in paragraph (e)(1)(v) of this section is paid when the beneficiary—

(i) Owns stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents; or

(ii) Rents stationary oxygen equipment that requires delivery of gaseous or liquid oxygen contents after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(4) The fee schedule amount for items described in paragraph (e)(1)(vi) of this section is paid when the beneficiary—

(i) Owns portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section; or Code of Federal Regulations/Title 42—Public Health/Vol. 3/2017–10–0166

(ii) Rents portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable oxygen equipment described in paragraphs (e)(1)(ii) or (e)(1)(iii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

(5) The fee schedule amount for items described in paragraph (e)(1)(vii) of this section is paid when the beneficiary has a prescribed flow rate of more than 4 liters per minute and—

(i) Owns portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section; or Code of Federal Regulations/Title 42—Public Health/Vol. 3/2017–10–0166

(ii) Rents portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section during the period of continuous use of 36 months described in paragraph (a)(1) of this section and does not rent stationary oxygen equipment; or

(iii) Rents portable liquid oxygen equipment described in paragraph (e)(1)(iii) of this section after the period of continuous use of 36 months described in paragraph (a)(1) of this section.

* * * * *

§ 414.230 [Amended]

■ 10. Section 414.230 is amended in paragraph (h) by removing the reference ''§ 414.226(f)'' and adding in its place the reference ''§ 414.226(h)''.

■ 11. Section 414.402 is amended by revising the definitions of ''Bid'' and ''Composite bid'', and adding the definition of ''Lead item'' in alphabetical order to read as follows:

§ 414.402 Definitions.

* * * * *

Bid means an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items.

* * * * *

Composite bid means the bid submitted by the supplier for the lead item in the product category.

* * * * *

Lead item is the item in a product category with multiple items with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition.

* * * * *

■ 12. Section 414.412 is amended—

■ a. By revising paragraphs (b)(1) and (2);

■ b. By revising paragraph (c);

■ c. By removing paragraph (d); and

■ d. By redesignating paragraphs (e) through (h) as paragraphs (d) through (g), respectively;

■ e. In newly redesignated paragraph (e)(2) by removing the reference ''paragraph (f)(1)'' and adding in its place the reference ''(e)(1)''; and

■ f. In newly redesignated paragraph (g)(2)(i)(D) by removing the reference ''paragraph (h)(3)'' and adding in its place the reference '' paragraph (g)(3)''.

The revisions read as follows:

§ 414.412 Submission of bids under a competitive bidding program.

* * * * *

(b) * * *

(1) Composite bids, as defined in § 414.402, are submitted for lead items, as defined in § 414.402.

(2) The bid submitted for each lead item and product category cannot exceed the payment amount that would otherwise apply to the lead item under subpart C of this part, without the application of § 414.210(g), or subpart D of this part, without the application of § 414.105.

* * * * *

(c) Furnishing of items. A bid must include all costs related to furnishing all items in the product category, including all services directly related to the furnishing of the items.

* * * * *

■ 13. Section 414.414 is amended by revising paragraph (e) to read as follows:

§ 414.414 Conditions for awarding contracts.

* * * * *

(e) Evaluation of bids. CMS evaluates composite bids submitted for a lead item within a product category by—

(1) Calculating the expected beneficiary demand in the CBA for the lead item in the product category;

(2) Calculating the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the lead item in the product category;

(3) Arraying the composite bids from the lowest composite bid price to the highest composite bid price;

(4) Calculating the pivotal bid for the product category; and

(5) Selecting all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category, and that meet the requirements in paragraphs (b) through (d) of this section.

* * * * *

■ 14. Section 414.416 is amended by revising paragraph (b) to read as follows:

§ 414.416 Determination of competitive bidding payment amounts.

* * * * *

(b) *Methodology for setting payment amount.* (1) The single payment amount for a lead item furnished under a competitive bidding program is equal to the maximum bid submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category.

(2) The single payment amount for a lead item must be less than or equal to

the amount that would otherwise be paid for the same item under subpart C or subpart D of this part.

(3) The single payment amount for an item in a product category furnished under a competitive bidding program that is not a lead item for that product category is equal to the single payment amount for the lead item in the same product category multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, the United States Virgin Islands), for the item to the average of the 2015 fee schedule amounts for all areas for the lead item.

§ 414.422 [Amended]

■ 15. Section 414.422 is amended by redesignating paragraphs (d)(4)(iii) through (d)(4)(vi) as paragraphs (d)(4)(ii) through (d)(4)(v).

■ 16. Section 414.423 is amended by revising paragraph (i)(8) to read as follows:

§ 414.423 Appeals process for breach of a DMEPOS competitive bidding program contract actions.

* * * * *

(i) * * *

(8) Comply with all applicable provisions of Title 18 and related provisions of the Act, the applicable regulations issued by the Secretary, and manual instructions issued by CMS.

* * * * *

Dated: October 26, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: October 29, 2018.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–24238 Filed 11–1–18; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 83 Wednesday,
No. 220 November 14, 2018

Part III

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 218

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the U.S. Navy Training and Testing Activities in the Atlantic Fleet Training and Testing Study Area; Final Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 218

[Docket No. 170720687–8965–02]

RIN 0648–BH06

Taking and Importing Marine Mammals; Taking Marine Mammals Incidental to the U.S. Navy Training and Testing Activities in the Atlantic Fleet Training and Testing Study Area

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

ACTION: Final rule.

SUMMARY: NMFS, upon request from the U.S. Navy (Navy), issues these regulations pursuant to the Marine Mammal Protection Act (MMPA) to govern the taking of marine mammals incidental to the training and testing activities conducted in the Atlantic Fleet Training and Testing (AFTT) Study Area over the course of five years beginning in November. These regulations, which allow for the issuance of Letters of Authorization (LOA) for the incidental take of marine mammals during the described activities and timeframes, prescribe the permissible methods of taking and other means of effecting the least practicable adverse impact on marine mammal species or stocks and their habitat, and establish requirements pertaining to the monitoring and reporting of such taking.

DATES: Effective from November 14, 2018 through November 13, 2023.

ADDRESSES: A copy of the Navy's application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.* In case of problems accessing these documents, please call the contact listed below (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT: Stephanie Egger, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Purpose of Regulatory Action

These regulations, issued under the authority of the MMPA (16 U.S.C. 1361 *et seq.*), establish a framework for authorizing the take of marine mammals incidental to the Navy's training and testing activities (categorized as military readiness activities) from the use of sonar and other transducers, in-water detonations, air guns, impact pile driving/vibratory extraction, and potential vessel strikes based on Navy movement throughout the AFTT Study Area, which includes areas of the western Atlantic Ocean along the East Coast of North America, portions of the Caribbean Sea, and the Gulf of Mexico (GOMEX).

We received an application from the Navy requesting five-year regulations and authorizations to incidentally take individuals of multiple species and stocks of marine mammals (''Navy's rulemaking/LOA application'' or ''Navy's application''). Take is anticipated to occur by Level A and Level B harassment as well as a very small number of serious injuries or mortalities incidental to the Navy's training and testing activities.

Section 101(a)(5)(A) of the MMPA (16 U.S.C. 1371(a)(5)(A)) directs 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, after notice and public comment, the agency makes certain findings and issues regulations that set forth permissible methods of taking pursuant to that activity, as well as monitoring and reporting requirements. Section 101(a)(5)(A) of the MMPA and the implementing regulations at 50 CFR part 216, subpart I, provide the legal basis for issuing this final rule and the subsequent LOAs. As directed by this legal authority, this final rule contains mitigation, monitoring, and reporting requirements.

Summary of Major Provisions Within the Final Rule

Following is a summary of the major provisions of this final rule regarding the Navy's activities. Major provisions include, but are not limited to:

- The use of defined powerdown and shutdown zones (based on activity);
- Measures to reduce or eliminate the likelihood of ship strikes, especially for North Atlantic right whales (*Eubalaena glacialis*) (NARW);
- Operational limitations in certain areas and times that are biologically important (*i.e.,* for foraging, migration, reproduction) for marine mammals;
- Implementation of a Notification and Reporting Plan (for dead, live stranded, or marine mammals struck by a vessel); and
- Implementation of a robust monitoring plan to improve our understanding of the environmental effects resulting from Navy training and testing activities.

Additionally, the rule includes an adaptive management component that allows for timely modification of mitigation or monitoring measures based on new information, when appropriate.

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 and the opportunity to submit comments.

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, other means of effecting the least practicable adverse impact on the species or stocks, and requirements pertaining to the monitoring and reporting of such takings are set forth. The MMPA states that the term ''take'' means to harass, hunt, capture, kill or attempt to harass, hunt, capture, or kill any marine mammal.

The National Defense Authorization Act of 2004 (2004 NDAA) (Pub. L. 108–136) amended section 101(a)(5) of the MMPA to remove the ''small numbers'' and ''specified geographical region'' provisions indicated above and amended the definition of ''harassment'' as it applies to a ''military readiness activity,'' along with certain research activities. The definitions of applicable MMPA statutory terms cited above are included in the relevant sections below.

More recently, the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (2019 NDAA) (Pub. L. 115–232) amended the MMPA to allow incidental take rules for military readiness activities to be issued for up to seven years. That recent amendment of the MMPA does not affect this final rule.

Summary and Background of Request

On June 16, 2017, NMFS received an application from the Navy for authorization to take marine mammals incidental to training and testing activities (categorized as military readiness activities) from the use of sonar and other transducers, in-water detonations, air guns, and impact pile driving/vibratory extraction in the AFTT Study Area. In addition, the Navy requested incidental take authorization for up to nine mortalities of four marine mammal species during ship shock trials, and authorization for up to three takes by serious injury or mortality from vessel strikes over the five-year period. On August 4, 2017, the Navy sent an amendment to its application, and the application was found to be adequate and complete. On August 14, 2017 (82 FR 37851), we published a notice of receipt of application (NOR) in the **Federal Register**, requesting comments and information related to the Navy's request for 30 days. On March 13, 2018, we published a notice of the proposed rulemaking (83 FR 10954) and requested comments and information related to the Navy's request for 45 days. On April 9, 2018, a proposed rule correction (83 FR 15117), which corrected *Table 4. Proposed Training* was published in the **Federal Register**. Sections of the table were missing from the preamble, specifically Amphibious Warfare, Anti-Submarine Warfare, Expeditionary Warfare, Mine Warfare, and a portion of Surface Warfare. Comments received during the NOR and the proposed rulemaking comment periods are addressed in this final rule. See further details addressing comments received in the *Comments and Responses* section. On September 13, 2018, Navy provided NMFS with a memorandum revising the takes by serious injury or mortality included in the Navy's rulemaking/LOA application (Chapter 5, Section 5.2 *Incidental Take Request from Vessel Strikes*). Specifically, after further analysis, the Navy withdrew the inclusion of the Western North Atlantic stock of blue whale and the Northern GOMEX stock of sperm whale from its request for authorization for take of three (3) large whales by serious injury or mortality from vessel strike. The information and assessment that supports this change is included in the *Estimated Take of Marine Mammals* section.

The Navy requested two five-year LOAs, one for training and one for testing activities to be conducted within the AFTT Study Area, which includes areas of the western Atlantic Ocean along the East Coast of North America, portions of the Caribbean Sea, and the GOMEX. Please refer to the Navy's rulemaking/LOA application, specifically Figure 1.1–1 for a map of the AFTT Study Area and Figures 2.2–1 through Figure 2.2–3 for additional maps of the range complexes and testing ranges.

The following types of training and testing, which are classified as military readiness activities pursuant to the MMPA, as amended by the 2004 NDAA, will be covered under the regulations and associated LOAs: amphibious warfare (in-water detonations), anti-submarine warfare (sonar and other transducers, in-water detonations), expeditionary warfare (in-water detonations), surface warfare (in-water detonations), mine warfare (sonar and other transducers, in-water detonations), and other warfare activities (sonar and other transducers, impact pile driving/vibratory extraction, air guns). In addition, ship shock trials, a specific testing activity related to vessel evaluation, will be conducted. Also, ship strike by Navy vessels is addressed and covered, as appropriate.

This will be NMFS' third series of rulemaking under the MMPA for activities in the AFTT Study Area. NMFS published the first rule effective from January 22, 2009 through January 22, 2014 on January 27, 2009 (74 FR 4844) and the second rule effective from November 14, 2013 through November 13, 2018 on December 4, 2013 (78 FR 73009). These regulations are also valid for five years, from November 14, 2018, through November 13, 2023.

The Navy's mission is to organize, train, equip, and maintain combat-ready naval forces capable of winning wars, deterring aggression, and maintaining freedom of the seas. This mission is mandated by federal law (10 U.S.C. 5062), which ensures the readiness of the naval forces of the United States. The Navy executes this responsibility by establishing and executing training and testing programs, including at-sea training and testing exercises, and ensuring naval forces have access to the ranges, operating areas (OPAREAs), and airspace needed to develop and maintain skills for conducting naval activities.

The Navy plans to conduct training and testing activities within the AFTT Study Area. The Navy has been conducting military readiness activities in the AFTT Study Area for well over a century and with active sonar for over 70 years. The tempo and types of training and testing activities have fluctuated because of the introduction of new technologies, the evolving nature of international events, advances in warfighting doctrine and procedures, and changes in force structure (organization of ships, weapons, and personnel). Such developments influenced the frequency, duration, intensity, and location of required training and testing activities. This rulemaking reflects the most up to date compilation of training and testing activities deemed necessary to accomplish military readiness requirements. The types and numbers of activities included in the rule accounts for fluctuations in training and testing in order to meet evolving or emergent military readiness requirements.

These regulations cover training and testing activities that would occur for a five-year period following the expiration of the current MMPA authorization for the AFTT Study Area, which expires on November 13, 2018.

Description of the Specified Activity

Additional detail regarding the specified activity was provided in our **Federal Register** notice of proposed rulemaking (83 FR 10954; March 13, 2018); please see that proposed rule or the Navy's application for more information. Since the proposed rule, the Navy has removed one of its testing activities in the Northeast Range Complex (four events for Undersea Warfare Testing (USWT), which decreased the number of takes by Level B harassment for the NARW by 115 takes annually. This change also decreased take by Level B harassment by approximately 200 takes annually for Endangered Species Act (ESA)-listed fin whale and 20 takes annually for sei whales as well as approximately 10,000 takes annually for harbor porpoise. NMFS and the Navy have also reached agreement on additional mitigation measures since the proposed rule, which are summarized below and discussed in greater detail in the *Mitigation Measures* section of this rule.

The Navy agrees to implement pre- and post-event observations as part of all in-water explosive event mitigations in the AFTT Study Area. The Navy has expanded the Northeast (NE) NARW Mitigation Area to match the updated NE NARW ESA-designated critical habitat. The Navy has agreed to broadcast awareness notification messages with NARW Dynamic Management Area information (*e.g.,* location and dates) to alert vessels to the possible presence of a NARW to further reduce the potential for a vessel strike. The Navy has agreed to additional coordination to aid in the implementation of procedural mitigation to minimize potential interactions with NARW in the

Jacksonville Operating Area. The Navy will also report the total hours and counts of active sonar and in-water explosives used in a Southeast (SE) NARW Critical Habitat Special Reporting Area in its annual training and testing activity reports submitted to NMFS. The Navy will minimize use of explosives (March to September) in the Navy Cherry Point Range Complex Nearshore Mitigation Area to the extent practicable.

In addition, the Navy will not conduct major training exercises (MTE) in the Gulf of Maine Planning Awareness Mitigation Area and the GOMEX Planning Awareness Mitigation Area. The Navy will also implement a 200 hour (hr)/year hull-mounted mid-frequency active sonar (MFAS) cap in the Gulf of Maine Planning Awareness Mitigation Area. The Navy has added a year-round, Bryde's Whale Mitigation Area, which will cover the biologically important area (BIA) as described in NMFS' 2016 Status Review (NMFS 2016) and implement a 200 hr/year hull-mounted MFAS cap and restrict all explosives except for mine warfare activities events in this mitigation area. The Navy has assessed and agreed to move the ship shock trial box east of the Mid-Atlantic Planning Awareness Mitigation Areas and move the northern GOMEX ship shock trial west of the Bryde's Whale Mitigation Area, including five nmi buffers from the mitigation areas.

The Navy has also revised its estimated serious injury or mortality takes of large whales and, as a result, withdrawn its request for serious injury or mortality incidental take for the Western North Atlantic stock of blue whale and Northern GOMEX stock of sperm whale due to the extremely low probability that vessel strike incidental to the training and testing activities in the AFTT Study Area would occur.

Overview of Training and Testing Activities

The Navy routinely trains and tests in the AFTT Study Area in preparation for national defense missions. Training and testing activities and exercises covered in these regulations are summarized below.

Primary Mission Areas

The Navy categorizes its activities into functional warfare areas called primary mission areas. These activities generally fall into the following seven primary mission areas: Air warfare; amphibious warfare; anti-submarine warfare (ASW); electronic warfare; expeditionary warfare; mine warfare (MIW); and surface warfare (SUW). Most activities addressed in the AFTT Final Environmental Impact Statement/Overseas Environmental Impact Statement (FEIS/OEIS) are categorized under one of the primary mission areas; the testing community has three additional categories of activities for vessel evaluation (including ship shock trials), unmanned systems, and acoustic and oceanographic science and technology. Activities that do not fall within one of these areas are listed as ''other warfare activities.'' Each warfare community (surface, subsurface, aviation, and expeditionary warfare) may train in some or all of these primary mission areas. The testing community also categorizes most, but not all, of its testing activities under these primary mission areas.

The Navy describes and analyzes the impacts of its training and testing activities within the AFTT FEIS/OEIS and the Navy's rulemaking/LOA application (documents available at *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities*). In its assessment, the Navy concluded that sonar and other transducers, in-water detonations, air guns, and pile driving/extraction were the stressors that would result in impacts on marine mammals that could rise to the level of harassment (also serious injury or mortality in ship shock trials or by vessel strike) as defined under the MMPA. Therefore, the rulemaking/LOA application provides the Navy's assessment of potential effects from these stressors in terms of the various warfare mission areas in which they would be conducted. In terms of Navy's primary warfare areas, this includes:

- Amphibious warfare (in-water detonations);
- anti-submarine warfare (sonar and other transducers, in-water detonations);
- expeditionary warfare (in-water detonations);
- surface warfare (in-water detonations);
- mine warfare (sonar and other transducers, in-water detonations); and
- other warfare activities (sonar and other transducers, impact pile driving/vibratory extraction, air guns).

Overview of Training Activities and Exercises Within the AFTT Study Area

An MTE is comprised of several ''unit level'' range exercises conducted by several units operating together while commanded and controlled by a single commander. These exercises typically employ an exercise scenario developed to train and evaluate the strike group in naval tactical tasks. In a MTE, most of the activities being directed and coordinated by the strike group commander are identical in nature to the activities conducted during individual, crew, and smaller unit level training events. In a MTE, however, these disparate training tasks are conducted in concert, rather than in isolation.

Some integrated or coordinated ASW exercises are similar in that they are comprised of several unit level exercises but are generally on a smaller scale than a MTE, are shorter in duration, use fewer assets, and use fewer hours of hull-mounted sonar per exercise. These coordinated exercises are conducted under anti-submarine warfare. For the purpose of analysis, three key factors used to identify and group the exercises are the scale of the exercise, duration of the exercise, and amount of hull-mounted sonar hours modeled/used for the exercise. NMFS considered the effects of all training exercises, not just the major training exercises in these regulations. Additional detail regarding the training activities was provided in our **Federal Register** notice of proposed rulemaking (83 FR 10954; March 13, 2018) and a proposed rule correction (83 FR 15117; April 9, 2018); please see those documents or the Navy's application for more information.

Overview of Testing Activities Within the AFTT Study Area

The Navy's research and acquisition community engages in a broad spectrum of testing activities in support of the fleet. These activities include, but are not limited to, basic and applied scientific research and technology development; testing, evaluation, and maintenance of systems (*e.g.,* missiles, radar, and sonar) and platforms (*e.g.,* surface ships, submarines, and aircraft); and acquisition of systems and platforms to support Navy missions and give a technological edge over adversaries. The individual commands within the research and acquisition community included in the Navy's rulemaking/LOA application are the Naval Air Systems Command, Naval Sea Systems Command, and the Office of Naval Research. Additional detail regarding the testing activities was provided in our **Federal Register** notice of proposed rulemaking (83 FR 10954; March 13, 2018); please see that proposed rule or the Navy's application for more information.

Dates and Duration

The specified activities may occur at any time during the five-year period of validity of the regulations. Planned number and duration of training and

testing activities are shown in the *Planned Activities* section (Tables 4 through 7).

Specific Geographic Area

The Navy's training and testing activities conducted within the AFTT Study Area (which includes areas of the western Atlantic Ocean along the East Coast of North America, portions of the Caribbean Sea, and the GOMEX), covers approximately 2.6 million square nautical miles (nmi ^{2}) of ocean area, oriented from the mean high tide line along the U.S. coast and extends east to the 45-degree west longitude line, north to the 65-degree north latitude line, and south to approximately the 20-degree north latitude line. Please refer to the Navy's rulemaking/LOA application, specifically Figure 1.1–1 for a map of the AFTT Study Area and Figures 2.2–1 through Figure 2.2–3 for additional maps of the range complexes and testing ranges.

Description of Acoustic and Explosive Stressors

The planned training and testing activities were evaluated to identify specific components that could act as stressors (acoustic and explosive) by having direct or indirect impacts on the environment. This analysis included identification of the spatial variation of the identified stressors.

The Navy uses a variety of sensors, platforms, weapons, and other devices, including ones used to ensure the safety of Sailors and Marines, to meet its mission. Training and testing with these systems may introduce acoustic (sound) energy into the environment. The Navy's rulemaking/LOA application describes specific components that could act as stressors by having direct or indirect impacts on the environment. This analysis included identification of the spatial variation of the identified stressors. The following subsections describe the acoustic and explosive stressors for biological resources within the AFTT Study Area. Because of the complexity of analyzing sound propagation in the ocean environment, the Navy relies on acoustic models in its environmental analyses that consider sound source characteristics and varying ocean conditions across the AFTT Study Area. Stressor/resource interactions that were determined to have de minimus or no impacts (*i.e.,* vessel, aircraft, or weapons noise) were not carried forward for analysis in the Navy's rulemaking/LOA application. NMFS reviewed the Navy's analysis and conclusions and finds them complete and supportable.

Acoustic Stressors

Acoustic stressors include acoustic signals emitted into the water for a specific purpose, such as sonar, other transducers (devices that convert energy from one form to another—in this case, to sound waves), and air guns, as well as incidental sources of broadband sound produced as a byproduct of impact pile driving and vibratory extraction. Explosives also produce broadband sound but are characterized separately from other acoustic sources due to their unique characteristics. In order to better organize and facilitate the analysis of approximately 300 sources of underwater sound used for training and testing by the Navy including sonars, other transducers, air guns, and explosives, a series of source classifications, or source bins, were developed. The source classification bins do not include the broadband sounds produced incidental to pile driving, vessel or aircraft transits, weapons firing, and bow shocks.

The use of source classification bins provides the following benefits: Provides the ability for new sensors or munitions to be covered under existing authorizations, as long as those sources fall within the parameters of a ''bin;'' improves efficiency of source utilization data collection and reporting requirements anticipated under the MMPA authorizations; ensures a conservative approach to all impact estimates, as all sources within a given class are modeled as the most impactful source (highest source level, longest duty cycle, or largest net explosive weight) within that bin; allows analyses to be conducted in a more efficient manner, without any compromise of analytical results; and provides a framework to support the reallocation of source usage (hours/explosives) between different source bins, as long as the total numbers of takes remain within the overall analyzed and authorized limits. This flexibility is required to support evolving Navy training and testing requirements, which are linked to real world events.

Sonar and Other Transducers

Active sonar and other transducers emit non-impulsive sound waves into the water to detect objects, safely navigate, and communicate. Passive sonars differ from active sound sources in that they do not emit acoustic signals; rather, they only receive acoustic information about the environment, or listen.

The Navy employs a variety of sonars and other transducers to obtain and transmit information about the undersea environment. Some examples are mid-frequency hull-mounted sonars used to find and track enemy submarines; high-frequency small object detection sonars used to detect mines; high frequency underwater modems used to transfer data over short ranges; and extremely high-frequency (>200 kilohertz [kHz]) Doppler sonars used for navigation, like those used on commercial and private vessels.

Additional detail regarding sound sources and platforms and categories of acoustic stressors was provided in our **Federal Register** notice of proposed rulemaking (83 FR 10954; March 13, 2018); please see that proposed rule or the Navy's application for more information.

Sonars and other transducers are grouped into classes that share an attribute, such as frequency range or purpose of use. Classes are further sorted by bins based on the frequency or bandwidth; source level; and, when warranted, the application in which the source would be used, as follows:

- Frequency of the non-impulsive acoustic source;
  - Low-frequency sources operate below 1 kHz;
  - Mid-frequency sources operate at and above 1 kHz, up to and including 10 kHz;
  - High-frequency sources operate above 10 kHz, up to and including 100 kHz;
  - Very high-frequency sources operate above 100 kHz but below 200 kHz;
- Sound pressure level of the non-impulsive source;
  - Greater than 160 decibels (dB) re 1 micro Pascal (μPa), but less than 180 dB re 1 μPa;
  - Equal to 180 dB re 1 μPa and up to 200 dB re 1 μPa;
  - Greater than 200 dB re 1 μPa;
- Application in which the source would be used;
  - Sources with similar functions that have similar characteristics, such as pulse length (duration of each pulse), beam pattern, and duty cycle.

The bins used for classifying active sonars and transducers that are quantitatively analyzed in the AFTT Study Area are shown in Table 1 below. While general parameters or source characteristics are shown in the table, actual source parameters are classified.

TABLE 1—SONAR AND TRANSDUCERS QUANTITATIVELY ANALYZED IN THE AFTT STUDY AREA

Source class category	Bin	Description
Low-Frequency (LF): Sources that produce signals less than 1 kHz.	LF3	LF sources greater than 200 dB.
	LF4	LF sources equal to 180 dB and up to 200 dB.
	LF5	LF sources less than 180 dB.
	LF6	LF sources greater than 200 dB with long pulse lengths.
Mid-Frequency (MF): Tactical and non-tactical sources that produce signals between 1–10 kHz.	MF1	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–53C and AN/SQS–61).
	MF1K	Kingfisher mode associated with MF1 sonars.
	MF3	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).
	MF4	Helicopter-deployed dipping sonars (*e.g.,* AN/AQS–22 and AN/AQS–13).
	MF5	Active acoustic sonobuoys (*e.g.,* DICASS).
	MF6	Active underwater sound signal devices (*e.g.,* MK84).
	MF8	Active sources (greater than 200 dB) not otherwise binned.
	MF9	Active sources (equal to 180 dB and up to 200 dB) not otherwise binned.
	MF10	Active sources (greater than 160 dB, but less than 180 dB) not otherwise binned.
	MF11	Hull-mounted surface ship sonars with an active duty cycle greater than 80%.
	MF12	Towed array surface ship sonars with an active duty cycle greater than 80%.
	MF14	Oceanographic MF sonar.
High-Frequency (HF): Tactical and non-tactical sources that produce signals between 10–100 kHz.	HF1	Hull-mounted submarine sonars (*e.g.,* AN/BQQ–10).
	HF3	Other hull-mounted submarine sonars (classified).
	HF4	Mine detection, classification, and neutralization sonar (*e.g.,* AN/SQS–20).
	HF5	Active sources (greater than 200 dB) not otherwise binned.
	HF6	Active sources (equal to 180 dB and up to 200 dB) not otherwise binned.
	HF7	Active sources (greater than 160 dB, but less than 180 dB) not otherwise binned.
	HF8	Hull-mounted surface ship sonars (*e.g.,* AN/SQS–61).
Very High-Frequency Sonars (VHF): Non-tactical sources that produce signals between 100–200 kHz.	VHF1	VHF sources greater than 200 dB.
Anti-Submarine Warfare (ASW): Tactical sources (e.g., active sonobuoys and acoustic counter-measures systems) used during ASW training and testing activities.	ASW1	MF systems operating above 200 dB.
	ASW2	MF Multistatic Active Coherent sonobuoy (*e.g.,* AN/SSQ–125).
	ASW3	MF towed active acoustic countermeasure systems (*e.g.,* AN/SLQ–25).
	ASW4	MF expendable active acoustic device countermeasures (*e.g.,* MK 3).
	ASW5	MF sonobuoys with high duty cycles.
Torpedoes (TORP): Source classes associated with the active acoustic signals produced by torpedoes.	TORP1	Lightweight torpedo (*e.g.,* MK 46, MK 54, or Anti-Torpedo Torpedo).
	TORP2	Heavyweight torpedo (*e.g.,* MK 48).
	TORP3	Heavyweight torpedo (*e.g.,* MK 48).
Forward Looking Sonar (FLS): Forward or upward looking object avoidance sonars used for ship navigation and safety.	FLS2	HF sources with short pulse lengths, narrow beam widths, and focused beam patterns.
Acoustic Modems (M): Systems used to transmit data through the water.	M3	MF acoustic modems (greater than 190 dB).
Swimmer Detection Sonars (SD): Systems used to detect divers and sub- merged swimmers.	SD1–SD2	HF and VHF sources with short pulse lengths, used for the detection of swimmers and other objects for the purpose of port security.
Synthetic Aperture Sonars (SAS): Sonars in which active acoustic signals are post-processed to form high-resolution images of the seafloor.	SAS1	MF SAS systems.
	SAS2	HF SAS systems.
	SAS3	VHF SAS systems.
	SAS4	MF to HF broadband mine countermeasure sonar.
Broadband Sound Sources (BB): Sonar systems with large frequency spectra, used for various purposes.	BB1	MF to HF mine countermeasure sonar.
	BB2	HF to VHF mine countermeasure sonar.
	BB4	LF to MF oceanographic source.
	BB5	LF to MF oceanographic source.
	BB6	HF oceanographic source.
	BB7	LF oceanographic source.

Notes: ASW: Anti-submarine Warfare; BB: Broadband Sound Sources; FLS: Forward Looking Sonar; HF: High-Frequency; LF: Low-Frequency; M: Acoustic Modems; MF: Mid-Frequency; SAS: Synthetic Aperture Sonars; SD: Swimmer Detection Sonars; TORP: Torpedoes; VHF: Very High-Frequency; dB: decibels.

Air guns

Small air guns with capacities up to 60 cubic inches (in^3) would be used during testing activities in various offshore areas in the AFTT Study Area, as well as near shore at Newport, RI.

Generated impulses would have short durations, typically a few hundred milliseconds, with dominant frequencies below 1 kHz. The root-mean-square sound pressure level (SPL) and peak pressure (SPL peak) at a distance 1 meter (m) from the airgun would be approximately 215 dB re 1 µPa and 227 dB re 1 µPa, respectively, if operated at the full capacity of 60 in^3 cubic inches.

Pile Driving/Extraction

Impact pile driving and vibratory pile removal would occur during construction of an Elevated Causeway System (ELCAS), a temporary pier that allows the offloading of ships in areas without a permanent port. The source levels of the noise produced by impact pile driving and vibratory pile removal from an actual elevated causeway pile driving and removal are shown in Table 2.

TABLE 2—ELEVATED CAUSEWAY SYSTEM PILE DRIVING AND REMOVAL UNDERWATER SOUND LEVELS IN THE AFTT STUDY AREA

Pile size and type	Method	Average sound levels at 10 m
24-in. Steel Pipe Pile	Impact [1]	192 dB re 1 µPa SPL rms; 182 dB re 1 µPa ^{2}s SEL (single strike).
24-in. Steel Pipe Pile	Vibratory [2]	146 dB re 1 µPa SPL rms; 145 dB re 1 µPa ^{2}s SEL (per second of duration).

[1] Illingworth and Rodkin (2016).
[2] Illingworth and Rodkin (2015).
Notes: dB re 1 µPa: decibels referenced to 1 micropascal; in.: inch; rms: root mean squared; SEL: Sound Exposure Level; SPL: Sound Pressure Level.

The size of the pier in an ELCAS event is approximately 1,520 ft long, requiring 119 supporting piles. Construction of the ELCAS would involve intermittent impact pile driving over approximately 20 days. Crews work 24 hours (hrs) a day and would drive approximately 6 piles in that period. Each pile takes about 15 minutes to drive with time taken between piles to reposition the driver. When training events that use the ELCAS are complete, the structure would be removed using vibratory methods over approximately 10 days. Crews would remove about 12 piles per 24-hour period, each taking about 6 minutes to remove.

Explosive Stressors

This section describes the characteristics of explosions during naval training and testing. The activities analyzed in the Navy's rulemaking/LOA application that use explosives are described in Appendix A (Navy Activity Descriptions) of the AFTT FEIS/OEIS. Additional detail regarding explosive stressors was provided in our **Federal Register** notice of proposed rulemaking (83 FR 10954; March 13, 2018); please see that proposed rule or the Navy's application for more information.

Explosive detonations during training and testing activities are associated with high-explosive munitions, including, but not limited to, bombs, missiles, rockets, naval gun shells, torpedoes, mines, demolition charges, and explosive sonobuoys. Explosive detonations during training and testing involving the use of high-explosive munitions (including bombs, missiles, and naval gun shells) could occur near the water's surface. Explosive detonations associated with torpedoes and explosive sonobuoys would occur in the water column; mines and demolition charges could be detonated in the water column or on the ocean bottom. Most detonations would occur in waters greater than 200 ft in depth, and greater than 3 nmi from shore, although mine warfare, demolition, and some testing detonations would occur in shallow water close to shore.

In order to better organize and facilitate the analysis of explosives used by the Navy during training and testing that could detonate in water or at the water surface, explosive classification bins were developed. Explosives detonated in water are binned by net explosive weight. The bins of explosives that are planned for use in the AFTT Study Area are shown in Table 3 below.

TABLE 3—EXPLOSIVES ANALYZED IN THE AFTT STUDY AREA

Bin	Net explosive weight [1] (lb)	Example explosive source
E1	0.1–0.25	Medium-caliber projectile.
E2	>0.25–0.5	Medium-caliber projectile.
E3	>0.5–2.5	Large-caliber projectile.
E4	>2.5–5	Mine neutralization charge.
E5	>5–10	5-inch projectile.
E6	>10–20	Hellfire missile.
E7	>20–60	Demo block/shaped charge.
E8	>60–100	Light-weight torpedo.
E9	>100–250	500 lb. bomb.
E10	>250–500	Harpoon missile.
E11	>500–650	650 lb mine.
E12	>650–1,000	2,000 lb bomb.
E14 [2]	>1,741–3,625	Line charge.
E16	>7,250–14,500	Littoral Combat Ship full ship shock trial.
E17	>14,500–58,000	Aircraft carrier full ship shock trial.

[1] Net Explosive Weight refers to the equivalent amount of TNT the actual weight of a munition may be larger due to other components.
[2] E14 is not modeled for protected species impacts in water because most energy is lost into the air or to the bottom substrate due to detonation in very shallow water.

Explosive Fragments

Marine mammals could be exposed to fragments from underwater explosions associated with the specified activities. When explosive ordnance (*e.g.,* bombs or missiles) detonates, fragments of the weapons are thrown at high-velocity from the detonation point, which can injure or kill marine mammals if they are struck. These fragments may be of variable size and are ejected at supersonic speed from the detonation. The casing fragments will be ejected at velocities much greater than debris from any target due to the proximity of the casing to the explosive material. Risk of fragment injury reduces exponentially with distance as the fragment density is reduced. Fragments underwater tend to be larger than fragments produced by in-air explosions (Swisdak and Montaro, 1992). Underwater, the friction of the water would quickly slow these fragments to a point where they no longer pose a threat. In contrast, the blast wave from an explosive detonation moves efficiently through seawater. Because the ranges to mortality and injury due to exposure to the blast wave are likely to far exceed the zone where fragments could injure or kill an animal, the threshold are assumed to encompass risk due to fragmentation.

Other Stressor—Vessel Strike

Vessel strikes are not specific to any particular training or testing activity, but rather a potential, limited, sporadic, and incidental result of Navy vessel movement within the AFTT Study Area. The average speed of large Navy ships ranges between 10 and 15 knots and submarines generally operate at speeds in the range of 8–13 knots, while a few specialized vessels can travel at faster speeds. Vessel strikes are likely to result in incidental take from serious injury and/or mortality and, accordingly, for the purposes of the analysis we assume that any authorized ship strike would result in serious injury or mortality. Information on Navy vessel movements is provided in the *Planned Activities* section. Additional detail on vessel strike was provided in our **Federal Register** notice of proposed rulemaking (83 FR 10954; March 13, 2018); please see that proposed rule or the Navy's application for more information. Additionally, as referenced above and described in more detail in the *Estimated Take of Marine Mammals* section, on September 13, 2018 the Navy provided additional information explaining why and withdrew certain species from their request for serious injury or mortality takes from vessel strike.

Planned Activities

Planned Training Activities

The training activities that the Navy plans to conduct in the AFTT Study Area are summarized in Table 4. The table is organized according to primary mission areas and includes the activity name, associated stressors applicable to these regulations, number of planned activities, and locations of those activities in the AFTT Study Area. For further information regarding the primary platform used (*e.g.,* ship or aircraft type) see Appendix A (Navy Activity Descriptions) of the AFTT FEIS/OEIS.

Table 4. Proposed Training Activities Analyzed within the AFTT Study Area.

Stressor Category	*Activity Name*	*Description*	*Source Bin*[1]	*Annual # of Activities*	*5-Year # of Activities*	*Location*[3]	*Duration per Activity*
Major Training Exercise – Large Integrated ASW							
Acoustic	Composite Training Unit Exercise	Aircraft carrier and its associated aircraft integrate with surface and submarine units in a challenging multi-threat operational environment in order to certify them for deployment.	ASW1, ASW2, ASW3, ASW4, ASW5, HF1, LF6, MF1, MF3, MF4, MF5, MF11, MF12	2–3[2]	12	VACAPES RC Navy Cherry Point RC JAX RC	21 days
Major Training Exercises – Medium Integrated Anti-Submarine Warfare							
Acoustic	Fleet Exercises/Sustainment Exercise	Aircraft carrier and its associated aircraft integrates with surface and submarine units in a challenging multi-threat operational environment in order to maintain their ability to deploy.	ASW1, ASW2, ASW3, ASW4, HF1, LF6, MF1, MF3, MF4, MF5, MF11, MF12	4	20	JAX RC	Up to 10 days
				2	10	VACAPES RC	
Integrated/Coordinated Training – Small Integrated Anti-Submarine Warfare Training							
Acoustic	Naval Undersea Warfare Training Assessment Course	Multiple ships, aircraft, and submarines integrate the use of their sensors to search for, detect, classify, localize, and track a threat submarine in order to launch an exercise torpedo.	ASW1, ASW3, ASW4, HF1, LF6, MF1, MF3, MF4, MF5, MF12	6	30	JAX RC	2-5 days
				3	15	Navy Cherry Point RC	
				3	15	VACAPES RC	
Integrated/Coordinated Training – Medium Coordinated Anti-Submarine Warfare Training							
Acoustic	Anti-Submarine Warfare Tactical Development Exercise	Surface ships, aircraft, and submarines coordinate to search for, detect, and track	ASW1, ASW3, ASW4, HF1,	2	10	JAX RC	5-7 days
				1	5	Navy Cherry Point RC	

		submarines.	LF6, MF1, MF3, MF4, MF5, MF11, MF12	1	5	VACAPES RC	
Integrated/Coordinated Training – Small Coordinated Anti-Submarine Warfare Training							
Acoustic	Group Sail	Surface ships and helicopters search for, detect, and track threat submarines.	ASW2, ASW3, ASW4, HF1, MF1, MF3, MF4, MF5, MF11, MF12	4	20	JAX RC	2-3 days
				5	25	Navy Cherry Point RC	
				5	25	VACAPES RC	
Amphibious Warfare							
Explosive	Naval Surface Fire Support Exercise – At Sea	Surface ship crews use large-caliber guns to support forces ashore; however, the land target is simulated at sea. Rounds are scored by passive acoustic buoys located at or near the target area.	E5	4	20	GOMEX RC	1-2 hrs of firing, 8 hrs total
				12	60	JAX RC	
				2	10	Navy Cherry Point RC	
				38	190	VACAPES RC	
Anti-Submarine Warfare							
Acoustic	Anti-submarine Warfare Torpedo Exercise – Helicopter	Helicopter aircrews search for, track, and detect submarines. Recoverable air launched torpedoes are employed against submarine targets.	MF4, MF5, TORP1	14	70	JAX RC	2-5 hrs
				4	20	VACAPES RC	
Acoustic	Anti-submarine Warfare Torpedo Exercise – Maritime Patrol Aircraft	Maritime patrol aircraft aircrews search for, track, and detect submarines. Recoverable air launched torpedoes are employed against submarine targets.	MF5, TORP1	14	70	JAX RC	2-8 hrs
				4	20	VACAPES RC	
Acoustic	Anti-Submarine Warfare Torpedo Exercise –Ship	Surface ship crews search for, track, and detect submarines. Exercise torpedoes are used.	ASW3, MF1, TORP1	16	80	JAX RC	2-5 hrs
				5	25	VACAPES RC	
Acoustic	Anti-Submarine Warfare Torpedo Exercise – Submarine	Submarine crews search for, track, and detect submarines. Exercise torpedoes are used.	ASW4, HF1, MF3, TORP2	12	60	JAX RC	8 hrs
				6	30	Northeast RC	
				2	10	VACAPES RC	

Acoustic	Anti-Submarine Warfare Tracking Exercise – Helicopter	Helicopter aircrews search for, track, and detect submarines.	MF4, MF5	24	120	Other AFTT Areas	2-4 hrs
				370	1,850	JAX RC	
				12	60	Navy Cherry Point RC	
				8	40	VACAPES RC	
Acoustic	Anti-Submarine Warfare Tracking Exercise – Maritime Patrol Aircraft	Maritime patrol aircraft aircrews search for, track, and detect submarines.	ASW5, ASW2, MF5	90	450	Northeast RC	2-8 hrs
				176	880	VACAPES RC	
				525	2,625	JAX RC	
				46	230	Navy Cherry Point RC	
Acoustic	Anti-Submarine Warfare Tracking Exercise – Ship	Surface ship crews search for, track, and detect submarines.	ASW1, ASW3, MF1, MF11, MF12	5*	25*	Northeast RC	2-4 hrs
				110*	550*	Other AFTT Areas	
				5*	25*	GOMEX RC	
				440*	2,200*	JAX RC	
				55*	275*	Navy Cherry Point RC	
				220*	1,100*	VACAPES RC	
Acoustic	Anti-Submarine Warfare Tracking Exercise – Submarine	Submarine crews search for, track, and detect submarines.	ASW4, HF1, MF3	44	220	Other AFTT Areas	8 hrs
				13	65	JAX RC	
				1	5	Navy Cherry Point RC	
				18	90	Northeast RC	
				6	30	VACAPES RC	
Expeditionary Warfare							
Explosive	Maritime Security Operations – Anti-Swimmer Grenades	Small boat crews engage in force protection activities by using anti-swimmer grenades to defend against hostile divers.	E2	2	10	GOMEX RC	1 hr
				2	10	JAX RC	
				2	10	Navy Cherry Point RC	
				4	20	Northeast RC	
				5	25	VACAPES RC	
Mine Warfare							
Acoustic	Airborne Mine Countermeasure -	Helicopter aircrews detect mines using	HF4	66	330	GOMEX RC	2 hrs

	Mine Detection	towed or laser mine detection systems.		317	1,585	JAX RC	
				371	1,855	Navy Cherry Point RC	
				244	1,220	NSWC Panama City	
				1,540	7,700	VACAPES RC	
Acoustic, Explosive	Civilian Port Defense – Homeland Security Anti-Terrorism/Force Protection Exercise	Maritime security personnel train to protect civilian ports against enemy efforts to interfere with access to those ports.	HF4, SAS2 E2, E4	1	3	Beaumont, TX; Boston, MA; Corpus Christi, TX; Delaware Bay, DE; Earle, NJ; GOMEX RC; Hampton Roads, VA; JAX RC; Kings Bay, GA; NS Mayport; Morehead City, NC; Port Canaveral, FL; Savannah, GA; Tampa Bay, FL; VACAPES RC; Wilmington, DE	Multiple days
Acoustic	Coordinated Unit Level Helicopter Airborne Mine Countermeasure Exercise	A detachment of helicopter aircrews train as a unit in the use of airborne mine countermeasures, such as towed mine detection and neutralization systems.	HF4	2	10	GOMEX RC	Multiple days
				2	10	JAX RC	
				2	10	Navy Cherry Point RC	
				2	10	VACAPES RC	
Acoustic, Explosive	Mine Countermeasures – Mine Neutralization – Remotely Operated Vehicle	Ship, small boat, and helicopter crews locate and disable mines using remotely operated underwater vehicles.	HF4, E4	132	660	GOMEX RC	1.5-4 hrs
				71	355	JAX RC	
				71	355	Navy Cherry Point RC	
				630	3,150	VACAPES RC	

Acoustic	Mine Countermeasures – Ship Sonar	Ship crews detect and avoid mines while navigating restricted areas or channels using active sonar.	HF4	22	110	GOMEX RC	1.5-4 hrs
				53	265	JAX RC	
				53	265	VACAPES RC	
Explosive	Mine Neutralization – Explosive Ordnance Disposal	Personnel disable threat mines using explosive charges.	E4, E5, E6, E7	6	30	Lower Chesapeake Bay	Up to 4 hrs
				16	80	GOMEX RC	
				20	100	JAX RC	
				17	85	Key West RC	
				16	80	Navy Cherry Point RC	
				524	2,620	VACAPES RC	
Surface Warfare							
Explosive	Bombing Exercise Air-to-Surface	Fixed-wing aircrews deliver bombs against surface targets.	E9, E10, E12	67	335	GOMEX RC	1 hr
				434	2,170	JAX RC	
				108	540	Navy Cherry Point RC	
				329	1,645	VACAPES RC	
Explosive	Gunnery Exercise Surface-to-Surface Boat Medium-Caliber	Small boat crews fire medium-caliber guns at surface targets.	E1	6	30	GOMEX RC	1 hr
				26	130	JAX RC	
				128	640	Navy Cherry Point RC	
				2	10	Northeast RC	
				260	1,300	VACAPES RC	
Explosive	Gunnery Exercise Surface-to-Surface Ship Large-Caliber	Surface ship crews fire large-caliber guns at surface targets.	E3,E5	10	50	Other AFTT Areas	Up to 3 hrs
				9	45	GOMEX RC	
				51	255	JAX RC	
				35	175	Navy Cherry Point RC	
				75	375	VACAPES RC	
Explosive	Gunnery Exercise Surface-to-Surface Ship Medium-Caliber	Surface ship crews fire medium-caliber guns at surface targets.	E1	41	205	Other AFTT Areas	2-3 hrs
				33	165	GOMEX RC	
				161	805	JAX RC	

				72	360	Navy Cherry Point RC	
				321	1,605	VACAPES RC	
Explosive	Integrated Live Fire Exercise	Naval forces defend against a swarm of surface threats (ships or small boats) with bombs, missiles, rockets, and small-, medium- and large-caliber guns.	E1, E3, E6, E10	2	10	VACAPES RC	6-8 hrs
				2	10	JAX RC	
Explosive	Missile Exercise Air-to-Surface	Fixed-wing and helicopter aircrews fire air-to-surface missiles at surface targets.	E6, E8, E10	102	510	JAX RC	1 hr
				52	260	Navy Cherry Point RC	
				88	440	VACAPES RC	
Explosive	Missile Exercise Air-to-Surface – Rocket	Helicopter aircrews fire both precision-guided and unguided rockets at surface targets.	E3	10	50	GOMEX RC	1 hr
				102	510	JAX RC	
				10	50	Navy Cherry Point RC	
				92	460	VACAPES RC	
Explosive	Missile Exercise Surface-to-Surface	Surface ship crews defend against surface threats (ships or small boats) and engage them with missiles.	E6, E10	16	80	JAX RC	2-5 hrs
				12	60	VACAPES RC	
Acoustic, Explosive	Sinking Exercise	Aircraft, ship, and submarine crews deliberately sink a seaborne target, usually a decommissioned ship (made environmentally safe for sinking according to U.S. Environmental Protection Agency standards), with a variety of munitions.	TORP2, E5, E8, E9, E10, E11	1	5	SINKEX Box	4-8 hrs, possibly over 1-2 days
Other Training Activities							
Acoustic	Elevated Causeway System	A temporary pier is constructed off the beach. Supporting pilings are driven into the sand and then later removed.	Impact hammer or vibratory extractor	1	5	Lower Chesapeake Bay	Up to 20 days for construction, and up to 10 days for removal
				1	5	Navy Cherry Point RC	
Acoustic	Submarine Navigation	Submarine crews operate sonar for	HF1, MF3	169	845	NSB New London	Up to 2 hrs

		navigation and object detection while transiting into and out of port during reduced visibility.		3	15	NSB Kings Bay	
				3	15	NS Mayport	
				84	420	NS Norfolk	
				23	115	Port Canaveral, FL	
Acoustic	Submarine Sonar Maintenance	Maintenance of submarine sonar systems is conducted pierside or at sea.	MF3	12	60	Other AFTT Areas	Up to 1 hr
				66	330	NSB New London	
				9	45	JAX RC	
				2	10	NSB Kings Bay	
				34	170	NS Norfolk	
				86	430	Northeast RC	
				2	10	Port Canaveral, FL	
				13	63	Navy Cherry Point RC	
				47	233	VACAPES RC	
Acoustic	Submarine Under Ice Certification	Submarine crews train to operate under ice. Ice conditions are simulated during training and certification events.	HF1	3	15	JAX RC	Up to 6 hrs per day over 5 days
				3	15	Navy Cherry Point RC	
				9	45	Northeast RC	
				9	45	VACAPES RC	
Acoustic	Surface Ship Object Detection	Surface ship crews operate sonar for navigation and object detection while transiting in and out of port during reduced visibility.	HF8, MF1K	76	380	NS Mayport	Up to 2 hrs
				162	810	NS Norfolk	
Acoustic	Surface Ship sonar Maintenance	Maintenance of surface ship sonar systems is conducted pierside or at sea.	HF8, MF1	50	250	JAX RC	Up to 4 hrs
				50	250	NS Mayport	
				120	600	Navy Cherry Point RC	
				235	1,175	NS Norfolk	
				120	600	VACAPES RC	

[1]Additional activities utilizing sources not listed in the Sonar Bin column may occur during integrated/coordinated exercises. All acoustic sources that may be used during training and testing activities have been accounted for in the modeling and analysis.

[2] For activities where the maximum number of events could vary between years, the information is presented as 'representative-maximum' number of events per year. For activities where no variation is anticipated, only the maximum number of events within a single year is provided.

[3] Locations given are areas where activities typically occur. However, activities could be conducted in other locations within the AFTT Study Area. Where multiple locations are provided within a single cell, the number of activities could occur in any of the locations, not in each of the locations.

* For anti-submarine warfare tracking exercise – Ship, the Planned Activity, 50 percent of requirements are met through synthetic training or other training exercises

Notes: GOMEX: Gulf of Mexico; JAX: Jacksonville; NS: Naval Station; NSB: Naval Submarine Base; NSWC: Naval Surface Warfare Center; RC: Range Complex; VACAPES: Virginia Capes

Planned Testing Activities

Testing activities covered in these regulations are described in Table 5 through Table 7.

Naval Air Systems Command

Table 5 summarizes the planned testing activities for the Naval Air Systems Command analyzed within the AFTT Study Area.

Table 5. Planned Naval Air Systems Command Testing Activities Analyzed in the AFTT Study Area.

Stressor Category	*Activity Name*	*Activity Description*	*Source Bin*	*Annual # of Activities* [1]	*5-Year # of Activities*	*Location* [2]	*Duration per Activity*
Anti-Submarine Warfare							
Acoustic	Anti-Submarine Warfare Torpedo Test	This event is similar to the training event torpedo exercise. Test evaluates anti-submarine warfare systems onboard rotary-wing (e.g., helicopter) and fixed-wing aircraft and the ability to search for, detect, classify, localize, track, and attack a submarine or similar target.	MF5, TORP1	20–43	146	JAX RC	2-6 flight hrs per event
				40–121	362	VACAPES RC	
Acoustic, Explosive	Anti-Submarine Warfare Tracking Test – Helicopter	This event is similar to the training event anti-submarine warfare tracking exercise – helicopter. The test evaluates the sensors and systems used to detect and track submarines and to ensure that helicopter systems used to deploy the tracking system perform to specifications.	MF4, MF5, E3	4–6	24	GOMEX RC	2 flight hrs per event
				0–12	24	JAX RC	
				2–27	35	Key West RC	
				28–110	304	Northeast RC	
				137–280	951	VACAPES RC	
Acoustic, Explosive	Anti-Submarine Warfare Tracking Test – Maritime Patrol Aircraft	The test evaluates the sensors and systems used by maritime patrol aircraft to detect and track submarines and to ensure that aircraft systems used to deploy the tracking systems perform to specifications and meet operational requirements.	ASW2, ASW5, E1, E3, MF5, MF6	10–15	60	GOMEX RC	4-6 flight hrs per event
				19	95	JAX RC	
				10–12	54	Key West RC	
				14–15	72	Navy Cherry Point RC	
				36–45	198	Northeast Point RC	

				25	125	VACAPES RC	
Acoustic	Kilo Dip	Functional check of a helicopter deployed dipping sonar system prior to conducting a testing or training event using the dipping sonar system.	MF4	2–6	14	GOMEX RC	1.5 flight hrs per event
				0–6	6	JAX RC	
				0–6	6	Key West RC	
				0–4	8	Northeast RC	
				20–40	140	VACAPES RC	
Acoustic, Explosive	Sonobuoy Lot Acceptance Test	Sonobuoys are deployed from surface vessels and aircraft to verify the integrity and performance of a production lot or group of sonobuoys in advance of delivery to the fleet for operational use.	ASW2, ASW5, HF5, HF6, LF4, MF5, MF6, E1, E3, E4	160	800	Key West RC	6 flight hrs per event
Mine Warfare							
Acoustic	Airborne Dipping Sonar Minehunting Test	A mine-hunting dipping sonar system deployed from a helicopter and uses high-frequency sonar for the detection and classification of bottom and moored mines.	HF4	16-32	96	NSWC Panama City	2 flight hrs per event
				6-18	42	VACAPES RC	
Explosive	Airborne Mine Neutralization System Test	A test of the airborne mine neutralization system evaluates the system's ability to detect and destroy mines from an airborne mine countermeasures capable helicopter. The airborne mine neutralization system uses up to four unmanned underwater vehicles equipped with high-frequency sonar, video cameras, and explosive and non-explosive neutralizers	E4	20-27	107	NSWC Panama City	2.5 flight hrs per event
				25-45	145	VACAPES RC	

Acoustic	Airborne Sonobuoy Minehunting Test	A mine-hunting system made up of a field of sonobuoys deployed by a helicopter. A field of sonobuoys, using high-frequency sonar, is used to detect and classify bottom and moored mines.	HF6	52	260	NSWC Panama City	2 flight hrs per event
				24	120	VACAPES RC	
Surface Warfare							
Explosive	Air-to-Surface Bombing Test	This event is similar to the training event bombing exercise air-to-surface. Fixed-wing aircraft test the delivery of bombs against surface maritime targets with the goal of evaluating the bomb, the bomb carry and delivery system, and any associated systems that may have been newly developed or enhanced.	E9	20	100	VACAPES RC	2 flight hrs per event
Explosive	Air-to-Surface Gunnery Test	This event is similar to the training event gunnery exercise air-to-surface. Fixed-wing and rotary-wing aircrews evaluate new or enhanced aircraft guns against surface maritime targets to test that the guns, gun ammunition, or associated systems meet required specifications or to train aircrews in the operation of a new or enhanced weapon system.	E1	25–55	215	JAX RC	2-2.5 flight hrs per event
				110–140	640	VACAPES RC	
Explosive	Air-to-Surface Missile Test	This event is similar to the training event missile exercise air-to-surface. Test may involve both fixed-wing and rotary-wing aircraft launching missiles at surface maritime targets to evaluate the weapon system or as part of another system's integration test.	E6, E9, E10	0–10	20	GOMEX RC	2-4 flight hrs per event
				29–38	167	JAX RC	
				117–148	663	VACAPES RC	
Explosive	Rocket Test	Rocket tests evaluate the integration, accuracy, performance, and safe separation of guided and unguided 2.75-inch rockets fired from a hovering or forward-flying helicopter.	E3	15–19	87	JAX RC	1.5-2.5 hrs per event
				31–35	167	VACAPES RC	

Other Testing Activities							
Acoustic	Undersea Range System Test	Following installation of a Navy underwater warfare training and testing range, tests of the nodes (components of the range) will be conducted to include node surveys and testing of node transmission functionality.	MF9 BB4	4–20	42	JAX RC	8 hrs

[1] For activities where the maximum number of events could vary between years, the information is presented as 'representative-maximum' number of events per year. For activities where no variation is anticipated, only the maximum number of events within a single year is provided.
[2] Locations given are areas where activities typically occur. However, activities could be conducted in other locations within the AFTT Study Area.
Notes: GOMEX: GOMEX; JAX: Jacksonville; NSWC: Naval Surface Warfare Center; RC: Range Complex; VACAPES: Virginia Capes

Naval Sea Systems Command

Table 6 summarizes the planned testing activities for the Naval Sea Systems Command analyzed within the AFTT Study Area.

Table 6. Planned Naval Sea Systems Command Testing Activities Analyzed in the AFTT Study Area.

Stressor Category	*Activity Name*	*Activity Description*	*Source Bin*	*Annual # of Activities*[1]	*5-Year # of Activities*	*Location*[2]	*Duration*
Anti-Submarine Warfare							
Acoustic	Anti-Submarine Warfare Mission Package Testing	Ships and their supporting platforms (e.g., helicopters, unmanned aerial systems) detect, localize, and attack submarines.	ASW1, ASW2, ASW3, ASW5, MF1, MF4, MF5, MF12, TORP1	42	210	JAX RC	1-2 wks, with 4-8 hrs of active sonar use with intervals on non-activity in between
				4	20	Newport, RI	
				4	20	NUWC Newport	
				26	130	VACAPES RC	
Acoustic	At-Sea Sonar Testing	At-sea testing to ensure systems are fully functional in an open ocean environment.	ASW3, ASW4, HF1, LF5, M3, MF1, MF1K, MF3, MF5, MF9, MF11, TORP2	2	10	JAX RC Navy Cherry Point RC Northeast RC VACAPES RC	From 4 hrs to 11 days
				1	5	JAX RC Navy Cherry Point RC VACAPES RC	
				2	10	offshore Fort Pierce, FL GOMEX RC JAX RC SFOMF Northeast RC VACAPES RC	
				4	20	JAX RC	
				2	10	Navy Cherry Point RC	
				8	40	NUWC Newport	
				12	60	VACAPES RC	
Acoustic	Pierside Sonar Testing	Pierside testing to ensure systems are fully functional in a controlled pierside	ASW3, HF1, HF3, HF8, M3, MF1,	1	5	NSB New London NS Norfolk Port Canaveral, FL	Up to 3 wks total per ship, with each source run independently and not
				11	55	Bath, ME	

		environment prior to at-sea test activities.	MF1K, MF3, MF9, MF10	5	25	NSB New London	continuously during this time.
				4	20	NSB Kings Bay	
				8	40	Newport, RI	
				13	65	NS Norfolk	
				2	10	Pascagoula, MS	
				3	15	Port Canaveral, FL	
				2	10	PNS	
Acoustic	Submarine Sonar Testing/ Maintenance	Pierside testing of submarine systems occurs periodically following major maintenance periods and for routine maintenance.	HF1, HF3, M3, MF3	16	80	Norfolk, VA	Up to 3 wks, with intermittent use of active sonar
				24	120	PNS	
Acoustic	Surface Ship Sonar Testing/ Maintenance	Pierside and at-sea testing of ship systems occur periodically following major maintenance periods and for routine maintenance.	ASW3, MF1, MF1K, MF9, MF10	1	5	JAX RC	Up to 3 wks, with intermittent use of active sonar
				1	5	NS Mayport	
				3	15	NS Norfolk	
				3	15	VACAPES RC	
Acoustic, Explosive	Torpedo (Explosive) Testing	Air, surface, or submarine crews employ explosive and non-explosive torpedoes against artificial targets.	ASW3, HF1, HF5, HF6, MF1, MF3, MF4, MF5, MF6, TORP1, TORP2, E8, E11	4	20	GOMEX RC offshore Fort Pierce, FL Key West RC Navy Cherry Point RC Northeast RC VACAPES RC	1-2 day during daylight hrs
				2	10	GOMEX RC JAX RC Northeast RC VACAPES RC	
Acoustic	Torpedo (Non-	Air, surface, or submarine crews	ASW3, ASW4,	7	35	GOMEX RC	Up to 2 wks

	Explosive) Testing	employ non-explosive torpedoes against submarines or surface vessels. When performed on a testing range, these torpedoes may be launched from a range craft or fixed structures and may use artificial targets.	HF1, HF6, MF1, MF3, MF4, MF5, MF6, TORP1, TORP2, TORP 3	11	55	offshore Fort Pierce, FL	
				2	8	JAX RC	
				7	35	Navy Cherry Point RC	
				8	38	Northeast RC	
				30	150	NUWC Newport	
				11	55	VACAPES RC	
Acoustic	Counter-measure Testing	Countermeasure testing involves the testing of systems that will detect, localize, track, and attack incoming weapons including marine vessel targets. Testing includes surface ship torpedo defense systems and marine vessel stopping payloads.	ASW3, HF5, TORP1, TORP2	5	25	GOMEX RC JAX RC NUWC Newport VACAPES RC Key West RC	From 4 hrs to 6 days, depending on countermeasure being tested
				2-4	14	GOMEX RC JAX RC Northeast RC VACAPES RC	
Mine Warfare							
Explosive	Mine Counter-measure and Neutralization Testing	Air, surface, and subsurface vessels neutralize threat mines and mine-like objects.	E4, E11	13	65	NSWC Panama City	1-10 days, with intermittent use of countermeasure/ neutralization system during this period
				6	30	VACAPES RC	
Acoustic, Explosive	Mine Counter-measure Mission Package Testing	Vessels and associated aircraft conduct mine countermeasure operations.	HF4, SAS2, E4	19	95	GOMEX RC	1-2 wks with intervals of mine countermeasure mission package use during this time
				10	50	JAX RC	
				11	55	NSWC Panama City	
				2	10	SFOMF	

				5	25	VACAPES RC	
Acoustic	Mine Detection and Classification Testing	Air, surface, and subsurface vessels and systems detect, classify, and avoid mines and mine-like objects. Vessels also assess their potential susceptibility to mines and mine-like objects.	HF1,HF 4, HF8, MF1, MF1K, MF9	6	30	GOMEX RC	Up to 24 days, with up to 12 hrs of acoustic activity each day
				10	50	Navy Cherry Point RC	
				47-55	250	NSWC Panama City	
				7-12	43	Riviera Beach, FL	
				4	20	SFOMF	
				3	15	VACAPES RC	
Surface Warfare							
Explosive	Gun Testing – Large Caliber	Crews defend against targets with large-caliber guns.	E3, E5	12	60	GOMEX RC JAX RC Key West RC Navy Cherry Point RC Northeast RC VACAPES RC	1-2 wks
				1	5	GOMEX RC	
				1	5	JAX RC	
				1	5	Key West RC	
				1	5	Navy Cherry Point RC	
				1	5	Northeast RC	
				33	165	NSWC Panama City	
				5	25	VACAPES RC	
Explosive	Gun Testing – Medium-Caliber	Airborne and surface crews defend against targets with medium-caliber guns.	E1	12	60	GOMEX RC JAX RC Key West RC Navy Cherry Point RC Northeast RC VACAPES RC	1-2 wks, with intervals of gun testing
				102	510	NSWC Panama City	

				5	24	VACAPES RC	
Explosive	Missile and Rocket Testing	Missile and rocket testing includes various missiles or rockets fired from submarines and surface combatants. Testing of the launching system and ship defense is performed.	E6, E10	13	65	GOMEX RC JAX RC Key West RC Navy Cherry Point RC Northeast RC VACAPES RC	1 day to 2 wks
				1	5	GOMEX RC	
				2	10	JAX RC	
				5	25	Northeast RC	
				22	110	VACAPES RC	
Unmanned Systems							
Acoustic, Explosive	Unmanned Underwater Vehicle Testing	Testing involves the development or upgrade of unmanned underwater vehicles. This may include testing of mine detection capabilities, evaluating the basic functions of individual platforms, or complex events with multiple vehicles.	ASW4, FLS2, HF1, HF4, HF5, HF6, HF7, LF5, MF9, MF10, SAS1, SA2, SAS3, VHF1, E8	16	80	GOMEX RC JAX RC NUWC Newport	Up to 35 days. Some propulsion systems (gliders) could operate continuously for multiple months.
				41	205	GOMEX RC	
				25	125	JAX RC	
				145-146	727	NSWC Panama City	
				308-309	1,541	NUWC Newport	
				9	45	Riviera Beach, FL	
				42	210	SFOMF	
Vessel Evaluation							
Explosive	Large Ship Shock Trial	Underwater detonations are used to test new ships or major upgrades.	E17	0-1	1	GOMEX JAX RC VACAPES RC	Typically over 4 wks, with 1 detonation per week. However, smaller charges

							may be detonated on consecutive days.
Explosive	Surface Warfare Testing	Tests capability of shipboard sensors to detect, track, and engage surface targets. Testing may include ships defending against surface targets using explosive and non-explosive rounds, gun system structural test firing and demonstration of the response to Call for Fire against land-based targets (simulated by sea-based locations).	E1, E5, E8	2	10	GOMEX RC	7 days
				13	65	JAX RC	
				1	5	Key West RC	
				10	50	Northeast RC	
				9	45	VACAPES RC	
Acoustic	Undersea Warfare Testing	Ships demonstrate capability of countermeasure systems and underwater surveillance, weapons engagement, and communications systems. This tests ships' ability to detect, track, and engage underwater targets.	ASW3, ASW4, HF4, HF8, MF1, MF1K, MF4, MF5, MF9, MF10, TORP1, TORP2	2	10	JAX RC VACAPES RC	Up to 10 days
				0-2	4	JAX RC VACAPES RC Navy Cherry Point RC SFOMF	
				2	10	GOMEX RC	
				6	30	JAX RC	
				2	10	VACAPES RC	
Explosive	Small Ship Shock Trial	Underwater detonations are used to test new ships or major upgrades.	E16	0-3	3	JAX RC VACAPES RC	Typically over 4 wks, with 1 detonation per week. However, smaller charges

							may be detonated on consecutive days.
Acoustic	Submarine Sea Trials – Weapons System Testing	Submarine weapons and sonar systems are tested at-sea to meet integrated combat system certification requirements.	HF1, M3, MF3, MF9, MF10, TORP2	2	10	Offshore Fort Pierce, FL GOMEX RC JAX RC SFOMF Northeast RC VACAPES RC	Up to 7 days
				4	20	JAX RC	
				4	20	Northeast RC	
				4	20	VACAPES RC	
Other Testing Activities							
Acoustic	Insertion/ Extraction	Testing of submersibles capable of inserting and extracting personnel and payloads into denied areas from strategic distances.	MF3, MF9	4	20	Key West RC	Up to 30 days
				264	1,320	NSWC Panama City	
Acoustic	Acoustic Component Testing	Various surface vessels, moored equipment, and materials are tested to evaluate performance in the marine environment.	FLS2, HF5, HF7, LF5, MF9, SAS2	33	165	SFOMF	1 day to multiple months
Acoustic	Semi-Stationary Equipment Testing	Semi-stationary equipment (e.g., hydrophones) is deployed to determine functionality.	AG, ASW3, ASW4, HF5, HF6, LF4, LF5, MF9, MF10, SD1,SD 2	4	20	Newport, RI	From 20 min to multiple days
				11	55	NSWC Panama City	
				190	950	NUWC Newport	

Acoustic	Towed Equipment Testing	Surface vessels or unmanned surface vehicles deploy and tow equipment to determine functionality of towed systems.	HF6, LF4, MF9	36	180	NUWC Newport	Typically 2-8 hrs
Acoustic	Signature Analysis Operations	Surface ship and submarine testing of electromagnetic, acoustic, optical, and radar signature measurements.	ASW2, HF1, LF4, LF5, LF6, M3, MF9, MF10	1	5	JAX RC	Periodically over multiple days
				59	295	SFOMF	

Notes: JEB LC-FS: Joint Expeditionary Base Little Creek-Fort Story; NS: Naval Station; NSB: Naval Submarine Base; NSWC: Naval Surface Warfare Center; NUWC: Naval Undersea Warfare Center; PNS: Portsmouth Naval Shipyard; SFOMF: South Florida Ocean Measurement Facility Testing Range

[1] For activities where the maximum number of events could vary between years, the information is presented as 'representative-maximum' number of events per year. For activities where no variation is anticipated, only the maximum number of events within a single year is provided.

[2] Locations given are areas where activities typically occur. However, activities could be conducted in other locations within the AFTT Study Area. Where multiple locations are provided within a single cell, the number of activities could occur in any of the locations, not in each of the locations.

Office of Naval Research

Table 7 summarizes the planned testing activities for the Office of Naval Research analyzed within the AFTT Study Area.

Table 7. Planned Office of Naval Research Testing Activities Analyzed within the AFTT Study Area.

Stressor Activity	*Activity Name*	*Activity Description*	*Source Bin*	*Annual # of Activities*	*5-Year # of Activities*	*Location*	*Duration*
Acoustic and Oceanographic Science and Technology							
Acoustic, Explosive	Acoustic and Oceanographic Research	Research using active transmissions from sources deployed from ships and unmanned underwater vehicles. Research sources can be used as proxies for current and future Navy systems.	AG, ASW2, BB4, BB5, BB6, BB7, LF3, LF4, LF5, MF8, MF9, MF14, E1	2	10	Other AFTT Areas	Up to 14 days
				5	22	GOMEX RC	
				9	43	Northeast RC	
				3	12	VACAPES RC	
Acoustic	Emerging Mine Countermeasure Technology Research	Test involves the use of broadband acoustic sources on unmanned underwater vehicles.	BB1, BB2, SAS4	1	5	JAX RC	Up to 14 days
				2	10	Northeast RC	
				1	5	VACAPES RC	

Notes: GOMEX: GOMEX; JAX: Jacksonville, Florida; RC: Range Complex; VACAPES: Virginia Capes

Summary of Acoustic and Explosive Sources Analyzed for Training and Testing

Table 8 through Table 11 show the acoustic source classes and numbers, explosive source bins and numbers, air gun sources, and pile driving and removal activities associated with Navy training and testing activities in the AFTT Study Area that were analyzed in this rule. Table 8 shows the acoustic source classes (*i.e.,* LF, MF, and HF) that could occur in any year under the Planned Activity for training and testing activities. Under the Planned Activities, acoustic source class use would vary annually, consistent with the number of annual activities summarized above. The five-year total for the Planned Activities takes into account that annual variability.

Table 8. Acoustic Source Classes Analyzed and Numbers Used during Training and Testing Activities in the AFTT Study Area.

Source Class Category	*Bin*	*Description*	*Unit* [1]	*Training*		*Testing*	
				Annual[2]	*5-year Total*	*Annual*[2]	*5-year Total*
Low-Frequency (LF): Sources that produce signals less than 1 kHz	LF3	LF sources greater than 200 dB	H	0	0	1,308	6,540
	LF4	LF sources equal to 180 dB and up to 200 dB	H	0	0	971	4,855
			C	0	0	20	100
	LF5	LF sources less than 180 dB	H	9	43	1,752	8,760
	LF6	LF sources greater than 200 dB with long pulse lengths	H	145 – 175	784	40	200
Mid-Frequency (MF): Tactical and non-tactical sources that produce signals between 1 – 10 kHz	MF1	Hull-mounted surface ship sonars (*e.g.*, AN/SQS-53C and AN/SQS-61)	H	5,005 – 5,605	26,224	3,337	16,684
	MF1K	Kingfisher mode associated with MF1 sonars	H	117	585	152	760
	MF3	Hull-mounted submarine sonars (*e.g.*, AN/BQQ-10)	H	2,078 – 2,097	10,428	1,257	6,271
	MF4	Helicopter-deployed dipping sonars (*e.g.*, AN/AQS-22 and AN/AQS-13)	H	591 – 611	2,994	370 – 803	2,624
	MF5	Active acoustic sonobuoys (*e.g.*, DICASS)	C	6,708– 6,836	33,796	5,070 – 6,182	27,412
	MF6	Active underwater sound signal devices (*e.g.*, MK84)	C	0	0	1,256 – 1,341	6,390
	MF8	Active sources (greater than 200 dB) not otherwise binned	H	0	0	348	1,740
	MF9	Active sources (equal to 180 dB and up to 200 dB) not otherwise binned	H	0	0	7,395– 7,562	37,173

	MF10	Active sources (greater than 160 dB, but less than 180 dB) not otherwise binned	H	870	4,348	5,690	28,450
	MF11	Hull-mounted surface ship sonars with an active duty cycle greater than 80%	H	873 – 1,001	4,621	1,424	7,120
	MF12	Towed array surface ship sonars with an active duty cycle greater than 80%	H	367 – 397	1,894	1,388	6,940
	MF14	Oceanographic MF sonar	H	0	0	1,440	7,200
	HF1	Hull-mounted submarine sonars (*e.g.*, AN/BQQ-10)	H	1,928 – 1,932	9,646	397	1,979
	HF3	Other hull-mounted submarine sonars (classified)	H	0	0	31	154
	HF4	Mine detection, classification, and neutralization sonar (*e.g.*, AN/SQS-20)	H	5,411 – 6,371	29,935	30,772 – 30,828	117,916
High-Frequency (HF): Tactical and non-tactical sources that produce signals between 10 – 100 kHz	HF5	Active sources (greater than 200 dB) not otherwise binned	H	0	0	1,864 – 2,056	9,704
			C	0	0	40	200
	HF6	Active sources (equal to 180 dB and up to 200 dB) not otherwise binned	H	0	0	2,193	10,868
	HF7	Active sources (greater than 160 dB, but less than 180 dB) not otherwise binned	H	0	0	1,224	6,120
	HF8	Hull-mounted surface ship sonars (*e.g.*, AN/SQS-61)	H	20	100	2,084	10,419
Very High-Frequency Sonars (VHF): Non-tactical sources that produce signals between 100 – 200 kHz	VHF 1	VHF sources greater than 200 dB	H	0	0	12	60

Anti-Submarine Warfare (ASW): Tactical sources (*e.g.*, active sonobuoys and acoustic counter-measures systems) used during ASW training and testing activities	ASW 1	MF systems operating above 200 dB	H	582 – 641	3,028	820	4,100
	ASW 2	MF Multistatic Active Coherent sonobuoy (*e.g.*, AN/SSQ-125)	C	1,476 – 1,556	7,540	4,756 – 5,606	25,480
	ASW 3	MF towed active acoustic countermeasure systems (*e.g.*, AN/SLQ-25)	H	4,485 – 5,445	24,345	2,941– 3,325	15,472
	ASW 4	MF expendable active acoustic device countermeasures (*e.g.*, MK 3)	C	425 – 431	2,137	3,493	17,057
	ASW 5	MF sonobuoys with high duty cycles	H	572 – 652	3,020	608 – 628	3,080
Torpedoes (TORP): Source classes associated with the active acoustic signals produced by torpedoes	TOR P1	Lightweight torpedo (*e.g.*, MK 46, MK 54, or Anti-Torpedo Torpedo)	C	57	285	806 – 980	4,336
	TOR P2	Heavyweight torpedo (*e.g.*, MK 48)	C	80	400	344 – 408	1,848
	TOR P 3	Heavyweight torpedo (*e.g.*, MK 48)	C	0	0	100	440
Forward Looking Sonar (FLS): Forward or upward looking object avoidance sonars used for ship navigation and safety	FLS2	HF sources with short pulse lengths, narrow beam widths, and focused beam patterns	H	0	0	1,224	6,120
Acoustic Modems (M): Systems used to transmit data through the water	M3	MF acoustic modems (greater than 190 dB)	H	0	0	634	3,169
Swimmer Detection Sonars (SD): Systems used to detect divers and sub- merged swimmers	SD1 – SD2	HF and VHF sources with short pulse lengths, used for the detection of swimmers and other objects for the purpose of port security	H	0	0	176	880
Synthetic Aperture	SAS1	MF SAS systems	H	0	0	960	4,800

Sonars (SAS): Sonars in which active acoustic signals are post-processed to form high-resolution images of the seafloor	SAS2	HF SAS systems	H	0 – 8,400	25,200	3,512	17,560
	SAS3	VHF SAS systems	H	0	0	960	4,800
	SAS4	MF to HF broadband mine countermeasure sonar	H	0	0	960	4,800
Broadband Sound Sources (BB): Sonar systems with large frequency spectra, used for various purposes	BB1	MF to HF mine countermeasure sonar	H	0	0	960	4,800
	BB2	HF to VHF mine countermeasure sonar	H	0	0	960	4,800
	BB4	LF to MF oceanographic source	H	0	0	876 – 3,252	6,756
	BB5	LF to MF oceanographic source	H	0	0	672	3,360
	BB6	HF oceanographic source	H	0	0	672	3,360
	BB7	LF oceanographic source	C	0	0	120	600

1: C = Count; H = Hours
2: Expected annual use may vary per bin because the number of events may vary from year to year, as described in Chapter 1, Section 1.5 (*Planned Activity*) of the Navy's rulemaking/LOA application.

Table 9 shows the number of air gun shots planned in AFTT Study Area for training and testing activities.

TABLE 9—TRAINING AND TESTING AIRGUN SOURCES QUANTITATIVELY ANALYZED IN THE AFTT STUDY AREA

Source class category	*Bin*	*Unit*[1]	*Training*		*Testing*	
			Annual	*5-year total*	*Annual*	*5-year total*
Air guns (AG): Small underwater air guns	AG	C	0	0	604	3,020

[1] C = count. One count (C) of AG is equivalent to 100 air gun firings.

Table 10 summarizes the impact pile driving and vibratory pile removal activities that would occur during a 24-hour period. Annually, for impact pile driving, the Navy will drive 119 piles, two times a year for a total of 238 piles. Over the 5-year period of the rule, the Navy will drive a total of 1190 piles by impact pile driving. Annually, for vibratory pile removal, the Navy will remove 119 piles, two times a year for a total of 238 piles. Over the 5-year period of the rule, the Navy will remove a total of 1190 piles by vibratory pile removal.

TABLE 10—SUMMARY OF PILE DRIVING AND REMOVAL ACTIVITIES PER 24-HOUR PERIOD IN THE AFTT STUDY AREA

Method	Piles per 24-hour period	Time per pile (minutes)	Total estimated time of noise per 24-hour period (minutes)
Pile Driving (Impact)	6	15	90
Pile Removal (Vibratory)	12	6	72

Table 11 shows the number of in-water explosives that could be used in any year under the Planned Activity for training and testing activities. Under the Planned Activities, bin use would vary annually, consistent with the number of annual activities summarized above. The five-year total for the Specified Activities takes into account that annual variability.

TABLE 11–EXPLOSIVE SOURCE BINS ANALYZED AND NUMBERS USED DURING TRAINING AND TESTING ACTIVITIES IN THE AFTT STUDY AREA

Bin	Net explosive weight [1] (lb)	Example explosive source	Training		Testing	
			Annual [2]	5-year total	Annual [2]	5-year total
E1	0.1–0.25	Medium-caliber projectile	7,700	38,500	17,840–26,840	116,200
E2	>0.25–0.5	Medium-caliber projectile	210–214	1,062	0	0
E3	>0.5–2.5	Large-caliber projectile	4,592	22,960	3,054–3,422	16,206
E4	>2.5–5	Mine neutralization charge	127–133	653	746–800	3,784
E5	>5–10	5-inch projectile	1,436	7,180	1,325	6,625
E6	>10–20	Hellfire missile	602	3,010	28–48	200
E7	>20–60	Demo block/shaped charge	4	20	0	0
E8	>60–100	Light-weight torpedo	22	110	33	165
E9	>100–250	500 lb bomb	66	330	4	20
E10	>250–500	Harpoon missile	90	450	68–98	400
E11	>500–650	650 lb mine	1	5	10	50
E12	>650–1,000	2,000 lb bomb	18	90	0	0
E16 [3]	>7,250–14,500	Littoral Combat Ship full ship shock trial.	0	0	0–12	12
E17 [3]	>14,500–58,000	Aircraft carrier full ship shock trial	0	0	0–4	4

[1] Net Explosive Weight refers to the equivalent amount of TNT the actual weight of a munition may be larger due to other components.
[2] Expected annual use may vary per bin because the number of events may vary from year to year, as described in Section 1.5 (Planned Activity).
[3] Shock trials consist of four explosions each. In any given year there could be 0–3 small ship shock trials (E16) and 0–1 large ship shock trials (E17). Over a 5-year period, there could be three small ship shock trials (E16) and one large ship shock trial (E17).

Vessel Movement

Vessels used as part of the Planned Activity include ships, submarines and boats ranging in size from small, 22 ft (7 m) rigid hull inflatable boats to aircraft carriers with lengths up to 1,092 ft (333 m). Large Navy ships greater than 60 ft (18 m) generally operate at speeds in the range of 10 to 15 kn for fuel conservation. Submarines generally operate at speeds in the range of 8 to 13 kn in transits and less than those speeds for certain tactical maneuvers. Small craft, less than 60 ft (18 m) in length, have much more variable speeds (dependent on the mission). For small craft types, sizes and speeds vary during training and testing. Speeds generally range from 10 to 14 kn. While these speeds for large and small crafts are representative of most events, some vessels need to temporarily operate outside of these parameters.

The number of Navy vessels used in the AFTT Study Area varies based on military training and testing requirements, deployment schedules, annual budgets, and other unpredictable factors. Most training and testing activities involve the use of vessels. These activities could be widely dispersed throughout the AFTT Study Area, but would be typically conducted near naval ports, piers, and range areas.

Standard Operating Procedures

For training and testing to be effective, personnel must be able to safely use their sensors and weapon systems as they are intended to be used in a real-world situation and to their optimum capabilities. While standard operating procedures are designed for the safety of personnel and equipment and to ensure the success of training and testing activities, their implementation often yields additional benefits on environmental, socioeconomic, public health and safety, and cultural resources.

Because standard operating procedures are essential to safety and mission success, the Navy considers them to be part of the planned activities and has included them in the environmental analysis. Additional details on standard operating procedures were provided in our **Federal Register** notice of proposed rulemaking (83 FR 10954; March 13, 2018); please see that proposed rule or the Navy's application for more information.

Duration and Location

Training and testing activities would be conducted in the AFTT Study Area throughout the year from 2018 through 2023 for the five-year period covered by the regulations. The AFTT Study Area (see Figure 1.1–1 of the Navy's rulemaking/LOA application) includes areas of the western Atlantic Ocean along the East Coast of North America, portions of the Caribbean Sea, and the GOMEX. The AFTT Study Area begins at the mean high tide line along the U.S. coast and extends east to the 45-degree west longitude line, north to the 65-degree north latitude line, and south to approximately the 20-degree north latitude line. The AFTT Study Area also includes Navy pierside locations, bays, harbors, and inland waterways, and civilian ports where training and testing occurs. The AFTT Study Area generally follows the Commander Task Force 80 area of operations, covering approximately 2.6 million nmi^2 of ocean area, and includes designated Navy range complexes and associated operating areas (OPAREAs) and special use airspace. While the AFTT Study Area itself is very large, it is important to note that the vast majority of Navy training and testing occurs in designated range complexes and testing ranges.

A Navy range complex consists of geographic areas that encompass a water component (above and below the surface) and airspace, and may encompass a land component where training and testing of military platforms, tactics, munitions, explosives, and electronic warfare systems occur. Range complexes include established OPAREAs, which may be further divided to provide better control of the area for safety reasons.

Please refer to the regional maps provided in the Navy's rulemaking/LOA application (Figure 2.2–1 through Figure 2.2–3) for additional detail of the range complexes and testing ranges. Additional detail on range complexes and testing ranges was provided in our **Federal Register** notice of proposed rulemaking (83 FR 10954; March 13, 2018); please see that proposed rule or the Navy's application for more information.

Comments and Responses

We published a notice of proposed regulations in the **Federal Register** on March 13, 2018 (83 FR 10954), with a 45-day comment period. In that proposed rule, we requested public input on the request for authorization described therein, our analyses, and the proposed authorizations and requested that interested persons submit relevant information, suggestions, and comments. During the 45-day comment period, we received 28 total comment letters. Of this total, one submission was from another federal agency, two letters were from organizations or individuals acting in an official capacity (*e.g.,* non-governmental organizations (NGOs)) and 25 submissions were from private citizens. Letters from other NGOs and state departments that were received during the NOR were also considered further. NMFS has reviewed all public comments received on the proposed rule and issuance of the LOAs. All relevant comments and our responses are described below. We provide no response to specific comments that addressed species or statutes not relevant to our proposed actions under section 101(a)(5)(A) of the MMPA (*e.g.,* comments related to sea turtles). We outline our comment responses by major categories.

General Comments

The majority of the 25 comment letters from private citizens expressed general opposition toward the Navy's proposed training and testing activities and requested that NMFS not issue the LOAs, but without providing information relevant to NMFS' decisions. These comments appear to indicate a lack of understanding of the MMPA's requirement that NMFS ''shall issue'' requested authorizations when certain findings (see the *Background* section) are met; therefore, these comments were not considered further. The remaining comments are addressed below.

Impact Analysis

General

Comment 1: A Commenter recommends that NMFS consult with the Navy to collect more information regarding the number, nature, and timing of testing and training events that take place within, or within close proximity to, important habitat areas, essentially refining the scale of the analysis of training and testing activities to match the scale of the habitat areas considered to be important.

Response: In their take request and effects analysis provided to NMFS, the Navy considered historic use (number and nature of training and testing activities) and locational information of training and testing activities when developing modelling boxes. The timing of training cycles and testing needs varies based on deployment requirements to meet current and emerging threats. Due to the variability, the Navy's description of their specified activities is structured to provide flexibility in training and testing locations, timing, and number. In addition, information regarding the exact location of sonar usage is classified. Due to the variety of factors, many of which influence locations that cannot be predicted in advance (*e.g.,* weather), the analysis is completed at a scale that is necessary to allow for flexibility. The purpose of the Navy's quantitative acoustic analysis is to provide the best estimate of impact/take to marine mammals and ESA listed species for the regulatory and ESA section 7 consultation analyses. Specifically, the analysis must take into account multiple Navy training and testing activities over large areas of the ocean for multiple years; therefore, analyzing activities in multiple locations over multiple seasons produces the best estimate of impacts/take to inform the AFTT FEIS/OEIS and regulators. Also, the scale at which spatially explicit marine mammal density models are structured is determined by the data collection method and the environmental variables that are used to build the model. Therefore, altogether, given the variables that determine when and where the Navy trains and tests, as well as the resolution of the density data, the analysis of potential impacts is scaled to the level that the data fidelity will support. NMFS has worked with the Navy over the years to increase the spatio-temporal specificity of the descriptions of activities planned in or near areas of biological importance, when possible (*i.e.,* in NARW ESA-designated critical habitat), and NMFS is confident that the granularity of information provided sufficiently allows for an accurate assessment of both the impacts of the Navy's activities on marine mammal populations and the protective measures evaluated to mitigate those impacts.

Density Estimates

Comment 2: A Commenter noted that 30 iterations or Monte Carlo simulations is low for general bootstrapping methods used in those models but understands that increasing the number of iterations in turn increases the computational time needed to run the models. Accordingly, the Commenter suggests that the Navy consider increasing the iterations from 30 to at least 200 for activities that have yet to be modeled for Phase III and for all activities in Phase IV.

Response: The 30 iterations used in NAEMO represent the number of iterations run for each of the four seasons analyzed in AFTT Phase III, which results in a total of 120 iterations per year for each event analyzed. For other areas where only warm and cold seasons are analyzed, the number of iterations per season is increased to 60 so that the same 120 iterations per year are maintained. Navy reached this number of iterations by running two iterations of a scenario and calculating the mean of exposures, then running a third iteration and calculating the running mean of exposures, then a fourth iteration and so on. This is done until the running mean becomes stable. Through this approach, it was determined 120 iterations was sufficient to converge to a statistically valid answer and provides a reasonable uniformity of exposure predictions for most species and areas. There are a few exceptions for species with sparsely populated distributions or highly variable distributions. In these cases, the running mean may not flatten out (or become stable); however, there were so few exposures in these cases that while the mean may fluctuate, the overall number of exposures did not result in significant differences in the totals. In total, the number of simulations conducted for AFTT Phase III exceeded six million simulations and produced hundreds of terabytes of data. Increasing the number of iterations, based on the discussion above, would not result in a significant change in the results, but would incur a significant increase in resources (*e.g.,* computational and storage requirements). This would divert these resources from conducting other more consequential analysis without providing for meaningfully improved data. The Navy has

communicated that it is continually looking at ways to improve NAEMO and reduce data and computational requirements. As technologies and computational efficiencies improve, Navy will evaluate these advances and incorporate them where appropriate.

Comment 3: A Commenter recommends that the Navy (1) specify what modeling method and underlying assumptions were used to estimate PTS and TTS zones for pile driving activities and (2) accumulate energy for the entire day of proposed activities, and (3) clarify why those zones were estimated to be the same for LF and HF.

Response: The Navy has explained that it used measured values for source levels and transmission loss from pile driving of the Elevated Causeway System, the only pile driving activity included in the Proposed Action of the AFTT FEIS/OEIS. These recorded source waveforms were weighted using the auditory weighting functions. Low-frequency and high-frequency cetaceans have similar ranges for impact pile driving since low-frequency cetaceans would be relatively more sensitive to the low-frequency sound, which is below high-frequency cetaceans best range of hearing. Neither the NMFS user spreadsheet nor NAEMO were required for calculations. An area density model was developed in MS Excel, which calculated zones of influence to thresholds of interest (*e.g.,* behavioral response) based on durations of pile driving and the aforementioned measured and weighted source level values. The resulting area was then multiplied by density of each marine mammal species that could occur within the vicinity. This produced an estimated number of animals that could be impacted per pile, per day, and overall during the entire activity for both the impact pile driving and vibratory removal phases.

Regarding the appropriateness of accumulating energy for the entire day, based on the best available science regarding animal reaction to sound, selecting a reasonable SEL calculation period is necessary to more accurately reflect the time period an animal would likely be exposed to the sound. The Navy factored both mitigation effectiveness and animal avoidance of higher sound levels into the impact pile driving analysis. For impact pile driving, the mitigation zone extends beyond the average ranges to PTS for all hearing groups; therefore, mitigation will help prevent or reduce the potential for exposure to PTS. The impact pile driving mitigation zone also extends beyond or into a portion of the average ranges to TTS; therefore, mitigation will help prevent or reduce the potential for exposure to all TTS or some higher levels of TTS, depending on the hearing group. Mitigation effectiveness and animal avoidance of higher sound levels were both factored into the impact pile driving analysis as most marine mammals should be able to easily move away from the expanding ensonified zone of TTS/PTS within 60 seconds, especially considering the soft start procedure, or avoid the zone altogether if they are outside of the immediate area upon startup. Marine mammals and sea turtles are likely to leave the immediate area of pile driving and extraction activities and be less likely to return as activities persist. However, some ''naive'' animals may enter the area during the short period of time when pile driving and extraction equipment is being re-positioned between piles. Therefore, an animal ''refresh rate'' of 10 percent was selected. This means that 10 percent of the single pile zone of influence (ZOI) was added for each consecutive pile within a given 24-hour period to generate the daily ZOI per effect category. These daily ZOIs were then multiplied by the number of days of pile driving and pile extraction and then summed to generate a total ZOI per effect category (*i.e.,* behavioral response, TTS, PTS). The small size of the mitigation zone and its close proximity to the observation platform will result in a high likelihood that Lookouts would be able to detect marine mammals and sea turtles throughout the mitigation zone.

PTS/TTS Thresholds

Comment 4: A Commenter supports the weighting functions and associated thresholds as stipulated in Finneran (2016), which are the same as those used for Navy Phase III activities, but points to additional recent studies that provide additional behavioral audiograms (*e.g.,* Branstetter *et al.,* 2017, Kastelein *et al.,* 2017b) and information on TTS (*e.g.,* Kastelein *et al.,* 2017a; 2017c). However, the Commenter recommends that the Navy should provide a discussion of whether those new data corroborate the current weighting functions and associated thresholds.

Response: The NMFS' revised *Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing* (NMFS 2018), which was used in the assessment of effects for this action, compiled, interpreted, and synthesized the best available scientific information for noise-induced hearing effects for marine mammals to derive updated thresholds for assessing the impacts of noise on marine mammal hearing, including the articles that the Commenter references that were published subsequent to the publication of the first version of 2016 Acoustic Technical Guidance. The new data included in those articles are consistent with the thresholds and weighting functions included in the current version of the Acoustic Technical Guidance (NMFS 2018).

NMFS will continue to review and evaluate new relevant data as it becomes available and consider the impacts of those studies on the Acoustic Technical Guidance to determine what revisions/updates may be appropriate. Thus far, no new information has been published or otherwise conveyed that would fundamentally change the assessment of impacts or conclusions of this rule.

Comment 5: A Commenter commented that the criteria that the agency has produced to estimate temporary threshold shift (TTS) and permanent threshold shift (PTS) in marine mammals are erroneous and non-conservative. The Commenter specifically cited many supposed issues with NMFS' Acoustic Technical Guidance, including adoption of ''erroneous'' models, broad extrapolation from a small number of individuals, and disregarding ''non-linear accumulation of uncertainty.'' The Commenter suggests that NMFS retain the historical 180-dB rms Level A harassment threshold as a ''conservative upper bound'' or conduct a ''sensitivity analysis'' to ''understand the potential magnitude'' of the supposed errors.

Response: NMFS disagrees with this characterization of the Acoustic Technical Guidance and the associated recommendation. The Acoustic Technical Guidance is a compilation, interpretation, and synthesis of the scientific literature that provides the best available information regarding the effects of anthropogenic sound on marine mammals' hearing. The technical guidance was classified as a Highly Influential Scientific Assessment and, as such, underwent three independent peer reviews, at three different stages in its development, including a follow-up to one of the peer reviews, prior to its dissemination by NMFS. In addition, there were three separate public comment periods, during which time we received and responded to similar comments on the guidance (81 FR 51694), which we cross-reference here, and more recent public and interagency review under Executive Order 13795.

The Acoustic Technical Guidance updates the historical 180-dB rms injury threshold, which was based on professional judgement (*i.e.,* no data

were available on the effects of noise on marine mammal hearing at the time this original threshold was derived). NMFS does not believe the use of the Acoustic Technical Guidance provides erroneous results. The 180-dB rms threshold is plainly outdated, as the best available science indicates that rms SPL is not even an appropriate metric by which to gauge potential auditory injury (whereas the scientific debate regarding Level B behavioral harassment thresholds is not about the proper metric but rather the proper level or levels and how these may vary in different contexts).

Multiple studies from humans, terrestrial mammals, and marine mammals have demonstrated less TTS from intermittent exposures compared to continuous exposures with the same total energy because hearing is known to experience some recovery in between noise exposures, which means that the effects of intermittent noise sources such as tactical sonars are likely overestimated. Marine mammal TTS data have also shown that, for two exposures with equal energy, the longer duration exposure tends to produce a larger amount of TTS. Most marine mammal TTS data have been obtained using exposure durations of tens of seconds up to an hour, much longer than the durations of many tactical sources (much less the continuous time that a marine mammal in the field would be exposed consecutively to those levels), further suggesting that the use of these TTS data are likely to overestimate the effects of sonars with shorter duration signals.

Regarding the suggestion of pseudo-replication and erroneous models, since marine mammal hearing and noise-induced hearing loss data are limited, both in the number of species and in the number of individual's available, attempts to minimize pseudoreplication would further reduce these already limited data sets. Specifically, with marine mammal behavioral temporary threshold shift studies, behaviorally derived data are only available for two mid-frequency cetacean species (bottlenose dolphin, beluga) and two phocids (in-water) pinniped species (harbor seal and northern elephant seal), with otariid (in-water) pinnipeds and high-frequency cetaceans only having behaviorally-derived data from one species. Arguments from Wright (2015) regarding pseudoreplication within the TTS data are therefore largely irrelevant in a practical sense because there are so few data. Multiple data points were not included for the same individual at a single frequency. If multiple data existed at one frequency, the lowest TTS onset was always used. There is only a single frequency where TTS onset data exist for two individuals of the same species: 3 kHz for dolphins. Their TTS (unweighted) onset values were 193 and 194 dB re 1 μPa^2s. Thus, NMFS believes that the current approach makes the best use of the given data. Appropriate means of reducing pseudoreplication may be considered in the future, if more data become available. Many other comments from Wright (2015) and the comments from Racca *et al.* (2015b) appear to be erroneously based on the idea that the shapes of the auditory weighting functions and TTS/PTS exposure thresholds are directly related to the audiograms; *i.e.,* that changes to the composite audiograms would directly influence the TTS/PTS exposure functions (*e.g.,* Wright (2015) describes weighting functions as ''effectively the mirror image of an audiogram'' (p. 2) and states, ''The underlying goal was to estimate how much a sound level needs to be above hearing threshold to induce TTS.'' (p. 3)). Both statements are incorrect and suggest a fundamental misunderstanding of the criteria/threshold derivation. This would require a constant (frequency-independent) relationship between hearing threshold and TTS onset that is not reflected in the actual marine mammal TTS data. Attempts to create a ''cautionary'' outcome by artificially lowering the composite audiogram thresholds would not necessarily result in lower TTS/PTS exposure levels, since the exposure functions are to a large extent based on applying mathematical functions to fit the existing TTS data.

Behavioral Harassment Thresholds

Comment 6: A Commenter suggests that NMFS fails to set proper thresholds for behavioral impacts. Referencing the biphasic function that assumes an unmediated dose response relationship at higher received levels and a context-influenced response at lower received levels that NMFS uses to quantify Level B behavioral harassment from sonar, the Commenter suggests that resulting functions depend on some inappropriate assumptions that tend to significantly underestimate effects. The Commenter expresses concern that every data point that informs the agency's pinniped function, and nearly two-thirds of the data points informing the odontocete function (30/49), are derived from a captive animal study. Additionally, they assert that the risk functions do not incorporate (nor does NMFS apparently consider) a number of relevant studies on wild marine mammals. It is not clear from the proposed rule, or from the Navy's recent technical report on acoustic ''criteria and thresholds,'' on which NMFS' approach here is based, exactly how each of the studies that NMFS employed was applied in the analysis, or how the functions were fitted to the data, but the available evidence on behavioral response raises concerns that the functions are not conservative for some species. The Commenter recommends NMFS make additional technical information available, including from any expert elicitation and peer review, so that the public can fully comment.

Response: The *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Impacts to Marine Mammals and Sea Turtles technical report* (U.S. Department of the Navy, 2017) details how the Navy's proposed method, which was determined appropriate and adopted by NMFS, accounted for the differences in captive and wild animals in the development of the behavioral response functions. The Navy uses the best available science, which has been reviewed by external scientists and approved by NMFS, in the analysis. The Navy and NMFS have utilized all available data that relate known or estimable received levels to observations of individual or group behavior as a result of sonar exposure (which is needed to inform the behavioral response function) for the development of updated thresholds. Limiting the data to the small number of field studies that include these necessary data would not provide enough data with which to develop the new risk functions. In addition, NMFS agrees with the assumptions made by the Navy to include the fact that captive animals may be less sensitive, in that the scale at which a moderate to severe response was considered to have occurred is different for captive animals than for wild animals, as the agency understands those responses will be different.

The new risk functions were developed in 2016, before several recent papers were published or the data were available. As new science is published, the NMFS and the Navy continue to evaluate the information. The thresholds have been rigorously vetted among scientists and within the Navy community during expert elicitation and then reviewed by the public before being applied. It is unreasonable to revise and update the criteria and risk functions every time a new paper is published. These new and future papers provide additional information, and the Navy has already begun to consult them for updates to the thresholds in the future, when the next round of updated criteria will be developed. Thus far, no

new information has been published or otherwise conveyed that would fundamentally change the assessment of impacts or conclusions of the AFTT FEIS/OEIS or this rule. To be included in the behavioral response function, data sets need to relate known or estimable received levels to observations of individual or group behavior. Melcon *et al.* (2012) does not relate observations of individual/group behavior to known or estimable received levels (at that individual/group). In Melcon *et al.* (2012), received levels at the HARP buoy averaged over many hours are related to probabilities of D-calls, but the received level at the blue whale individuals/group are unknown.

As noted, the derivation of the behavioral response functions is provided in the 2017 technical report titled *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III).* The appendices to this report detail the specific data points used to generate the behavioral response functions. Data points come from published data that is readily available and cited within the technical report.

Comment 7: Commenters have concerns with the use of distance ''cut-offs'' in the Level B behavioral harassment thresholds, and the recommend that NMFS refrain from using cut-off distances in conjunction with the Bayesian BRFs and re-estimate the numbers of marine mammal takes based solely on the Bayesian BRFs.

Response: The consideration of proximity (cut-off distances) was part of the criteria developed in consultation between Navy and NMFS and was applied within the Navy's acoustic effects model. Cut-off distances were used to better reflect the take potential for military readiness activities as defined in the MMPA. The derivation of the behavioral response functions and associated cut-off distances is provided in the 2017 technical report titled *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III).* Much of the data used to derive the behavioral response functions was from nearby, scaled sources, thereby potentially confounding results since it is difficult to tell whether the focal marine mammal is reacting to the sound level or the proximity of the source and/or vessel, amongst other potentially confounding contextual factors that are unlike actual Navy events for which the behavioral response functions (BRFs) are being derived. To account for these non-applicable contextual factors, all available data on marine mammal reactions to actual Navy activities and other sound sources (or other large scale activities such as seismic surveys when information on proximity to sonar sources is not available for a given species group, *i.e.,* harbor porpoises) were reviewed to find the farthest distance to which significant behavioral reactions were observed. These distances were rounded up to the nearest 5 or 10 km interval, and for moderate to large scale activities using multiple or louder sonar sources, these distances were greatly increased — doubled in most cases. The Navy's BRFs applied within these distance is currently the best known method for providing the public and regulators with a more realistic (but still conservative where some uncertainties exist) estimate of impact and potential take under military readiness for the proposed actions within the AFTT FEIS/OEIS. NMFS has independently assessed the Navy's Level B behavioral harassment thresholds and believe that they appropriately apply the best available science and it is not necessary to recalculate take estimates.

A Commenter also specifically expresses concern that distance ''cut-offs'' alleviate some of the exposures that would otherwise have been counted if the received level alone were considered. It is unclear why the Commenter finds this inherently inappropriate, as this is what the data show. As noted previously, there are multiple studies illustrating that in situations where one would expect a Level B behavioral harassment because of the received levels at which previous responses were observed, it has not occurred when the distance from the source was larger than the distance of the first observed response.

Comment 8: Regarding cut-off distances, a Commenter further notes that dipping sonar appears a significant predictor of deep-dive rates in beaked whales on Southern California Anti-submarine Warfare Range (SOAR), with the dive rate falling significantly (*e.g.,* to 35 percent of that individual's control rate) during sonar exposure, and likewise appears associated with habitat abandonment. Importantly, these effects were observed at substantially greater distances (*e.g.,* 30 or more km) from dipping sonar than would otherwise be expected given the systems' source levels and the beaked whale response thresholds developed from research on hull-mounted sonar. They suggest that the analysis, and associated cut-off distances, do not properly consider the impacts of dipping sonar.

Response: The Navy relied upon the best science that was available to develop the behavioral response functions in consultation with NMFS. The Navy's current beaked whale BRF acknowledges and incorporates the increased sensitivity observed in beaked whales during both behavioral response studies and during actual Navy training events, as well as the fact that dipping sonar can have greater effects than some other sources with the same source level. Specifically, the distance cut-off for beaked whales is 50 km, larger than any other group. Moreover, although dipping sonar has a significantly lower source level than hull-mounted sonar, it is included in the category of sources with larger distance cut-offs, specifically in acknowledgement of its unpredictability and association with observed effects. This means that ''takes'' are reflected at lower received levels that would have been excluded because of the distance for other source types. The referenced article (*Associating patterns in movement and diving behavior with sonar use during military training exercises: A case study using satellite tag data from Cuvier's beaked whales at the Southern California Anti-submarine Warfare Range* (Falcone, 2015)) was not available at the time the behavioral response functions were developed. However, NMFS and the Navy have reviewed the article and concur that neither this article nor any other new information that has been published or otherwise conveyed would significantly change the assessment of impacts or conclusions in the AFTT FEIS/OEIS or in this rulemaking. Nonetheless, the new information and data presented in the new article were recently thoroughly reviewed by the Navy and will be quantitatively incorporated into future behavioral response functions, as appropriate.

Comment 9: Regarding the behavioral thresholds for explosives, a Commenter recommends that NMFS estimate and ultimately authorize behavior takes of marine mammals during all explosive activities, including those that involve single detonations.

Response: The derivation of the explosive injury criteria is provided in the 2017 technical report titled *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III),* and NMFS has applied the general rule the Commenter references to single explosives for years, *i.e.,* that marine mammals are unlikely to respond to a single instantaneous detonation in a manner that would rise to the level of a take. Neither NMFS nor the Navy are aware of evidence to support the assertion that animals will have significant behavioral reactions (*i.e.,* those that would rise to the level of a take) to temporally and spatially

isolated explosions. The Navy has been monitoring detonations since the 1990's and has not observed these types of reactions. TTS and all other higher order impacts are assessed for all training and testing events that involve the use of explosives or explosive ordnance. All of Navy's monitoring projects, reports, and publications are available on the marine species monitoring web page (*https://www.navymarinespeciesmonitoring.us/*). NMFS will continue to review applicable monitoring and science data and consider modifying these criteria when and if new information suggests it is appropriate.

Mortality and Injury Thresholds for Explosions

Comment 10: A Commenter recommends that NMFS require the Navy to (1) explain why the constants and exponents for onset mortality and onset slight lung injury thresholds for Phase III have been amended, (2) ensure that the modified equations are correct, and (3) specify any additional assumptions that were made.

Response: The derivation of the explosive injury equations, including any assumptions, is provided in the 2017 technical report titled *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III).* It is our understanding that the constants and exponents for onset mortality and onset slight lung injury were amended by the Navy since Phase II to better account for the best available science. Specifically, the equations were modified in Phase III to fully incorporate the injury model in Goertner (1982), specifically to include lung compression with depth. The derivation of the Phase III equations and all associated assumptions are fully documented in the Navy's 2017 technical report *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III).* NMFS independently reviewed and concurred with this approach.

Comment 11: A Commenter commented on circumstances of the deaths of multiple common dolphins during one of the Navy's underwater detonation events in March 2011 (Danil and St. Leger 2011) and indicated that the Navy's mitigation measures are not fully effective, especially for explosive activities. The Commenter believes it would be more prudent for the Navy to estimate injuries and mortalities based on onset rather than a 50-percent incidence of occurrence. The Navy did indicate that it is reasonable to assume for its impact analysis—thus its take estimation process—that extensive lung hemorrhage is a level of injury that would result in mortality for a wild animal (U.S. Department of the Navy 2017a). Thus, the Commenters notes that it is unclear why the Navy did not follow through with that premise. The Commenter recommends that NMFS use onset mortality, onset slight lung injury, and onset GI tract injury thresholds to estimate both the numbers of marine mammal takes and the respective ranges to effect.

Response: Based on an extensive review of the incident referred to by the commenter, the Navy, in consultation with NMFS, revised and updated the mitigation for these types of events, which did not previously include consideration of the distance an animal could travel while the detonation was ''delayed.'' There have been no further incidents since these mitigation changes were instituted.

The Navy used the range to one percent risk of mortality, as well as injury (referred to as ''onset'' in the AFTT DEIS/OEIS), to inform the development of mitigation ranges for explosions. In all cases, the proposed mitigation ranges for explosives extend beyond the range to one percent risk of non-auditory injury, even for a small animal (representative mass = 5 kg). In the AFTT FEIS/OEIS, the Navy clarified that the ''onset'' non-auditory injury and mortality criteria are actually one percent risk criteria.

Over-predicting impacts, which would occur with the use of one percent non-auditory injury risk criteria in the quantitative analysis, would not afford extra protection to any animal. The Navy, in coordination with NMFS, has determined that the 50 percent incidence of occurrence is a reasonable mechanism for quantifying the likely effect, given the use of mitigation zones based on onset. Ranges to effect based on one percent risk criteria were examined to ensure that explosive mitigation zones would encompass the range to any potential mortality or non-auditory injury, affording actual protection against these effects. NMFS concurs with the Navy's approach for mitigating and quantifying injury and mortality from explosives.

Although the commenter implies that the Navy did not use extensive lung hemorrhage as indicative of mortality, that statement is incorrect. Extensive lung hemorrhage is assumed to result in mortality, and the explosive mortality criteria are based on extensive lung injury data. See the technical report titled *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Effects Analysis (Phase III).*

Range to Effects

Comment 12: A Commenter notes an apparent error in Table 6.4–3 of the Navy's rulemaking/LOA application and recommends that NMFS determine what the appropriate ranges to TTS should be for bin LF5 and amend the ranges for the various functional hearing groups in the various tables accordingly.

Response: The error in the table has been fixed; specifically, the ranges for MF cetaceans have been revised. Note that the distances are shorter than initially provided in proposed rule, indicating that the impacts of exposure to this bin are fewer than initially implied by the table. Regardless, the error was only associated with the information presented in this table; there was no associated error in any distances used in the take estimation, and both the take estimates and our findings remain the same.

Comment 13: A Commenter recommends that the Navy use its spatially and temporally dynamic simulation models (*e.g.,* randomly-generated munition trajectories and animat simulations) rather than simple probability calculations to estimate strike probabilities and number of takes from expended munitions and non-explosive materials.

Response: The recommendation of the Commenter to use a dynamic simulation model to estimate expended munitions and non-explosive materials strike probability was considered, but the Navy found, and NMFS agrees, that while the current analysis used in the AFTT FEIS/OEIS is more conservative and almost certainly over-estimates the potential impacts to marine mammals, it was preferable given the uncertainty involved in the prediction. An analysis of direct strike resulting from expended materials conducted in a dynamic simulation model such as NAEMO would also be a probability analysis; however, it would be conducted in a different manner. The current analysis provides an over-estimation of the probability of a strike for the following reasons: It (1) calculates the probability of a single military item (of all the items expended over the course of the year) hitting a single animal at its species' highest seasonal density; (2) does not take into account the possibility that an animal may avoid military activities; (3) does not take into account the possibility that an animal may not be at the water surface; (4) does not take into account that most projectiles fired during training and testing activities are fired at targets, and not all projectiles would hit the water with their maximum velocity and force; and (5)

does not quantitatively take into account the Navy avoiding animals that are sighted through the implementation of mitigation measures. Given the uncertainty, and in order to be more conservative, NMFS and the Navy will continue using this method.

Mitigation and Avoidance Calculations

Comment 14: Commenters cite concerns that there was not enough information by which to evaluate the Navy's post-modeling calculations to account for mitigation and avoidance and imply that Level A harassment takes and mortality takes may be underestimated. A Commenter recommends that the Navy (1) provide the total numbers of model-estimated Level A harassment (PTS and slight lung and GI injuries) and mortality takes rather than reduce the estimated numbers of takes based on the Navy's post-model analyses and (2) include the model-estimated Level A harassment and mortality takes in its rulemaking/application to inform NMFS' negligible impact determination analyses.

Response: The consideration of marine mammal avoidance and mitigation effectiveness is integral to the Navy's overall analysis of impacts from sonar and explosive sources. NMFS has independently evaluated the method and agrees that it is appropriately applied to augment the model in the prediction and authorization of injury and mortality as described in the rule. Details of this analysis are provided in the Navy's 2018 technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing.*

Sound levels diminish quickly below levels that could cause PTS. Studies have shown that all animals observed avoid areas well beyond these zones; therefore, the vast majority of animals are likely to avoid sound levels that could cause injury to their ear. As discussed in the Navy's 2018 technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing,* animats in the Navy's acoustic effects model do not move horizontally or ''react'' to sound in any way. The current best available science based on a growing body of behavioral response research shows that animals do in fact avoid the immediate area around sound sources to a distance of a few hundred meters or more depending upon the species. Avoidance to this distance greatly reduces the likelihood of impacts to hearing such as TTS and PTS.

Specifically, behavioral response literature, including the recent 3S and SOCAL BRS studies, indicate that the multiple species from different cetacean suborders do in fact avoid approaching sound sources by a few hundred meters or more, which would reduce received sound levels for individual marine mammals to levels below those that could cause PTS. The ranges to PTS for most marine mammal groups are within a few tens of meters and the ranges for the most sensitive group, the HF cetaceans, average about 200 m, to a maximum of 270 m in limited cases; however HF cetaceans such as harbor porpoises, have been observed reacting to anthropogenic sound at greater distances than other species and are likely to avoid their zones to hearing impacts (TTS and PTS) as well.

As discussed in the Navy's 2018 technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing,* the Navy's acoustic effects model does not consider procedural mitigations (*i.e.,* power-down or shut-down of sonars, or pausing explosive activities when animals are detected in specific zones adjacent to the source), which necessitates consideration of these factors in the Navy's overall acoustic analysis. Credit taken for mitigation effectiveness is extremely conservative. For example, if Lookouts can see the whole area, they get credit for it in the calculation; if they can see more than half the area, they get half credit; if they can see less than half the area, they get no credit. Not considering animal avoidance and mitigation effectiveness would lead to a great overestimate of injurious impacts. NMFS concurs with the analytical approach used.

Last, the Navy's 2018 technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing* very clearly explains in detail how species sightability, the Lookout's ability to observe the range to PTS (for sonar and other transducers) and mortality (for explosives), the portion of time when mitigation could potentially be conducted during periods of reduced daytime visibility (to include inclement weather and high sea state) and the portion of time when mitigation could potentially be conducted at night, and the ability for sound sources to be positively controlled (powered down) are considered in the post-modeling calculation to account for mitigation and avoidance. It is not necessary to view the many tables of numbers generated in the assessment to evaluate the method.

Comment 15: A Commenter stated in regards to the method in which the Navy's post-model calculation considers avoidance specifically (*i.e.,* assuming animals present beyond the range of PTS for the first few pings will be able to avoid it and incur only TTS), given that sound sources are moving, it may not be until later in an exercise that the animal is close enough to experience PTS, and it is those few close pings that contribute to the potential to experience PTS. An animal being beyond the PTS zone initially has no bearing on whether it will come within close range later during an exercise since both sources and animals are moving. In addition, Navy vessels may move faster than the ability of the animals to evacuate the area. The Navy should have been able to query the dosimeters of the animats to verify whether its five-percent assumption was valid.

Response: The consideration of marine mammals avoiding the area immediately around the sound source is provided in the Navy's 2018 technical report titled *Quantitative Analysis for Estimating Acoustic and Explosive Impacts to Marine Mammals and Sea Turtles.* As the Commenter correctly articulates: ''For avoidance, the Navy assumed that animals present beyond the range to onset PTS for the first three to four pings are assumed to avoid any additional exposures at levels that could cause PTS. That equated to approximately five percent of the total pings or 5 percent of the overall time active; therefore, 95 percent of marine mammals predicted to experience PTS due to sonar and other transducers were instead assumed to experience TTS.'' In regard to the comment about vessels moving faster than animals' ability to get out of the way, as discussed in the Navy's 2018 technical report titled *Quantitative Analysis for Estimating Acoustic and Explosive Impacts to Marine Mammals and Sea Turtles,* animats in the Navy's acoustic effects model do not move horizontally or ''react'' to sound in any way, necessitating the additional step of considering animal avoidance of close-in PTS zones. NMFS independently reviewed this approach and concurs that it is fully supported by the best available science. Based on a growing body of behavioral response research, animals do in fact avoid the immediate area around sound sources to a distance of a few hundred meters or more depending upon the species. Avoidance to this distance greatly reduces the likelihood of impacts to hearing such as TTS and PTS, respectively. Specifically,

the ranges to PTS for most marine mammal groups are within a few tens of meters and the ranges for the most sensitive group, the HF cetaceans, average about 200 m, to a maximum of 270 m in limited cases; however HF cetaceans such as harbor porpoises have been observed reacting to anthropogenic sound at greater distances than other species and are likely to avoid their zones to hearing impacts (TTS and PTS) as well. Querying the dosimeters of the animats would not produce useful information since, as discussed previously, the animats do not move in the horizontal and are not programmed to ''react'' to sound or any other stimulus.

Comment 16: A Commenter asserted that the Navy's adjustment of injury and mortality numbers for ''mitigation effectiveness'' is also problematic. The analysis starts with species-specific g(0) factors (probability of detection of animals at zero distance) applied in professional marine mammal abundance surveys, then multiplies them by a simple factor to reflect the relative effectiveness of the Navy's Lookouts in routine operating conditions. Yet the Navy's sighting effectiveness is likely to be much poorer than that of experienced biologists dedicated exclusively to marine mammal detection, operating under conditions that maximize sightings. As one recent paper observed, for example, abundance survey rates declined significantly as sea states rose above Beaufort 1, and average Beaufort sea states in the mid- and southeast Atlantic average Beaufort 3–4 throughout the year (see Table 1). Given this, it seems that Navy visual surveys can seldom approximate the sighting effectiveness of a large-vessel abundance survey.

Response: Information about the quantitative analysis process, including the consideration of mitigation effectiveness, is described in detail in the 2018 technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing.* The Navy quantitatively assessed the effectiveness of its mitigation measures on a per-scenario basis using four factors: (1) Species sightability, (2) a Lookout's ability to observe the range to permanent threshold shift (for sonar and other transducers) and range to mortality (for explosives), (3) the portion of time when mitigation could potentially be conducted during periods of reduced daytime visibility (to include inclement weather and high sea-state) and the portion of time when mitigation could potentially be conducted at night, and (4) the ability for sound sources to be positively controlled (*e.g.,* powered down). The g(0) values used by the Navy for their mitigation effectiveness adjustments take into account the differences in sightability with sea state, and utilize averaged g(0) values for sea states of 1–4 and weighted as suggested by Barlow (2015). This helps to account for reduced sightability in varying conditions, as does the fact that, during active sonar activities, Navy Lookouts tend to look in the water near the vessel, within 1 km, rather than out to the horizon as Marine Mammal Observers (MMO) do. During training and testing activities, there is typically at least one, if not numerous, support personnel involved in the activity (*e.g.,* range support personnel aboard a torpedo retrieval boat or support aircraft). In addition to the Lookout posted for the purpose of mitigation, these additional personnel observe for and disseminate marine species sighting information amongst the units participating in the activity whenever possible as they conduct their primary mission responsibilities. However, as a conservative approach to assigning mitigation effectiveness factors, the Navy elected to account only for the minimum number of required Lookouts used for each activity; therefore, the mitigation effectiveness factors may underestimate the likelihood that some marine mammals (as well as sea turtles) may be detected during activities that are supported by additional personnel who may also be observing the mitigation zone. NMFS independently reviewed and concurs with this analysis.

Comment 17: A Commenter comments on the potential for serious injury and mortality that could occur in the event of a ship strike or as a result of marine mammal exposure to explosive detonations (ship shock trials) and suggests that NMFS' prediction that only these few takes will result from Navy's thousands of hours of training and testing activities has misrepresented the science. Specifically, the Commenter discusses the risk of ship strike to NARW and suggested that it appears as a glaring omission from the list of species authorized for lethal take. While the Commenter concurred with NMFS' refusal to authorize a single ship strike to the NARW, they do not share the agency's level of confidence that the Navy will be able to effectively mitigate the potential for a ship strike to occur. They further suggest that NMFS has failed to consider the indirect effects of noise on ship-strike risk. They also assert that indirect ship strike risk resulting from habitat displacement must be accounted for in NMFS' analysis. The Commenter recommends additional mitigation measures slowing ships to 10 kn.

Response: As described in greater detail in the *Take from Vessel Strikes* section of the final rule, although NMFS' analysis shows that NARWs have a low probability of being struck even one time within the five-year period of the rule when strikes across all activity types (including non-Navy) are considered (10.11 percent, lower than all other stocks except North Atlantic sperm whales), when the enhanced mitigation measures the Navy will implement for NARWs are considered in combination with this low probability, the Navy and NMFS have determined that a vessel strike is highly unlikely and, therefore, it was not requested and is not authorized.

In addition to procedural mitigation, the Navy will limit MTEs and implement additional protective measures in mitigation areas used by NARW for foraging, calving, and migration (where individuals are concentrated and more likely to be struck). These measures, which go above and beyond those focused on other species (*e.g.,* funding of and communication with sightings systems, implementation of speed reductions during applicable circumstances in certain areas) have helped the Navy avoid striking a NARW during training and testing activities in the past; and eliminate the potential for future strikes to occur in the five years of the rule. In particular, the mitigation pertaining to communication among vessels, including the continued participation in and sponsoring of the Early Warning System (EWS, a comprehensive information exchange network dedicated to reducing the risk of vessel strikes to NARW in the Southeast) and NOAA's NARW Sighting Advisory System in the Northeast, will help Navy vessels avoid NARW during transits and training and testing activities.

Implementation of these measures is expected to significantly reduce the probability of striking this particular species during the five-year period of the rule. Further, the Navy has agreed to expand the requirement for Navy vessels to contact the EWS from just the NARW ESA-designated critical habitat to the entire Jacksonville OPAREA. Additionally the Navy has developed a new mitigation measure to broadcast Dynamic Management Area information based on potential changes in NARW distribution. Platforms will use Dynamic Management Area information to assist their visual observation of

applicable mitigation zones during training and testing activities. This will make units even more aware of NARW aggregations to better plan and conduct activities to minimize interactions with this species. Not only will this mitigation measure help the Navy further avoid or reduce potential impacts on NARW from vessel movements, it will also help aid the implementation of applicable procedural mitigation measures for acoustic, explosive, and physical disturbance and strike stressors when Dynamic Management Areas are in effect.

Ship strikes are a fluke encounter for which the probability can never be zero for any vessel. However, the probability for any particular ship striking a marine mammal is primarily a product of the ability of the ship to detect a marine mammal and the ability to effectively act to avoid it. Navy combat ships are inherently among the best at both of these abilities because compared to large commercial vessels, they have trained Lookouts which have received specialized MMO training and the most maneuverable ships, which means that they are more likely to sight a marine mammal and more likely to be able to maneuver to avoid it in the available time—both of which decrease the probability of striking a marine mammal below what it would have been in the absence of those abilities. In the case of the NARW, the extensive communication/detection network described above, which is in use in the areas of highest NARW occurrence and where they may be more susceptible to strike, further increases the likelihood of detecting a NARW and thereby avoiding it, which further reduces the probability of NARW strike. Because of these additional mitigation measures combined with the already low probability that a NARW will be struck, it is extremely unlikely the Navy will strike a NARW and mortality/serious injury of a NARW from vessel strike is neither anticipated nor authorized. Regarding the likelihood of mortality from explosives, the Commenter does not offer any data or rationale to support the assertion that NMFS has underestimated the mortality from explosives. The analysis and estimates contained in the final rule are based on the best available science and accurately represent the appropriate take numbers for mortality and injury from explosives.

Underestimated Beaked Whale Injury and Mortality

Comment 18: A Commenter claims that NMFS is underestimating serious injury and mortality for beaked whales. They note the statement in the proposed rule that because a causal relationship between Navy MFAS use and beaked whale strandings has not been established in all instances, and that, in some cases, sonar was considered to be only one of several factors that, in aggregate, may have contributed to the stranding event, NMFS does ''not expect strandings, serious injury, or mortality of beaked whales to occur as a result of training activities.'' (83 FR 11084). This opinion is inconsistent with best available science and does not take into account the fact that the leading explanation for the mechanism of sonar-related injuries—that whales suffer from bubble growth in organs that is similar to decompression sickness, or ''the bends'' in human divers—has now been supported by numerous papers. At the same time, the commenter argues that NMFS fails to seriously acknowledge that sonar can seriously injure or kill marine mammals at distances well beyond those established for permanent hearing loss (83 FR 10999) and dismisses the risk of stranding and other mortality events (83 FR 11084) based on the argument that such effects can transpire only under the same set of circumstances that occurred during known sonar-related events—an assumption that is arbitrary and capricious. In conclusion, they argue that none of NMFS' assumptions regarding the expected lack of serious injury and mortality for beaked whales are supported by the record, and all lead to an underestimation of impacts.

Response: The Commenter's characterization of NMFS' analysis is incorrect. NMFS does not disregard the fact that it is possible for naval activities using hull-mounted tactical sonar to contribute to the death of marine mammals in certain circumstances (that are not present in the AFTT Study Area) via strandings resulting from behaviorally mediated physiological impacts or other gas-related injuries. NMFS discusses these potential causes and outlines the few cases where active naval sonar (in the U.S. or, largely, elsewhere) has either potentially contributed to or (as with the Bahamas example) been more definitively causally linked with marine mammal strandings. As noted, there are a suite of factors that have been associated with these specific cases of strandings directly associated with sonar (steep bathymetry, multiple hull-mounted platforms using sonar simultaneously, constricted channels, strong surface ducts, etc.) that are not present together in the AFTT Study Area and during the specified activities (and which the Navy takes care across the world not to operate under without additional monitoring). Further, there have never been any strandings associated with Navy sonar use in the AFTT Study Area. For these reasons, NMFS does not anticipate that the Navy's AFTT training or testing activities will result in marine mammal strandings, and none are authorized.

Ship Strike

Comment 19: A Commenter asserted that the Navy's analysis, which NMFS used to support its vessel-strike analysis in the rule, does not address the potential for increased strike risk by non-Navy vessels as a consequence of acoustic disturbance. For example, some types of anthropogenic noise have been shown to induce near-surfacing behavior in NARW, increasing the risk of ship-strike at relatively moderate levels of exposure. An analysis based on reported strikes by Navy vessels does not account for this additional risk. In assessing ship-strike risk, the Navy should include offsets to account for potentially undetected and unreported collisions.

Response: There is no evidence that Navy training and testing activities (or other acoustic activities) increase the risk of nearby non-Navy vessels (or other nearby Navy vessels not involved in the referenced training or testing) striking marine mammals. Further, any increase in the probability of hitting a NARW resulting from this speculated effect would already inherently be accounted for in the probability included in our analysis, which is based on the actual estimated number of NARW strikes (which accounts for unreported non-Navy vessel strikes). Lastly, the anthropogenic noise signal referred to in the comment was developed specifically to elicit a response from NARWs. This type of signal is not analogous to any sound source used by Navy.

Comment 20: A Commenter asserts that NMFS and the Navy's analyses fail to account for the likelihood that the number of ship strikes are grossly underestimated because some animals are struck and not recovered or reported.

Response: While NMFS agrees that broadly speaking the number of total ship strikes may be underestimated due to incomplete information from other sectors (shipping, etc.), NMFS is confident that whales struck by Navy vessels are detected and reported, and Navy strikes are the numbers used in NMFS' analysis to support the authorized number of strikes. Navy ships have multiple Lookouts, including

on the forward part of the ship that can visually detect a hit whale (which has occasionally occurred), in the unlikely event ship personnel do not feel the strike. Navy's strict internal procedures and implementation of past mitigation measures require reporting of any vessel strikes of marine mammals and the Navy's discipline and chain of command give NMFS a high level of confidence that all strikes actually get reported. Accordingly, NMFS is confident that the information used to support the analysis is accurate and complete.

Mitigation and Monitoring

Least Practicable Adverse Impact Determination

Comment 21: A Commenter comments that deaths of or serious injuries to marine mammals that occur pursuant to activities conducted under an incidental take authorization, while perhaps negligible to the overall health and productivity of the species or stock and of little consequence at that level, nevertheless are clearly adverse to the individuals involved and results in some quantifiable (though negligible) adverse impact on the population; it reduces the population to some degree. Under the least practicable adverse impact requirement, and more generally under the purposes and policies of the MMPA, the Commenter asserts that Congress embraced a policy to minimize, whenever practicable, the risk of killing or seriously injuring a marine mammal incidental to an activity subject to section 101(a)(5)(A), including providing measures in an authorization to eliminate or reduce the likelihood of lethal taking. The Commenter recommends that NMFS address this point explicitly in its analysis and clarify whether it agrees that the incidental serious injury or death of a marine mammal always should be considered an adverse impact for purposes of applying the least practicable adverse impact standard.

Response: NMFS disagrees that it is necessary or helpful to explicitly address the point the Commenter raises in the general description of the LPAI standard. The discussion of this standard already notes that there can be population-level impacts that fall below the ''negligible'' standard, but that are still appropriate to mitigate under the LPAI standard. It is always NMFS' practice to mitigate mortality to the greatest degree possible, as death is the impact that is most easily linked to reducing the probability of adverse impacts to populations. However, we cannot agree that one mortality will always decrease any population in a quantifiable or meaningful way. For example, for very large populations, one mortality may fall well within typical known annual variation and not have any effect on population rates. Further, we do not understand the problem that the Commenter's recommendation is attempting to fix. Applicants generally do not express reluctance to mitigate mortality, and we believe that modifications of this nature would confuse the issue.

Comment 22: A Commenter recommends that NMFS address the habitat component of the least practicable adverse impact provision in greater detail. It asserts that NMFS' discussion of ESA-designated critical habitat, marine sanctuaries, and BIAs in the proposed rule is not integrated with the discussion of the least practicable adverse impact standard. It would seem that, under the least practicable adverse impact provision, adverse impacts on important habitat should be avoided whenever practicable. Therefore, to the extent that activities would be allowed to proceed in these areas, NMFS should explain why it is not practicable to constrain them further.

Response: Marine mammal habitat value is informed by marine mammal presence and use and, in some cases, there may be overlap in measures for the species or stock directly and for use of habitat. In this rule, we have identified time-area mitigations based on a combination of factors that include higher densities and observations of specific important behaviors of marine mammals themselves, but also that clearly reflect preferred habitat (*e.g.,* feeding areas in the Northeast, NARW calving areas in the Southeast). In addition to being delineated based on physical features that drive habitat function (*e.g.,* bathymetric features, among others for some BIAs), the high densities and concentration of certain important behaviors (*e.g.,* feeding) in these particular areas clearly indicate the presence of preferred habitat. The Commenter seems to suggest that NMFS must always consider separate measures aimed at marine mammal habitat; however, the MMPA does not specify that effects to habitat must be mitigated in separate measures, and NMFS has clearly identified measures that provide significant reduction of impacts to both ''marine mammal species and stocks and their habitat,'' as required by the statute.

Comment 23: A Commenter recommends that NMFS rework its evaluation criteria for applying the least practicable adverse impact standard to separate the factors used to determine whether a potential impact on marine mammals or their habitat is adverse and whether possible mitigation measures would be effective. In this regard, the Commenter asserts that it seems as though the proposed ''effectiveness'' criterion more appropriately fits as an element of practicability and should be addressed under that prong of the analysis. In other words, a measure not expected to be effective should not be considered a practicable means of reducing impacts.

Response: In the *Mitigation Measures* section, NMFS has explained in detail our interpretation of the LPAI standard, the rationale for our interpretation, and our approach for implementing our interpretation. The ability of a measure to reduce effects on marine mammals is entirely related to its ''effectiveness'' as a measure, whereas the effectiveness of a measure is not connected to its practicability. The Commenter provides no support for its argument, and NMFS has not implemented the Commenter's suggestion.

Comment 24: A Commenter recommends that NMFS recast its conclusions to provide sufficient detail as to why additional measures either are not needed (*i.e.,* there are no remaining adverse impacts) or would not be practicable to implement. The Commenter states that the most concerning element of NMFS' implementation of the least practicable adverse impact standard is its suggestion that the mitigation measures proposed by the Navy will sufficiently reduce impacts on the affected mammal species and stocks and their habitats (83 FR 11045). That phrase suggests that NMFS is applying a ''good-enough'' standard to the Navy's activities. Under the statutory criteria, however, those proposed measures are ''sufficient'' only if they have either (1) eliminated all adverse impacts on marine mammal species and stocks and their habitat or (2) if adverse impacts remain, it is impracticable to reduce them further.

Response: The statement that the Commenter references does not indicate that NMFS applies a ''good-enough'' standard to determining least practicable adverse impact. Rather, it indicates that the mitigation measures are sufficient to meet the statutory legal standard. In addition, as NMFS has explained in our description of the least practicable adverse impact standard, NMFS does not view the necessary analysis through the yes/no lens that the Commenter seeks to prescribe. Rather, NMFS' least practicable adverse impact analysis considers both the reduction of adverse effects and the practicability. Further, since the proposed rule was

published, the Navy and NMFS have evaluated additional measures in the context of both their practicability and their ability to further reduce impacts to marine mammals and have determined that the addition of several measures (see *Mitigation Measures*) is appropriate. Regardless, beyond these new additional measures, where the Navy's AFTT activities are concerned, the Navy has indicated that further procedural or area mitigation of any kind (beyond that prescribed in this final rule) would be entirely impracticable.

Comment 25: A Commenter recommends that any ''formal interpretation'' of the least practicable adverse impact standard by NMFS be issued in a stand-alone, generally applicable rulemaking (*e.g.,* in amendments to 50 CFR 216.103 or 216.105) or in a separate policy directive, rather than in the preambles to individual proposed rules.

Response: We appreciate the Commenter's recommendation and may consider the recommended approaches in the future. We note, however, that providing relevant explanations in a proposed incidental take rule is an effective and efficient way to provide information to the reader and solicit focused input from the public, and ultimately affords the same opportunities for public comment as a stand-alone rulemaking would. NMFS has provided similar explanations of the least practicable adverse impact standard in other recent section 101(a)(5)(A) rules, including: U.S. Navy Operations of Surveillance Towed Array Sensor System Low Frequency Active (SURTASS LFA) Sonar; Geophysical Surveys Related to Oil and Gas Activities in the GOMEX; and the proposed rule for U.S. Navy Training and Testing in the Hawaii-Southern California Training and Testing (HSTT) Study Area.

Comment 26: A Commenter cites two judicial decisions and comments that while there have been some improvements in mitigation relative to NMFS' 2013–2018 final rule for AFTT activities, the ''least practicable adverse impact'' standard has not been met. The Commenter asserts, for example, that if in prescribing protective measures in important habitat NMFS concludes after careful analysis that complete exclusion of unit-level sonar training from the area is not practicable, the agency should consider what reductions in activity are practicable, as by looking at particular types of exercises or testing activities or by limiting the amount of activity that can take place. The Commenter argues that the MMPA sets forth a ''stringent standard'' for mitigation that requires the agency to minimize impacts to the lowest practicable level, and that the agency must conduct its own analysis and clearly articulate it: it ''cannot just parrot what the Navy says.''

Response: NMFS disagrees with much of what the Commenter asserts. When a suggested or recommended mitigation measure is impracticable, NMFS has explored variations of that mitigation to determine if a practicable form of related mitigation exists. This is clearly illustrated in NMFS' independent mitigation analysis process explained in this rule. First, the type of mitigation required varies by mitigation area, demonstrating that NMFS has engaged in a site-specific analysis to ensure mitigation is tailored only when practicability demands, *i.e.,* some forms of mitigation were practicable in some areas but not others. Other examples of NMFS' analysis on this issue appear throughout the rule. For instance, while it was not practicable for the Navy to expand the SE NARW Mitigation Area to the full extent recommended, the Navy did agree to some expansion of the SE NARW Mitigation Area to provide better protection. Additionally, while the Navy cannot alleviate all training in the NE NARW Mitigation Area due to changes in requirements, Navy removed one impactful testing activity (four events) that reduced takes for NARW and other species significantly.

Nonetheless, NMFS agrees that the agency must conduct its own analysis, which it has done here, and not just accept what is provided by the Navy. That does not mean, however, that NMFS cannot review the Navy's analysis of effectiveness and practicability, and concur with those aspects of the Navy's analysis with which NMFS agrees. The Commenter seems to suggest that NMFS must describe in the rule in detail the rationale for not adopting every conceivable permutation of mitigation, which is neither reasonable nor required by the MMPA. NMFS has described our well-reasoned process for identifying the measures needed to meet the LPAI standard in the *Mitigation Measures* section in this rule, and we have followed the approach described there when analyzing potential mitigation for the Navy's activities in the AFTT Study Area. Discussion regarding specific recommendations for mitigation measures provided by the Commenter on the proposed rule are discussed separately.

Procedural Mitigation Effectiveness and Recommendations

Comment 27: A Commenter commented that the Phase III proposed mitigation zones would not protect various functional hearing groups from PTS. For example, the mitigation zone for an explosive sonobuoy is 549 m but the mean PTS zones range from 2,205–3,324 m for HF cetaceans and 308–1,091 m for LF cetaceans. Similarly, the mitigation zone for an explosive torpedo is 1,920 m but the mean PTS zones range from 13,105–14,627 m for HF cetaceans, 3,133–3,705 m for LF cetaceans, and 3,072–3,232 for pinnipeds in water (PW). Mitigation effectiveness is further complicated when platforms fire munitions (*e.g.,* for missiles and rockets) at targets 28 to 140 km away from the firing platform, as described in the AFTT DEIS/OEIS. An aircraft would clear the target area well before it positions itself at the launch location and launches the missile or rocket. Ships, on the other hand, do not clear the target area before launching the missile or rocket. In either case, marine mammals could be present in the target area at the time of the launch unbeknownst to the Navy.

Response: NMFS is aware that some mitigation zones do not fully cover the area in which an animal from a certain hearing group may incur PTS. For this small subset of circumstances, NMFS discussed potential enlargement of the mitigation zones with the Navy but concurred with the Navy's assessment that further enlargement would be impracticable. Specifically, the Navy explained that explosive mitigation zones, as discussed in Chapter 5 of the AFTT FEIS/OEIS, any additional increases in mitigation zone size (beyond what is depicted for each explosive activity), or additional observation requirements would be impracticable to implement due to implications for safety, sustainability, the Navy's ability to meet Title 10 requirements to successfully accomplish military readiness objectives, and the Navy's ability to conduct testing associated with required acquisition milestones or as required on an as-needed basis to meet operational requirements. Additionally, Navy Senior Leadership has approved and determined that the mitigation detailed in Chapter 5 (Mitigation) of the AFTT FEIS/OEIS provides the greatest extent of protection that is practicable to implement. The absence of mitigation to avoid all Level A harassment in some of these circumstances has been analyzed, however, and the Navy is authorized for any of these Level A harassment takes that may occur.

Comment 28: A Commenter believes that rather than simply reducing the size of the mitigation zones it plans to monitor, the Navy should supplement

its visual monitoring efforts with other monitoring measures. Specifically, the Commenter further suggests that sonobuoys could be deployed with the target in the various target areas prior to the activity for the Navy to better determine whether the target area is clear and remains clear until the munition is launched. The Commenter also suggests that the Navy's instrumented Undersea Warfare Training Range (USWTR) could be used for real-time mitigation and refers to Navy-cited improvements in the use of other ranges for monitoring. The Navy did propose to supplement visual monitoring with passive acoustic monitoring during three explosive activity types but not during the remaining explosive activities or during low-, mid-, and high-frequency active sonar activities. Further, the Commenter recommends that NMFS require the Navy to use passive and active acoustic monitoring, whenever practicable, to supplement visual monitoring during the implementation of its mitigation measures for all activities that could cause injury or mortality beyond those explosive activities for which passive acoustic monitoring already was proposed. This includes use of the instrumented USWTR in the coming years.

Response: For explosive mitigation zones, as discussed in Chapter 5 of the AFTT FEIS/OEIS, any additional increases in mitigation zone size (beyond what is depicted for each explosive activity) or observation requirements would be impracticable to implement due to implications for safety, sustainability, and the Navy's ability to meet Title 10 requirements to successfully accomplish military readiness objectives. We do note, however, that since the proposed rule, the Navy has committed to implementing pre-event observations for all in-water explosives events (including some that were not previously monitored) and to using additional platforms if available in the vicinity of the detonation area to help with this monitoring.

As discussed in the comment, the Navy does employ passive acoustic monitoring when practicable to do so (*i.e.,* when assets that have passive acoustic monitoring capabilities are already participating in the activity). For other explosive events, there are no platforms participating that have passive acoustic monitoring capabilities. Adding a passive acoustic monitoring capability (either by adding a passive acoustic monitoring device to a platform already participating in the activity, or by adding a platform with integrated passive acoustic monitoring capabilities to the activity, such as a sonobuoy) for mitigation is not practicable. As discussed in Section 5.5.3 (Active and Passive Acoustic Monitoring Devices) of the AFTT FEIS/OEIS, there are significant manpower and logistical constraints that make constructing and maintaining additional passive acoustic monitoring systems or platforms for each training and testing activity impracticable. Additionally, diverting platforms that have passive acoustic monitoring platforms would impact their ability to meet their Title 10 requirements and reduce the service life of those systems.

Regarding the use of instrumented ranges such as USTWR for real-time mitigation, the commenter is correct that the Navy continues to develop the technology and capabilities on their Ranges for use in marine mammal monitoring, which can be effectively compared to operational information after the fact to gain information regarding marine mammal response, and occasionally used to support small-scale real-time mitigation. However, as discussed above, the manpower and logistical complexity involved in detecting and localizing marine mammals in relation to multiple fast-moving sound source platforms in order to implement real-time mitigation is significant. USWTR is not scheduled to go active until late 2019 (half of USWTR); however, the Navy continues to explore mechanisms by which the Range will contribute to marine mammal mitigation and monitoring. Lastly, the mitigation zones for active sonar systems encompass the ranges to potential injury.

Comment 29: A Commenter recommends that NMFS require the Navy to conduct additional pre-activity overflights before conducting any activities involving detonations barring any safety issues (*e.g.,* low fuel), as well as post-activity monitoring for activities involving medium- and large caliber projectiles, missiles, rockets, and bombs.

Response: The Navy has agreed to implement pre-event observation mitigation, as well as post-event observation, for all in-water explosive events. If there are other platforms participating in these events and in the vicinity of the detonation area, they will also visually observe this area as part of the mitigation team.

Comment 30: A Commenter discusses that since 2010, the Navy has been collaborating with researchers at the University of St. Andrews to study Navy Lookout effectiveness. The Navy does not appear to have mentioned that study in its AFTT DEIS/OEIS for Phase III and NMFS did not discuss it in the rule. For its Phase II DEISs, the Navy noted that data collected in that study were insufficient to yield statistically significant results. Nevertheless, the Commenter continues to consider the basic information provided by the studies to be useful and cites several specific instances where MMOs sighted marine mammals that were not sighted by Navy Lookouts.

Response: The Lookout effectiveness study that the Commenter references is still ongoing. This type of study has never been conducted, is extremely complex to ensure data validity, and requires a substantial amount of data to conduct meaningful statistical analysis. The Navy has stated that it is committed to completing it; however, as noted by the Commenter, there has not been enough data collected to conduct a sufficient analysis. Therefore drawing conclusions from an incomplete data set is not scientifically valid.

Comment 31: A Commenter commented that NMFS should increase the exclusion zone to the 120 dB isopleth. Since some animals are sensitive to sonar at low levels of exposure, the exclusion zone should ensure lower exposure than 120 dB. Additionally, there should be buffer zones along the boundaries of the mitigation areas to ensure that the mitigation areas are not exposed to sources higher than the 120 dB.

Response: First, it is important to note that the Commenter is suggesting that NMFS require mitigation that would eliminate all take, which is not what the applicable standard requires. Rather, NMFS is required to put in place measures that effect the ''least practicable adverse impact.'' Separately, NMFS acknowledges that some marine mammals may respond to sound at 120 dB in some circumstances; however, based on the best available data, only a subset of those exposed at that low level respond in a manner that would be considered harassment under the MMPA. NMFS and the Navy have quantified those individuals of certain stocks where appropriate, analyzed the impacts, and authorized them where needed. Further, NMFS and the Navy have identified exclusion zone sizes that are best suited to minimize impacts to marine mammal species and stocks and their habitat while also being practicable (see *Mitigation Measures* section of this rule). Buffer zones are addressed in Comment 50.

Comment 32: A Commenter recommended NMFS impose a 10 kn ship speed in biologically important areas for marine mammals to reduce

vessel strikes and that NMFS should mandate that ship speed be reduced to a maximum of 10 kn in mitigation areas or in the presence of marine mammals to decrease the probability of strikes and decrease sound disturbance from engines.

Response: This issue is addressed elsewhere in the *Comments and Responses* section and for specific mitigation areas, but we also reiterate here that the Navy has applied conditional ship-speed restrictions in the areas where it is practicable. However, generally speaking, it is impracticable (because of impacts to mission effectiveness) to further reduce ship speeds for Navy activities, and, moreover, given the maneuverability of Navy ships at higher speeds and effective Lookouts, any further reduction in speed would reduce the already low probability of ship strike little, if any.

Mitigation Areas

Introduction

The Navy included a comprehensive proposal of mitigation measures in their initial application that included procedural mitigations that reduce the likelihood of mortality, injury, hearing impairment, and more severe behavioral responses for most species. The Navy also included time/area mitigation that further protects areas where important behaviors are conducted and/or sensitive species congregate, which reduces the likelihood of takes that are likely to impact reproduction or survival (as described in the *Mitigation Measures* section of the final rule and the Navy's application). As a general matter, where an applicant proposes measures that are likely to reduce impacts to marine mammals, the fact that they are included in the proposal and application indicates that the measures are practicable, and it is not necessary for NMFS to conduct a detailed analysis of the measures the applicant proposed (rather, they are simply included). However, it is necessary for NMFS to consider whether there are additional practicable measures that could also contribute to the reduction of adverse effects on the species or stocks through effects on annual rates of recruitment or survival. In the case of the Navy's application, NMFS raised potential additional mitigation measures for consideration, and discussion between the Navy and NMFS of the multiple factors considered in a least practicable adverse impact analysis resulted in the expansion of the SE NARW Mitigation Area by 500 mi^2.

During the public comment period on the proposed rule, NMFS received numerous recommendations for the Navy to implement additional mitigation measures, both procedural and time/area limitations. Extensive discussion of the recommended mitigation measures in the context of the factors considered in the least practicable adverse impact analysis (considered in the *Mitigation Measures* section of the final rule and described below), as well as considerations of alternate iterations or portions of the recommended measures considered to better address practicability concerns, resulted in the addition of several procedural mitigations and expansion of multiple time/area mitigations (see the *Mitigation Measures* section in the final rule). These additional areas reflect, for example, the concerning stock status of the NARW and Bryde's whales (which resulted in expanded time/area mitigation), focus on areas where important behaviors and habitat are found (which resulted in NARW mitigation areas expanded to better reflect ESA-designated critical habitat in the Southeast calving area and Northeast feeding areas), and enhancement of the Navy's ability to detect and reduce injury and mortality (which resulted in expanded monitoring before and after explosive events and movement of ship shock trials outside of Bryde's whale areas and the Mid-Atlantic Planning Awareness Mitigation Areas). Through extensive discussion, NMFS and the Navy worked to identify and prioritize additional mitigation measures that are likely to reduce impacts on marine mammal species or stocks and their habitat and are also possible for the Navy to implement. Ultimately, the Navy adopted all mitigation measures that are possible without jeopardizing their mission and Title 10 responsibilities. In other words, a comprehensive assessment by Navy leadership of the final, entire list of mitigation measures concluded that the inclusion of any further mitigation beyond those measures identified here in the final rule would be entirely impracticable. Below is additional discussion regarding specific recommendations for mitigation measures.

Mitigation Area Recommendations

Comment 33: In several places in their comment letter, a Commenter recommends that the Navy use an approach similar to that of the settlement agreement in *Conservation Council for Hawaii* v. *NMFS,* 97 F.Supp. 3d 1210 (D. Haw. 2015), which, while barring or restricting active sonar and explosives activities, reserved the Navy's authority to proceed regardless, provided that certain conditions were met: (1) That the Navy deemed the activity necessary for national defense; (2) that the authority could be invoked only by the highest Command authority; and (3) that any invocation of the authority be reported to NMFS and, through the Navy's Annual and Five-Year Exercise Reports, to the public.

Response: Following the publication of the 2013 HSTT Study Area MMPA incidental take rule, a settlement agreement that resulted from the litigation prohibited or restricted Navy activities within specific areas in the HSTT Study Area. As a general note, the provisional prohibitions and restrictions on activities within the HSTT Study Area were derived pursuant to negotiations with the plaintiffs in that case and were specifically not evaluated or selected based on the type of thorough examination of best available science that occurs through the rulemaking process under the MMPA, or through related analyses conducted under the National Environmental Policy Act (NEPA) or the ESA. The agreement did not constitute a concession by the Navy as to the potential impacts of Navy activities on marine mammals or any other marine species. Furthermore, the Navy's adoption of restrictions on its HSTT activities as part of a relatively short-term settlement does not mean that those restrictions are necessarily supported by the best available science, likely to reduce impacts to marine mammals species or stocks and their habitat, or practicable to implement from a military readiness standpoint over the longer term in either the HSTT Study Area or other Study Areas, including AFTT. The Fleet Commander and senior Navy leadership have approved the mitigation and explicitly determined that this is the maximum amount of mitigation that is practicable to implement. Permission schemes would impede on commanding officers who are empowered to train their crews and operate their vessels to maintain readiness and ensure personnel safety.

North Atlantic Right Whale

Comment 34: As a general matter, several comments were provided in regards to the NARW.

Response: NMFS appreciates the concerns expressed by Commenters regarding NARW in the Northeast in their feeding and mating areas and along the Atlantic Coast during migration, as well as in the Southeast during calving. As an agency, NMFS is working to address the numerous issues facing

NARW, including continued work to reduce deaths due to ship strike by non-military vessels and entanglement in fishing gear, ongoing investigation of the Unusual Mortality Event (UME), and other measures to investigate and address the status of the species. The best available scientific information shows that the majority of NARW sightings in the Southeast occur in NARW calving areas from roughly November through April, with individual NARWs migrating to and from these areas through Mid-Atlantic shelf waters.

Since the proposed rule, the Navy has expanded the NE NARW Mitigation Area to match designated ESA-designated critical habitat in the Northeast. This further minimizes LFAS/MFAS/HFAS and explosives in the mitigation area year-round and incorporates mitigation measures to avoid ship strike to NARW (which will also reduce potentially ship strike to other large whales). The Navy will obtain Early Warning System NARW sightings data in the Jacksonville Operating Area and report this information to all units to help vessels and aircraft reduce potential interactions with NARW. The Navy will also broadcast awareness notification messages with NARW Dynamic Management Area information *(e.g.,* location and dates) to applicable Navy assets operating in the vicinity of the Dynamic Management Area. The Navy added the SE NARW Critical Habitat Special Reporting Area and will report the total hours and counts of active sonar and in-water explosives used in the Southeast NARW ESA-designated critical habitat). Additionally, the Navy has removed one of their testing activities in the Northeast Range Complex (four events—USWTR) which decreased the number of Level B harassment takes annually for NARW by 115 takes. Separately, this change also decreased annual Level B harassment takes by approximately 200 takes for ESA-listed fin whale, 20 takes for sei whales, and approximately 10,000 takes for harbor porpoise, which are discussed elsewhere in comments and responses. Additional discussion on NARW is provided below, organized geographically north to south.

NARW Northeast

Comment 35: Several Commenters recommended expanding the Navy's NE NARW Mitigation Area spatially and temporally to include important areas such as Jeffreys Ledge and the central Gulf of Maine. Commenters recommended that NMFS include (1) both Jeffreys Ledge and the central Gulf of Maine in the Navy's NE NARW Mitigation Area, at least during the timeframes noted by LaBrecque *et al.* (2015a). A Commenter stated that, if NMFS chooses not to implement their recommendation for both Jeffreys Ledge and the central Gulf of Maine during the timeframes noted by LaBrecque *et al.* (2015a), that NMFS require the Navy to (1) implement speed restrictions of no more than 10 kn during vessel transits, (2) obtain the latest NARW sightings information from the Northeast Fisheries Science Center's NARW Sighting Advisory System prior to transits, (3) use the sightings information to reduce potential interactions with NARWs during transits, and (4) implement speed reductions after a vessel observes a NARW, if a vessel is within 5 nmi of a sighting reported to the NARW Sighting Advisory System within the past week, and when operating at night or during periods of reduced visibility. A Commenter also recommended that a 10 kn vessel speed restriction be required for the NE NARW Mitigation Area and also within the boundaries of Jeffreys Ledge, at a minimum between the months of June-July and October-December.

Response: In response to the recommendations of enlarging the NE NARW Mitigation Area, the Navy has agreed to expand the NE NARW Mitigation Area to match the NE NARW ESA-designated critical habitat. The expanded NE NARW Mitigation Area encompasses key BIAs, as described below. In general, the expanded NE NARW Mitigation Area encompasses all or nearly 100 percent of Cape Cod Bay, Jeffreys Ledge, the western edge of Georges Bank, and the northern portion of the Great South Channel BIAs. One hundred percent of the NARW feeding area on Jeffreys Ledge and the NARW mating area in the central Gulf of Maine are included in the expanded NE NARW Mitigation Area (as well as covering 100 percent in the Gulf of Maine Planning Awareness Area). One hundred percent of the NARW feeding area on Cape Cod Bay and Massachusetts Bay are included in the expanded NE NARW Mitigation Area. Additionally, 95.08 percent of the NARW feeding area in the Great South Channel and the northern edge of Georges Bank is included in the expanded NE NARW Mitigation Area. The mitigation measures required in the previous NE NARW Mitigation Areas will carry over to the expanded NE NARW Mitigation Area and be implemented year-round.

In response to the recommendation to implement additional vessel speed-related mitigation measures for NARW on Jeffreys Ledge and the central Gulf of Maine, these areas are now in fact encompassed by the expanded NE NARW Mitigation Area, as described above, and vessel speed-related mitigation measures are being implemented during activities using non-explosive torpedoes (the same described in proposed rule). Specifically, in the NE NARW Mitigation Area, during non-explosive torpedo events only, the Navy will (1) maintain a ship speed of no more than 10 kn during transits and normal firing; no more than 18 kn during submarine target firing; and during vessel target firing, vessel speeds may exceed 18 kn for brief periods of time (*e.g.,* 10–15 min.); (2) before vessel transits within the NARW Mitigation Area, conduct a web query or email inquiry to the Northeast Fisheries Science Center's NARW Sighting Advisory System to obtain the latest NARW sightings information; (3) vessels will use the sightings information to reduce potential interactions with NARW during transits; and (4) in the NE NARW Mitigation Area, vessels will implement speed reductions after they observe a NARW, if they are within 5 nmi of a sighting reported to the NARW Sighting Advisory System within the past week, and when operating at night or during periods of reduced visibility.

Comment 36: A Commenter recommends that NMFS prohibit all active low-, mid-, and high-frequency sonar and limit non-explosive torpedo use from April through June in the Great South Channel and from February through April in Cape Cod Bay within the NE NARW Mitigation Area.

Response: As discussed above, the Navy has agreed to expand the NE NARW Mitigation Area to encompass all of the ESA-designated critical habitat in the Northeast year-round. Therefore, within the expanded NE NARW Mitigation Area, the Navy has agreed to minimize, but not eliminate, the use of low-frequency active sonar, mid-frequency active sonar, and high-frequency active sonar to the maximum extent practicable. The Navy will not use Improved Extended Echo Ranging sonobuoys within three nmi of the mitigation area and not use explosive and non-explosive bombs, in-water detonations, and explosive torpedoes within the mitigation area. While this does not include non-explosive torpedoes within the NE NARW Mitigation Area, there are only a small number of Level B harassment takes from this activity. The Navy analyzed this area and determine that non-explosive torpedo activities could not be removed from this area as described

below. There are 33 estimated takes from TORPEX. This region provides a variety of bathymetric and environmental conditions necessary to ensure functionality and accuracy of systems and platforms in areas analogous to where the military operates. Testing locations are typically located near systems command support facilities, which provide critical safety, platform, and infrastructure support and technical expertise necessary to conduct testing. The Navy has used these same torpedo testing areas in this region for decades because they provide critical bathymetric and oceanographic features, and using these same areas provides data collection consistency, which is critical for comparative data analysis. In short, NMFS concurs with the Navy that the addition of this measure would be impracticable. However to mitigate for non-explosive torpedo events, the Navy has already agreed to several procedural mitigation steps to avoid NARW as follows. The Navy will conduct activities during daylight hours in Beaufort sea state 3 or less. The Navy will use three Lookouts (one positioned on a vessel and two in an aircraft during dedicated aerial surveys) to observe the vicinity of the activity. An additional Lookout will be positioned on the submarine, when surfaced. Immediately prior to the start of the activity, Lookouts will observe for floating vegetation and marine mammals; if observed, the activity will not commence until the vicinity is clear or the activity is relocated to an area where the vicinity is clear. During the activity, Lookouts will observe for marine mammals; if observed, the activity will cease. To allow a sighted NARW (or any other marine mammals) to leave the area, the Navy will not recommence the activity until one of the following conditions has been met: (1) The animal is observed exiting the vicinity of the activity; (2) the animal is thought to have exited the vicinity of the activity based on a determination of its course, speed, and movement relative to the activity location; or (3) the area has been clear from any additional sightings for 30 min.

Northeast Planning Awareness Mitigation Area

Comment 37: A Commenter recommends Navy/NMFS further limiting MTEs and prohibiting/limiting other activities to reduce cumulative exposures to range-limited beaked whale and sperm whale populations that may inhabit the NE Planning Awareness Mitigation Areas. The Commenter recommends that NMFS consult with the Navy and consider prohibiting the planning and conduct of major exercises within these areas, using the *Conservation Council* settlement-agreement approach as described earlier in the *Mitigation Areas* of this *Comments and Responses* section. If MTEs cannot absolutely be avoided, the Commenter recommends that NMFS should prohibit conduct of more than two MTEs per year, with each exercise carried out in different NE Planning Awareness Mitigation Areas (*i.e.,* one exercise in the northern Mitigation Area, and one exercise in the southern Mitigation Area), to ensure that marine mammal populations with site fidelity are not exposed to multiple major training exercises within a single year. Similarly, the Commenter asserts that NMFS should consider prohibiting testing and unit-level sonar and in-water explosives training, or alternatively, and less preferably, reducing the number of hours allowable in a given year, with the prohibition or restriction structured as in the *Conservation Council* settlement agreement.

Response: As part of the NE Planning Awareness Mitigation Areas, the Navy already agrees to avoid conducting MTEs within the mitigation area to the maximum extent practicable. However, if Navy needs to conduct MTE's, it will not conduct more than four per year within the mitigation area. The Commenter indicated that range-limited beaked whale populations have been found on the shelf break off Cape Hatteras, areas off Canada, in the Mediterranean, off Southern California, in the Bahamas, and around the Hawaiian Islands, and range-limited sperm whale populations have been found off Cape Hatteras, the GOMEX, and off Western Australia. The Commenter assumed that beaked whales and sperm whales are also range-limited within the NE Planning Awareness Mitigation Areas, and as a result, recommended additional mitigation to limit MTEs and other activities to reduce cumulative exposure in the NE Planning Awareness Mitigation Areas. However, NMFS agrees with the Navy's assessment that the best available science does not indicate that beaked whales and sperm whales are range-limited within the NE Planning Awareness Mitigation Areas. NMFS relied on the best available scientific information (*e.g.,* NMFS' Stock Assessment Reports (SARs); Roberts *et al.,* 2016, 2017; and numerous study reports from Navy-funded monitoring and research in the specific geographic region) in assessing density, distribution, and other information regarding marine mammal use of habitats in the study area. In addition, NMFS consulted LaBrecque *et al.* (2015), which provides a specific, detailed assessment of known BIAs and provides the best available science to help inform regulatory and management decisions about some, though not all, important cetacean areas. BIAs, which may be region-, species-, and/or time-specific, include reproductive areas, feeding areas, migratory corridors, and areas in which small and resident populations are concentrated. There are currently no BIAs for beaked whales or sperm whales along the Atlantic Coast.

As discussed in the *Analysis and Negligible Impact Determination* section, a few minor to moderate TTS or behavioral reactions to an individual over the course of a year are unlikely to have an impact on individual reproduction or survival. Considering these factors and the required mitigation measures, adverse impacts for the species or stock via effects on recruitment or survival are not expected. The Navy does not typically schedule MTEs in the Northeast Range Complexes, as indicated in Table 64. For training and testing that does occur here, this area provides a wide range of bathymetric and topographic opportunities that support critical smaller scale training and testing necessary to meet mission requirements. Additionally, MTEs originally planned for other locations may have to change during an exercise, or in exercise planning, based on an assessment of the performance of the units, or due to other conditions such as weather and mechanical issues. These contingency requirements preclude the Navy from completely eliminating MTEs from occurring in this area.

Comment 38: A Commenter recommends prohibiting/limiting sonar and in-water explosives activities within the southern portion of the Northeast Canyons and Seamounts National Marine Monument, including the Bear Seamount and Physalia Seamount.

Response: Currently the Northeast Canyons and Seamounts National Monument overlap the Gulf of Maine Planning Awareness Mitigation Area and the NE Planning Awareness Mitigation Areas, respectively. Bear Seamount and Physalia Seamount are contained within the Seamount Unit. The Navy is already limiting activities within the NE Planning Awareness Mitigation Areas by avoiding conducting MTEs to the maximum extent practicable (and avoiding MTEs completely within the Gulf of Maine Planning Awareness Mitigation Area). In its assessment of the practicability of

potential mitigation, the Navy indicated that it had considered implementing additional restrictions on active sonar and explosives in the Northeast Canyons and Seamounts National Marine Monument. Navy's operational assessment determined that implementing additional mitigation is impracticable for the reasons stated in Section 5.4.2 of the AFTT FEIS/OEIS (Mitigation Areas off the Northeastern United States) and also would be impracticable due to implications for safety (the ability to avoid potential hazards), sustainability (maintain readiness), and the Navy's ability to continue meeting its Title 10 requirements to successfully accomplish military readiness objectives. The Navy's operational input indicates that designating additional mitigation areas (including the southern portion of the Northeast Canyons and Seamounts National Marine Monument) or implementing further restrictions on the level, number, or timing (seasonal or time of day) of training or testing activities within the mitigation areas (including, but not limited to, limiting MTEs and other activities to reduce cumulative exposures) would have a significant impact on (1) the ability of Navy units to meet their individual training and certification requirements, preventing them from deploying with the required level of readiness necessary to accomplish their missions; (2) the ability to certify strike groups to deploy to meet national security tasking, limiting the flexibility of Combatant Commanders and warfighters to project power, engage in multi-national operations, and conduct the full range of naval warfighting capability in support of national security interests; (3) the ability of program managers and weapons system acquisition programs to meet testing requirements and required acquisition milestones; (4) operational costs due to extending distance offshore, which would increase fuel consumption, maintenance, and time on station to complete required training and testing activities; (5) the safety risk associated with conducting training and testing at extended distances offshore, farther away from critical medical and search and rescue capabilities; (6) accelerated fatigue-life of aircraft and ships, leading to increased safety risk and higher maintenance costs; (7) training and testing realism due to reduced access to necessary environmental or oceanographic conditions that replicate potential real world areas in which combat may occur; and (8) the ability for Navy sailors to train and become proficient in using the sensors and weapons systems as would be required in a real world combat situation. NMFS concurs with the Navy's determination that the recommended additional mitigation is impracticable and, accordingly, has not included it in the requirements of the rule.

Gulf of Maine Planning Awareness Mitigation Area

Comment 39: A Commenter comments that, although the Gulf of Maine Planning Awareness Area represents a significant geographic area, the mitigation requirements are less limited compared to the NE NARW Mitigation Area. Within the boundaries of this area between the months of July–September, the Commenter recommends prohibiting/further limiting mid- and high-frequency sonar and prohibit explosives activities within the biologically important area for harbor porpoise. The Commenter recommends prohibiting low-, mid-, and high-frequency sonar activities from March through November in biologically important feeding habitat for minke whales at Cashes Ledge, as well as prohibiting explosives activities in this area year-round. The Commenter also recommends prohibiting/limiting sonar and in-water explosives activities within the northern portion of the Northeast Canyons and Seamounts National Marine Monument.

Response: In regards to harbor porpoise, 81.87 percent of the small and resident population BIA within the U.S. Exclusive Economic Zone (EEZ) overlaps the now expanded year-round NE NARW Mitigation Area, and 100 percent is contained within the Gulf of Maine Planning Awareness Mitigation Area.

In regards to minke whales, 100 percent of the BIA falls within the now expanded year-round NE NARW Mitigation Area, and 100 percent also falls within the Gulf of Maine Planning Awareness Mitigation Area. The Navy is minimizing the use of low-, mid-, and high-frequency active sonar to the maximum extent practicable and limiting the use of explosives, explosive and non-explosive bombs, in-water detonations, and explosive torpedoes within the expanded NE NARW Mitigation Area year-round. Specifically, the Navy will not use Improved Extended Echo Ranging sonobuoys within 3 nmi of the mitigation area. The Navy has now agreed (since the proposed rule) not to conduct MTEs within the year-round Gulf of Maine Planning Awareness Mitigation Area and will cap the sonar use in the mitigation area to less than 200 hours of hull-mounted MFAS per year, thereby reducing impacts to harbor porpoise further. As discussed in the *Analysis and Negligible Impact Determination* section, the activities conducted by the Navy are of short duration (minutes to a few hours) and widely dispersed temporally and geographically and are not expected to significantly affect natural behavioral patterns of harbor porpoises or minke whales, such as feeding, breeding, etc., in a manner that would adversely affect either stock via impacts on rates of recruitment or survival.

In regards to the use of active sonar and in-water explosives being prohibited or limited in the area year-round within the boundaries of the northern portion of the Northeast Canyons and Seamounts Marine National Monument, the northern portion (Canyon Unit) falls inside of the Gulf of Maine Planning Awareness Mitigation area. The Navy is already limiting their use of hull-mounted MFAS by capping use at 200 hrs per year and now will not conduct MTEs within the mitigation area. However, there are no limitations on explosives in this area. The Navy has worked collaboratively with NMFS to develop mitigation areas using inputs from the operational community, the best available science discussed in Chapter 3 (Affected Environment and Environmental Consequences) of the AFTT FEIS/OEIS, published literature, predicted activity impact footprints, and marine species monitoring and density data. The Navy has communicated that it completed an extensive biological assessment and operational analysis (based on a detailed and lengthy review by training experts and leadership responsible for meeting statutory readiness requirements) of potential mitigation areas throughout the entire Study Area. The mitigation identified in this final rule represents what the Navy has stated is the maximum mitigation that is practicable to implement under the Proposed Action. Operational input indicates that designating additional mitigation areas (including, but not limited to, within the northern portion of the Northeast Canyons and Seamounts Marine National Monument) and implementing further restrictions on the level, number, or timing (seasonal or time of day) of training or testing activities within the mitigation areas (including, but not limited to, limiting MTEs and other activities) would have a significant impact on (1) the ability for units to meet their individual training and certification requirements, preventing them from

deploying with the required level of readiness necessary to accomplish their missions; (2) the ability to certify strike groups to deploy to meet national security tasking, limiting the flexibility of Combatant Commanders and warfighters to project power, engage in multi-national operations, and conduct the full range of naval warfighting capability in support of national security interests; (3) the ability of program managers and weapons system acquisition programs to meet testing requirements and required acquisition milestones; (4) operational costs due to extending distance offshore, which would increase fuel consumption, maintenance, and time on station to complete required training and testing activities; (5) the safety risk associated with conducting training and testing at extended distances offshore farther away from critical medical and search and rescue capabilities; (6) accelerated fatigue-life of aircraft and ships leading to increased safety risk and higher maintenance costs; (7) training and testing realism due to reduced access to necessary environmental or oceanographic conditions that replicate potential real world areas in which combat may occur; and (8) the ability for Navy sailors to train and become proficient in using the sensors and weapons systems as would be required in a real world combat situation. The Navy has stated that it is unclear how it would be able to train and test without access to the ranges and locations that have been carefully developed over decades. Additionally, limiting access to ranges would deny operational commanders the ability to respond to emerging national security challenges, placing national security at risk and sailors in danger by not being properly prepared to perform their missions. Likewise, the Navy has stated that these restrictions would have a significant impact on the testing of current systems and the development of new systems. This would deny weapons system program managers and research, testing, and development program managers the flexibility to rapidly field or develop necessary systems due to the required use of multiple areas within limited timeframes. NMFS concurs with the Navy's practicability assessment.

NARW Mid-Atlantic

Comment 40: A Commenter recommends that the Navy should not plan activities in the Mid-Atlantic Planning Awareness Mitigation Areas to avoid times of predicted higher NARW occurrence, and that NMFS should consult experts in the NARW Consortium, including the New England Aquarium, for the best available information on the timing of the NARW migration and the months in which NARW are most likely to be present within the Mid-Atlantic Planning Awareness Mitigation Areas.

Response: By late March, NARW typically leave the calving grounds of the southeast and travel up the U.S. continental shelf to the Gulf of Maine (Kenney *et al.,* 2001; Knowlton *et al.,* 2002 as cited in LaBrecque *et al.,* 2015), and during this migration, the animals will traverse these training areas (*e.g.,* Virginia Capes). Additionally, recent evidence suggests distributional shifts of NARW, with passive acoustic data indicating nearly year-round presence of this species in the mid-Atlantic area (Davis *et al.,* 2017). As described in the final rule, the Navy will avoid conducting MTEs within the mitigation area (Composite Training Unit Exercises or Fleet Exercises/Sustainment Exercises) to the maximum extent practicable but cannot avoid the area completely and will not conduct more than four MTEs per year.

Locations for training and testing activities are chosen based on their proximity of associated training and testing ranges, operating areas (*e.g.,* VACAPES), available airspace (*e.g.,* W–50), unobstructed sea space, and aircraft emergency landing fields (*e.g.,* Naval Air Station Oceana), and with consideration for public safety (*e.g.,* avoiding areas popular for recreational boating). The Navy has indicated that further restrictions in this area (*e.g.,* further restricting the number of major training events or seasonal restrictions on major training exercises based on predicted density of marine mammal species) for mitigation would be impracticable to implement and would significantly impact the scheduling, training, and certifications required to prepare naval forces for deployment. It would be impracticable to implement seasonal or temporal restrictions for all training and testing in this region because training and testing schedules are based on national tasking, the number and duration of training cycles identified in the Optimized Fleet Response Plan and various training plans, and forecasting of future testing requirements (including emerging requirements). Although the Navy has indicated that it has the ability to restrict the number of major training exercises in the Mid-Atlantic Planning Awareness Mitigation Areas, the Navy is unable to eliminate all MTEs in this area, because it provides air and sea conditions necessary to meet real-world requirements. Additionally, MTEs originally planned for other locations may have to change during an exercise, or in exercise planning, based on an assessment of the performance of the units or due to other conditions such as weather and mechanical issues. The Navy has indicated that these contingency requirements preclude it from completely prohibiting MTEs from occurring in this area. NMFS concurs with the Navy's practicability assessment.

Mid-Atlantic Planning Awareness Mitigation Areas

Comment 41: A Commenter recommends extending the boundaries of the Mid-Atlantic Planning Awareness Mitigation Areas to fully encompass the Cape Hatteras Special Research Area (CHSRA), prohibiting all training, and testing activities within the boundary of the CHSRA.

Response: Although the Navy has the ability to restrict the number of MTEs in the Mid-Atlantic Planning Awareness Mitigation Areas (no more than four), the Navy has communicated that it is unable to prohibit all MTEs in this area, as it provides air and sea conditions necessary to meet real-world requirements. Additionally, MTEs originally planned for other locations may have to change during an exercise, or in exercise planning, based on an assessment of the performance of the units or due to other conditions such as weather and mechanical issues. These contingency requirements preclude the Navy from completely prohibiting MTEs from occurring in this area.

In its assessment of potential mitigation, the Navy considered implementing additional restrictions on active sonar and explosives in the U.S. mid-Atlantic region, including expanding the boundaries of the mitigation area to fully encompass the CHSRA, limiting MTEs, and planning activities to avoid times of predicted high NARW density. Navy operators determined that implementing additional mitigation beyond what is described in this final rule would be impracticable due to implications for safety, sustainability, and the Navy's ability to continue meeting its Title 10 requirements to successfully accomplish military readiness objectives. Some of the Navy's considerations regarding why it would be impracticable to implement additional mitigation in the mid-Atlantic region, which NMFS has reviewed and concurs with, are provided below.

The waters off the mid-Atlantic and southeastern United States encompass part of the primary water space in the AFTT Study Area where unit-level training, integrated training, and

deployment certification exercises occur and are critical for these and other training and testing activities. The Navy conducts training and testing activities off the mid-Atlantic and southeastern United States because this region provides valuable access to air and sea space conditions that are analogous to areas where the Navy operates or may need to operate in the future. This contributes to safety of personnel, skill proficiency, and validation of testing program requirements. For training and testing, areas in this region where exercises are scheduled to occur are chosen to allow for the realistic tactical development of the myriad of training and testing scenarios that Navy units are required to complete to be mission effective. Certain activities, such as deployment certification exercises using integrated warfare components, require large areas of the littorals and open ocean for realistic and safe training.

Locations for other training and testing activities are chosen due to the proximity of associated training and testing ranges and operating areas (*e.g.,* VACAPES), available airspace (*e.g.,* W–50), unobstructed sea space, and aircraft emergency landing fields (*e.g.,* Naval Air Station Oceana) and with consideration for public safety (*e.g.,* avoiding areas popular for recreational boating). Further restrictions in this area (*e.g.,* further restricting the number of major training events or seasonal restrictions on MTEs based on predicted density of marine mammal species) for mitigation would be impracticable to implement and would significantly impact the scheduling, training, and certifications required to prepare naval forces for deployment. It would be impracticable to implement seasonal or temporal restrictions for all training and testing in this region (including within the CHSRA) because training and testing schedules are based on national tasking, the number and duration of training cycles identified in the Optimized Fleet Response Plan and various training plans, and forecasting of future testing requirements (including emerging requirements).

Comment 42: A Commenter also recommends further limiting MTE and prohibiting/further limiting other activities to reduce cumulative exposures in the Mid-Atlantic Planning Awareness Mitigation Areas. Commenter asserts that if MTEs cannot absolutely be avoided, NMFS should consider limiting the number of MTEs allowable to two per year, with each exercise carried out in different Mid-Atlantic Planning Awareness Mitigation Areas (*i.e.,* one exercise in the northern Mitigation Area, and one exercise in the southern Mitigation Area), to ensure that marine mammal populations with site fidelity are not exposed to multiple MTEs within a single year. Similarly, the Commenter states that NMFS should consider prohibiting testing, unit-level sonar, and in-water explosives training in the mitigation areas, or alternatively, and less preferably, reducing the number of hours allowable in a given year, with the prohibition or restriction structured as in the *Conservation Council* settlement agreement to provide flexibility.

Response: The Navy has indicated that although it has the ability to restrict the number of MTEs in the Mid-Atlantic Planning Awareness Mitigation Areas (no more than four), the Navy is unable to prohibit all MTEs in this area, as it provides air and sea conditions necessary to meet real-world requirements. MTE locations may have to change during an exercise, or in exercise planning, based on an assessment of the performance of the units, or due to other conditions such as weather and mechanical issues, which precludes the ability to completely prohibit major training exercises from occurring in this area.

In its assessment of potential mitigation, the Navy considered implementing additional restrictions on active sonar and explosives in the U.S. mid-Atlantic region and limiting MTEs and planning activities to further limit activities in times and areas of predicted high NARW density. Navy operators determined that implementing additional mitigation beyond what is described in Section 5.4.3 (Mitigation Areas off the mid-Atlantic and southeastern United States) of the AFTT FEIS/OEIS and this final rule (which provides a significant reduction of impacts on NARW, as discussed in the *Mitigation Measures* section in this final rule) would be impracticable due to implications for safety, sustainability, and the Navy's ability to continue meeting its Title 10 requirements to successfully accomplish military readiness objectives. As the Navy explains, it would be impracticable to implement additional mitigation in the U.S. mid-Atlantic region for several reasons. NMFS reviewed and concurs with the Navy's assessment of practicality, effects on mission effectiveness, and personnel safety. First, the waters off the mid-Atlantic and southeastern United States encompass part of the primary water space in the AFTT Study Area where unit-level training, integrated training, and deployment certification exercises occur and are critical for these and other training and testing activities. The Navy conducts training and testing activities off the mid-Atlantic and southeastern United States because this region provides valuable access to air and sea space conditions that are analogous to areas where the Navy operates or may need to operate in the future. This contributes to ensure safety of personnel, skill proficiency, and validation of testing program requirements. Areas in this region where activities are scheduled to occur are chosen to allow for the realistic tactical development of the myriad training and testing scenarios that Navy units are required to complete to be mission effective. Certain activities, such as deployment certification exercises using integrated warfare components, require large areas of the littorals and open ocean for realistic and safe training. Locations for other training and testing activities are chosen due to the proximity of associated training and testing ranges and operating areas (*e.g.,* VACAPES), available airspace (*e.g.,* W–50 in VACAPES), unobstructed sea space, aircraft emergency landing fields (*e.g.,* Naval Air Station Oceana), and with consideration for public safety (*e.g.,* avoiding areas popular for recreational boating). Further restrictions in this area (*e.g.,* further restricting the number of major training events or seasonal restrictions on MTEs based on predicted density of marine mammal species, such as NARW) for mitigation would be impracticable to implement and would significantly impact the scheduling, training, and certifications required to prepare naval forces for deployment. It would be impracticable to implement seasonal or temporal restrictions for all training and testing in this region (including within the CHSRA) because training and testing schedules are based on national tasking, the number and duration of training cycles identified in the Optimized Fleet Response Plan and various training plans, and forecasting of future testing requirements (including emerging requirements).

Comment 43: A Commenter recommends that NMFS require the Navy to move the ship shock trial areas beyond the extents of the two Mid-Atlantic Planning Awareness Areas and allow a minimum of a five nmi buffer between the Planning Awareness Areas and the ship shock trial areas.

Response: The Navy assessed the practicality and effects on mission effectiveness and personnel safety, of this measure and agreed to move the ship shock trial box east of the Mid-Atlantic Planning Awareness Mitigation Areas, including a five nmi buffer.

NMFS included the requirement in the final rule.

NARW Southeast

Comment 44: Several commenters recommended expanding the Navy's SE NARW mitigation areas to encompass additional areas of NARW occurrence or the entirety of the ESA-designated critical habitat in the Southeast, and/or expanding the limitations on Navy activities within these areas. Further, a Commenter recommended that if NMFS was not going to expand the SE NARW Mitigation Area, that NMFS should require the Navy to further implement measures of vessel speed restrictions and obtain NARW sighting information to reduce NARW and potential vessel interactions on the NARW calving BIA. A Commenter commented that NMFS should include the entire extent of the NARW calving BIA as depicted in LaBrecque *et al.* (2015a) in the SE NARW Mitigation Area. Another commenter requested that the Navy add an ''expanded mitigation area'' (geographically corresponding to the current SE NARW ESA-designated critical habitat, minus the Navy's current SE NARW Mitigation Area). A Commenter suggested that if NMFS chooses not to implement the NARW calving BIA as depicted in and during the timeframes noted by LaBrecque *et al.* (2015a), then they recommend that NMFS require the Navy to (1) implement speed restrictions of no more than 10 kn during vessel transits, (2) obtain the latest NARW sightings information prior to transits from the Southeast Regional Office's (SERO) NARW Early Warning System, (3) use the sightings information to reduce potential interactions with NARWs during transits, and (4) implement speed reductions after a vessel observes a NARW, if a vessel is within 5 nmi of a sighting reported to the SE Regional Office NARW Early Warning System within the past week, and when operating at night or during periods of reduced visibility. Similarly, a commenter also requested that the Navy minimize activities requiring vessel speeds greater than 10 kn for all vessels 65 ft or greater operating within the current SE NARW Mitigation Area as well as an ''expanded mitigation area'' (spatially corresponding to the current SE NARW ESA-designated critical habitat, minus the Navy's current SE NARW Mitigation Area).

Response: The SE NARW Mitigation Area remains the same from the proposed rule but as a result of recommendations from and discussion with NMFS, the Navy has expanded this area from the previous rule authorizing incidental take between 2013 and 2018. The SE NARW Mitigation Area occurs off the coast of Florida and Georgia and encompasses a portion of the calving ESA-designated critical habitat for this species. The best available scientific information shows that the majority of NARW sightings in the Southeast occur in calving areas from roughly November through April, with individual NARW migrating to and from these areas through mid-Atlantic shelf waters. Because of these concerns regarding NARW, the Navy proposed mitigation in its rulemaking/LOA application in the SE NARW Mitigation Area from November 15 to April 15. These measures are expected to largely avoid disruption of behavioral patterns for NARW and to minimize overall acoustic exposures. Major training exercises and most activities using active sonar will not occur in some portions of the calving ESA-designated critical habitat in the SE NARW Mitigation Area. The Navy will not conduct: (1) Low-frequency active sonar (except as noted below), (2) mid-frequency active sonar (except as noted below), (3) high-frequency active sonar, (4) missile and rocket activities (explosive and non-explosive), (5) small-, medium-, and large-caliber gunnery activities, (6) Improved Extended Echo Ranging sonobuoy activities, (7) explosive and non-explosive bombing activities, (8) in-water detonations, and (9) explosive torpedo activities within the mitigation area. Further, to the maximum extent practicable, the Navy has already agreed to minimize the use of: (1) Helicopter dipping sonar, (2) low and mid-frequency active sonar for navigation training and object detection exercises within the mitigation area, and (3) other activities. The activities resulting in most of the Level B harassment within ESA-designated critical habitat and within the Navy's SE NARW Mitigation Area are from navigation (37 takes) and ship object detection exercise (82 takes) which each last for approximately 30 min or less as the vessel or submarine is transiting into or out of port. With the exception of the Composite Training Unit Exercise, all activities using sonar that are expected to result in Level B harassment by TTS and behavioral disturbance of NARW in this area are either short-term (*e.g.,* 30 min to 4 hours during submarine navigation and signature analysis testing) or involve a limited number of sonar platforms (since there are a limited number of sonar platforms and both the sonar platforms and animals are moving, there is a low likelihood of co-occurrence for more than a short period of time). These factors limit the potential for these instances of Level B harassment by TTS and behavioral disturbance to result in long duration exposures. Consistent with literature described previously on the response of marine mammals to sonar, we anticipate that exposed animals will be able to return to normal behavior patterns shortly after the exposure is over (minutes to hours) (See, *e.g.,* Goldbogen *et al.,* 2013; Sivle *et al.,* 2015). For longer duration activities (*e.g.,* MTEs), particularly those utilizing multiple sonar platforms, the chance of a longer term exposure and associated response is increased, but as described below, we do not expect long-term exposures to occur from these activities. Depending on animal movement and where these longer duration activities actually occur within the operating areas, such exercises have the potential to result in sustained and/or repeated exposure of NARW. However, the Navy's geographic mitigations for MTEs and other exercises using active sonar (with the exception of navigation and ship object detection) minimize the likelihood of exposures of animals to these activities in ESA-designated critical habitat. MTEs will not be conducted in most of the Southeast ESA-designated critical habitat. Further, the Navy's modeling indicated very limited impacts to NARW from MTEs in the southeast (*i.e.,* one instance of Level B behavioral harassment in the Jacksonville Range Complex, which could occur within the ESA-designated critical habitat designated for the species).

Based on this short duration of exposure, and the minor behavioral response expected to occur from the exposure, we do not expect these responses to affect the health of individual NARWs in any way that could affect reproduction or survival, even though some individual animals may experience Level B harassment more than once annually in this area. NARW may be present in or near the SE NARW Mitigation Area for approximately 20 events per year (5.48 percent) for navigation and 57 approximate events per year (15.61 percent) for object detection. This does not necessarily mean NARW will be impacted by Level B harassment takes during these short duration activities (approximately 30 min, up to 2 hrs). NMFS believes that the mitigation in the Southeast avoids impacts to the NARWs while on the calving grounds. While the Navy could not expand the SE NARW Mitigation Area to the full extent of ESA-designated critical habitat, the Navy has agreed to include the full

extent of ESA-designated critical habitat in a special reporting area and annually report training and testing activities in this area to NMFS. The Navy will report the total hours and counts of active sonar and in-water explosives used in the SE NARW Critical Habitat Special Reporting Area (November 15 through April 15) (*i.e.,* the Southeast NARW ESA-designated critical habitat) in its annual training and testing activity reports submitted to NMFS.

In response to the recommendation to implement additional vessel speed related mitigation measures for NARW in the calving BIA (as depicted by LaBrecque *et al.,* 2015), the SE NARW Mitigation Area has not been expanded from the proposed rule. However, the Navy has added mitigation measures related to vessels, including the addition of the Jacksonville Operating Area Mitigation Area (November 15 through April 15), where additional communication will occur for all training and testing activities occurring in this area to fleet vessels to minimize potential interaction with NARW. The Jacksonville Operating Area Mitigation Area overlaps with the SE NARW ESA-designated critical habitat/calving BIA. Regarding measures to avoid vessel strikes in the southeast, in the SE NARW Mitigation Area, (1) the Navy will implement vessel speed reductions after they observe a NARW; (2) before transiting or conducting training or testing activities in the SE NARW Mitigation Area, the Navy will initiate communication with the Fleet Area Control and Surveillance Facility, Jacksonville to obtain Early Warning System NARW sightings data; (3) the Fleet Area Control and Surveillance Facility, Jacksonville will advise vessels of all reported NARW sightings in the vicinity to help vessels and aircraft reduce potential interactions with NARW; and (4) vessels will implement speed reductions if they are within 5 nmi of a sighting reported within the past 12 hrs, or when operating at night or during periods of poor visibility. To the maximum extent practicable, vessels will minimize north-south transits. The Navy will use the reported sightings information as it plans specific details of events (*e.g.,* timing, location, duration) to minimize potential interactions with NARW to the maximum extent practicable. The Navy will use the reported sightings information to assist visual observations of applicable mitigation zones and to aid in the implementation of procedural mitigation.

Finally, since the proposed rule, the Navy has agreed to broadcast awareness notification messages with NARW Dynamic Management Area information (*e.g.,* location and dates) to applicable Navy assets operating in the vicinity (NARW Dynamic Management Area notification). The information will alert assets to the possible presence of a NARW to maintain safety of navigation and further reduce the potential for a vessel strike. Units will use the information to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation, including but not limited to, mitigation for vessel movement.

For this rule, within the mid-Atlantic and southeastern region, NMFS and the Navy worked to identify an opportunity to expand the mitigation area for NARW off the southeastern United States in a way that would enhance protections for the species, while balancing the practicability of implementation. The Navy expanded the SE NARW Mitigation Area to correlate with the occurrence of NARW to the maximum extent practicable based on readiness requirements.

Certain activities, such as deployment certification exercises using integrated warfare components, require large areas of the littorals and open ocean for realistic and safe training. Locations for other training activities are chosen due to the proximity of associated training ranges (*e.g.,* Jacksonville Range Complex), available airspace (*e.g.,* avoiding airspace conflicts with major airports such as Jacksonville International Airport), unobstructed sea space, aircraft emergency landing fields (*e.g.,* Naval Air Station Jacksonville), and with consideration for public safety (*e.g.,* avoiding areas popular for recreational boating). The Jacksonville Operating Area and Charleston Operating Area represent critical training sea spaces that are necessary to prepare naval forces for combat. Areas where testing events are scheduled to occur are chosen to allow the Navy to test systems and platforms in a variety of bathymetric and environmental conditions to ensure functionality and accuracy in real world environments. Test locations are typically located near the support facilities of the systems commands, which provide critical safety, platform, and infrastructure support and technical expertise necessary to conduct testing (*e.g.,* proximity to air squadrons).

In conclusion, the Navy has indicated that additional expansion of the SE NARW Mitigation Area eastward to mirror the boundary of the expanded ESA-designated critical habitat or northward to encompass all areas of potential occurrence, would require training to move farther north or farther out to sea, which would be impracticable due to implications for safety and sustainability, as detailed in Section 5.4.3 (Mitigation Areas off the Mid-Atlantic and Southeastern United States) of the AFTT FEIS/OEIS. Additionally, the Navy has explained why further limitations on activities within this area would be impracticable. NMFS reviewed, and concurs with, the Navy's assessment of practicality, effects on mission effectiveness, personnel safety.

Comment 45: A Commenter recommended dipping sonar and low-frequency sonar be prohibited in the Navy's SE NARW Mitigation Area.

Response: Regarding dipping sonar, as discussed in Section 5.4.3 (Mitigation Areas off the Mid-Atlantic and Southeastern United States) of the AFTT FEIS/OEIS, the Navy will minimize the use of helicopter dipping sonar to the maximum extent practicable. The only helicopter dipping sonar activity that could potentially be conducted in the mitigation area is Kilo Dip, which could involve 1–2 pings of active sonar infrequently. Kilo Dip is a functional check activity that needs to occur close to an air station in the event of a system failure (*i.e.,* all systems are not functioning properly). During this activity, the Navy will implement the procedural mitigation described in Section 5.3.2.1 (Active Sonar) of the AFTT FEIS/OEIS, with visual observations aided by Early Warning System NARW data.

Regarding LFAS, as discussed in Section 5.4.3 (Mitigation Areas off the Mid-Atlantic and Southeastern United States) of the AFTT FEIS/OEIS, the Navy will not conduct LFAS in the mitigation area, with the exception of LFAS used for navigation training, which will be minimized to the maximum extent practicable. During this activity, crews train to operate sonar for navigation, an ability that is critical for safety while transiting into and out of port during periods of reduced visibility. The Navy will implement the procedural mitigation described in Section 5.3.2.1 (Active Sonar), with visual observations aided by Early Warning System NARW sightings data.

Additionally, since the proposed rule, the Navy added a SE NARW Critical Habitat Special Reporting Area (November 15 through April 15) where the Navy will report the total hours and counts of active sonar and in-water explosives used in the Special Reporting Area in its annual training and testing activity reports submitted to NMFS.

Geographically speaking, this Special Reporting Area is the same area as the SE NARW ESA-designated critical habitat, and the reporting will help NMFS and the Navy understand in a more refined way the actual scale of activities occurring in NARW habitat, which will inform future analyses and, as appropriate, adaptive management.

GOMEX Planning Awareness Mitigation Areas/Bryde's Whale Mitigation Area

Comment 46: Commenters recommend that NMFS (1) expand Area 2 in the GOMEX Planning Awareness Mitigation Areas to include the waters (a) out to the 400-m isobath along Area 2's entire extent and (b) from the 100- to 400-m isobaths from Pensacola, Florida, to Mobile Bay, Alabama for the biologically important area identified by LaBrecque *et al.* (2015) for Bryde's whale, which in the proposed rule is not fully capturing the extent of important habitat within the De Soto Canyon. A Commenter also recommends moving, as necessary, the ship shock trial area farther offshore to allow a minimum of a five nmi buffer between the expanded Area 2 (as recommended above) in the GOMEX Planning Awareness Mitigation Areas and the ship shock trial area, and restricting the Navy from conducting underwater detonations in Area 2 in the GOMEX Planning Awareness Mitigation Areas. Further, a Commenter recommends that NMFS require the Navy to implement year-round speed restrictions of no more than 10 kn during vessel transits in Area 2 of the GOMEX Planning Awareness Mitigation Areas.

Response: Since the proposed rule, the Navy has agreed to the addition of a year-round, Bryde's Whale Mitigation Area which will cover the BIA as described in NMFS' 2016 Status Review and include the area between 100 to 400 m isobaths between 87.5 degrees W to 27.5 degrees N. The Navy has agreed to move the northern GOMEX ship shock trial box west, out of the Bryde's whale BIA/Bryde's Whale Mitigation Area, including a five nmi buffer. Within the mitigation area, the Navy will not conduct more than 200 hrs of hull-mounted MFAS per year and will not use explosives (except during mine warfare activities). The Navy will report the total hours and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS. Based on the Navy's assessment of practicality and effects on mission effectiveness and personnel safety, which NMFS reviewed and concurs with, the new mitigation represents the maximum level of mitigation that is practicable to implement within this area. Due to low numbers of Bryde's whale, almost exclusively limited to the GOMEX, and limited Navy ship traffic that overlaps with Bryde's whale habitat, the Navy does not anticipate any ship strike takes. Furthermore, there have been no documented Bryde's whale ship strikes by Navy vessels; therefore, the speed restrictions would not lower the already low potential for ship strike for this species. Further, the Navy will implement procedural mitigation during any vessel movements to reduce potential ship strike for all marine mammals including Bryde's whales.

Comment 47: A Commenter recommended prohibiting or reducing deployment of all unit-level active low-, mid-, and high-frequency sonar and underwater explosives in the GOMEX Planning Awareness Mitigation Areas or alternatively, and less preferably, reducing the number of hours allowable in a given year.

Response: Since the proposed rule, the Navy expanded and renamed a portion of the GOMEX Planning Awareness Mitigation Areas as the Bryde's Whale Mitigation Area. As described in more detail in Comment Response 46, the Bryde's Whale Mitigation Area allows a limited amount of MFAS and prohibits the use of explosives. The Navy also will now not conduct MTEs in the GOMEX Planning Awareness Mitigation Areas.

However, the Navy has communicated that the GOMEX encompasses part of the primary water space in the AFTT Study Area where unit-level training, integrated training, and deployment certification exercises occur and it is critical for these and other training and testing activities. The Navy conducts training and testing activities in the GOMEX because this region provides valuable access to air and sea space conditions that are analogous to areas where the Navy operates or may need to operate in the future. This contributes to ensure safety of personnel, skill proficiency, and validation of testing program requirements. For training, areas in this region where exercises are scheduled to occur are chosen to allow for the realistic tactical development of the myriad of training scenarios Navy units are required to complete to be mission effective. Certain activities, such as deployment certification exercises using integrated warfare components, require large areas of the littorals and open ocean for realistic and safe training. Locations for other training activities are chosen due to the proximity of associated training ranges (*e.g.,* Pensacola Operating Area); available airspace (*e.g.,* avoiding airspace conflicts with major airports, such as Key West International Airport); unobstructed sea space (*e.g.,* throughout the New Orleans Operating Area); aircraft emergency landing fields (*e.g.,* Naval Air Station Pensacola), and with consideration of public safety (*e.g.,* avoiding areas popular for recreational boating). Areas where testing events are scheduled to occur are chosen to allow the Navy to test systems and platforms in a variety of bathymetric and environmental conditions to ensure functionality and accuracy in real world environments. Test locations are typically located near the support facilities of the systems commands, which provide critical safety, platforms, and infrastructure support and technical expertise necessary to conduct testing (*e.g.,* proximity to air squadrons). Based on the Navy's assessment of practicality and effects on mission effectiveness and personnel safety, which NMFS reviewed and concurs with, the Bryde's Whale Mitigation Area includes the maximum level of mitigation that is practicable to implement within this area.

Additional Mitigation Areas

Comment 48: A Commenter recommends adding additional mitigation areas for (1) the Charleston Bump (year-round), (2) coastal bottlenose dolphin habitat within the DWH oil spill area, and (3) habitat based management for the Cul de Sac, Great Bahama Canyon.

Response: First, we note regarding the Charleston Bump, the commenter cites the importance of the area to fish larvae and spawning, fishing, and sea turtles, with only a general reference to ''a diversity of marine mammals,'' without any indication that limiting activities in the area would reduce impacts to marine mammal species and stocks or their habitat. Regarding protection of coastal bottlenose dolphins affected by the Deepwater Horizon (DWH) oil spill, we note that of all the Northern GOMEX Estuarine stocks, only one overlaps with stressors from the Navy's activities, and that stock is authorized for one take by Level B harassment.

More importantly, separate from the fact that little, if any, protection of marine mammals would be achieved through the adoption of the recommended measures, the Navy has assessed the practicality and effect of these recommendations on mission effectiveness and personnel safety and determined that the measures would be impracticable, and NMFS concurs with this determination.

In its assessment of potential mitigation, the Navy considered implementing additional restrictions on active sonar and explosives in the U.S. mid-Atlantic and GOMEX regions, including at the Charleston Bump and areas affected by the DWH oil spill. Navy operators determined that implementing additional mitigation beyond what is described in Section 5.4.3 and Section 5.4.4 (Mitigation Areas off the mid-Atlantic and Southeastern United States and Mitigation Areas in the GOMEX) of the AFTT FEIS/OEIS would be impracticable due to implications for safety (the ability to avoid potential hazards), sustainability (maintain readiness), and the Navy's ability to continue meeting its Title 10 requirements to successfully accomplish military readiness objectives.

It would be impracticable to implement additional mitigation in the U.S. mid-Atlantic and GOMEX for several reasons. The Navy has indicated that the mitigation identified in Section 5.4 (Mitigation Areas to be Implemented) of the AFTT FEIS/OEIS represents the maximum mitigation within the identified mitigation areas that is practicable to implement under the proposed activities. The Navy has communicated that operational input indicates that designating additional mitigation areas (including the Charleston Bump and areas affected by the DWH oil spill) would (1) have a significant impact on the ability for units to meet their individual training and certification requirements, preventing them from deploying with the required level of readiness necessary to accomplish their missions); (2) the ability to certify strike groups to deploy to meet national security tasking (limiting the flexibility of Combatant Commanders and warfighters to project power, engage in multi-national operations, and conduct the full range of naval warfighting capability in support of national security interests); (3) the ability of program managers and weapons system acquisition programs to meet testing requirements and required acquisition milestones; (4) operational costs (due to extending distance offshore, which would increase fuel consumption, maintenance, and time on station to complete required training and testing activities); (5) the safety risk associated with conducting training and testing at extended distances offshore (farther away from critical medical and search and rescue capabilities); (6) accelerated fatigue-life of aircraft and ships (leading to increased safety risk and higher maintenance costs); (7) training and testing realism (due to reduced access to necessary environmental or oceanographic conditions that replicate potential real world areas in which combat may occur); and (8) the ability for Navy Sailors to train and become proficient in using the sensors and weapons systems as would be required in a real world combat situation.

Furthermore, the iterative and cumulative impact of all commenter-proposed mitigation areas and seasonal or temporal restrictions would deny national command authorities the flexibility to respond to national security challenges and incur significant restrictions to required training and testing that entail movements to multiple operational areas along the Eastern seaboard and the GOMEX to conduct training within set time frames. Likewise, this iterative and cumulative impact would deny weapons system program managers and research, testing, and development program managers the flexibility to rapidly field or develop necessary systems due to the required use of multiple areas within limited timeframes. Additional information regarding the operational importance, significant negative impacts on Navy training and testing activities, and impracticability of implementing the mitigation area in each geographic region mentioned is provided in Chapter 5 (Mitigation) of the AFTT FEIS/OEIS.

Regarding Cul de Sac, Bahamas, the Navy did not consider mitigation for the Cul de Sac because it is not part of the AFTT Study Area. Therefore, NMFS did not consider mitigation in the final rule for the Cul de Sac because it is not part of the AFTT Study Area.

Comment 49: A Commenter recommends that efforts be undertaken to identify additional important habitat areas across the AFTT Study Area, using the full range of data and information available (*e.g.,* habitat-based density models, NOAA-recognized BIAs, survey data, etc.).

Response: NMFS and the Navy used the best available scientific information (*e.g.,* SARs; Roberts *et al.,* 2016, 2017; and numerous study reports from Navy-funded monitoring and research in the specific geographic region) in assessing density, distribution, and other information regarding marine mammal use of habitats in the AFTT Study Area. In addition, NMFS consulted LaBrecque *et al.* (2015), which provides a specific, detailed assessment of known BIAs, which may be region-, species-, and/or time-specific, include reproductive areas, feeding areas, migratory corridors, and areas in which small and resident populations are concentrated.

Comment 50: A Commenter recommended establishing stand-off distances around the Navy's mitigation areas to the greatest extent practicable, allowing for variability in size given the location of the area, the type of operation at issue, and the species of concern.

Response: Mitigation areas are typically developed in consideration of both the area that is being protected and the distance from the stressor in question that is appropriate to maintain to ensure the protection. Sometimes this results in the identification of the area plus a buffer, and sometimes both the protected area and the buffer are considered together in the designation of the edge of the area. We note that the edges of a protected area are typically of less importance to a protected stock or behavior, since important areas often have a density gradient that lessens towards the edge. In addition, while a buffer of a certain size may be ideal to alleviate all impacts of concern, a lessened buffer does not mean that the protective value is significantly reduced, as the core of the area is still protected. Also, one should not assume that activities are constantly occurring in the area immediately adjacent to the protected area. These issues were considered here, and the Navy has indicated that the mitigation identified in Section 5.4 (Mitigation Areas to be Implemented) of the AFTT FEIS/OEIS represents the maximum mitigation within mitigation areas and the maximum size of mitigation areas that are practicable to implement under the proposed activities. The Navy has communicated (and NMFS concurs with the assessment) that implementing additional mitigation (*e.g.,* stand-off distances that would extend the size of the mitigation areas) beyond what is described in Section 5.4 (Mitigation Areas to be Implemented) of the AFTT FEIS/OEIS would be impracticable due to implications for safety (the ability to avoid potential hazards), sustainability (based on the amount and type of resources available, such as funding, personnel, and equipment)), and the Navy's ability to continue meeting its Title 10 requirements.

Additional Mitigation Research

Comment 51: Commenters recommend that NMFS consider additional mitigation measures to prescribe or research including (1) research into sonar signal modifications, (2) thermal detection systems, (3) mitigation and research on Navy ship speeds, including requiring the Navy to

collect and report data on ship speed as part of the EIS process; and (4) compensatory mitigation for the adverse impacts of the permitted activity on marine mammals and their habitat that cannot be prevented or mitigated.

Response: NMFS consulted with the Navy regarding potential research into additional mitigation measures, as follows:

1. Research into sonar signal modification—Sonar signals are designed explicitly to provide optimum performance at detecting underwater objects (*e.g.,* submarines) in a variety of acoustic environments. The Navy acknowledges that there is very limited data, and some suggest that up or down sweeps of the sonar signal may result in different animal reactions; however, this is a very small data sample, and this science requires further development. If future studies indicate this could be an effective approach, then NMFS and the Navy will investigate the feasibility and practicability to modify signals, based on tactical considerations and cost, to determine how it will affect the sonar's performance.

2. Thermal detection—The Office of Naval Research Marine Mammals and Biology program is currently funding an ongoing project (2013–2018) that is testing the thermal limits of infrared based automatic whale detection technology (Principal Investigators: Olaf Boebel and Daniel Zitterbart). This project is focused on (1) capturing whale spouts at two different locations featuring subtropical and tropical water temperatures, (2) optimizing detector/classifier performance on the collected data, and (3) testing system performance by comparing system detections with concurrent visual observations. In addition, the Defense Advanced Research Projects Agency (DARPA) has funded six initial studies to test and evaluate current technologies and algorithms to automatically detect marine mammals (IR thermal detection being one of the technologies) on an unmanned surface vehicle. Based on the outcome of these initial studies, follow-on efforts and testing are planned for 2018–2019.

3. Mitigation for the Navy to collect and report data on ship speed as part of the EIS—The Navy conducted an operational analysis of potential mitigation areas throughout the entire Study Area to consider a wide range of mitigation options, including but not limited to vessel speed restrictions. As discussed in Section 3.0.3.3.4.1 (Vessels and In-Water Devices) of the AFTT FEIS/OEIS, Navy ships transit at speeds that are optimal for fuel conservation or to meet operational requirements. Operational input indicated that implementing additional vessel speed restrictions beyond what is identified in Section 5.4 (Mitigation Areas to be Implemented) of the AFTT FEIS/OEIS would be impracticable to implement due to implications for safety and sustainability. In its assessment of potential mitigation, the Navy considered implementing additional vessel speed restrictions (*e.g.,* expanding the 10 kn restriction to other activities). The Navy determined that implementing additional vessel speed restrictions beyond what is described in Section 5.5.2.2 (Restricting Vessel Speed) of the AFTT FEIS/OEIS would be impracticable due to implications for safety (the ability to avoid potential hazards), sustainability (maintain readiness), and the Navy's ability to continue meeting its Title 10 requirements to successfully accomplish military readiness objectives. Additionally, as described in Section 5.5.2.2 (Restricting Vessel Speed) of the AFTT FEIS/OEIS, any additional vessel speed restrictions would prevent vessel operators from gaining skill proficiency, would prevent the Navy from properly testing vessel capabilities, or would increase the time on station during training or testing activities as required to achieve skill proficiency or properly test vessel capabilities, which would significantly increase fuel consumption. As discussed in Section 5.3.4.1 (Vessel Movement) of the AFTT FEIS/OEIS, the Navy implements mitigation to avoid vessel strikes throughout the Study Area. As directed by the Chief of Naval Operations Instruction (OPNAVINST) 5090.1D, Environmental Readiness Program, Navy vessels report all marine mammal incidents worldwide, including ship speed. Therefore, the data required for ship strike analysis discussed in the comment is already being collected. Any additional data collection required would create an unnecessary and impracticable administrative burden on the Navy.

4. Compensatory mitigation—For years, the Navy has implemented a very broad and comprehensive range of measures to mitigate potential impacts to marine mammals from military readiness activities. As the AFTT FEIS/OEIS documents in Chapter 5 (Mitigation), the Navy is proposing to expand these measures further where practicable. Aside from direct mitigation, as noted by a Commenter, the Navy engages in an extensive spectrum of other activities that greatly benefit marine species in a more general manner that is not necessarily tied to just military readiness activities. As noted in Section 3.0.1.1 (Marine Species Monitoring and Research Programs) of the AFTT FEIS/OEIS, the Navy provides extensive investment for research programs in basic and applied research. The U.S. Navy is one of the largest sources of funding for marine mammal research in the world, which has greatly enhanced the scientific community's understanding of marine species much more generally. The Navy's support and marine mammal research includes: Marine mammal detection, including the development and testing of new autonomous hardware platforms and signal processing algorithms for detection, classification, and localization of marine mammals; improvements in density information and development of abundance models of marine mammals; and advancements in the understanding and characterization of the behavioral, physiological (hearing and stress response), and potentially population-level consequences of sound exposure on marine life. In addition, the Navy is a critical sponsor of the NARW Early Warning System and the winter aerial surveys, which have contributed to a marked reduction in vessel strikes of the NARW in the Southeast ESA-designated critical habitat, particularly by commercial vessels, which represent one of the biggest threats to the NARW. Compensatory mitigation is not required to be imposed upon federal agencies under the MMPA. Importantly, the Commenter did not recommend any specific measure(s), rendering it impossible to conduct any meaningful evaluation of its recommendation. Finally, many of the methods of compensatory mitigation that have proven successful in terrestrial settings (purchasing or preserving land with important habitat, improving habitat through plantings, etc.) are not applicable in a marine setting with such far-ranging species. Thus, any presumed conservation value from such an idea would be purely speculative at this time.

Monitoring Recommendations

Comment 52: A Commenter recommends that NMFS prioritize Navy research projects of long-term monitoring that aim to provide baseline information and quantify the impact of training and testing activities at the individual, and ultimately, population level, and the effectiveness of mitigation. The Commenter recommends individual-level behavioral-response studies, such as focal follows and tagging using DTAGs, carried out before, during, and after Navy training and testing activities. The

Commenter recommends prioritizing DTAG studies that further characterize the suite of vocalizations related to social interactions. The Commenter recommends the use of unmanned aerial vehicles. The Commenter recommends that NMFS require the Navy to use these technologies for assessing marine mammal behavior before, during, and after Navy training and testing (*e.g.,* swim speed and direction, group cohesion). The Commenter recommends NMFS ask the Navy to expand funding to explore the utility of other, simpler modeling methods that could provide at least an indicator of population-level effects, even if each of the behavioral and physiological mechanisms are not fully characterized. The Commenter recommends studies aimed at exploring other potential proxy measures of changes in population-level abundance in order to develop an early-detection system for populations that may be experiencing a decline as a result of Navy activities.

Response: Broadly speaking, NMFS works closely with the Navy in the identification of monitoring priorities and the selection of projects to conduct, continue, modify, and/or stop through the Adaptive Management process, which includes annual review and debriefs by all scientists conducting studies pursuant to the Navy's MMPA rule. The process NMFS and the Navy have developed allows for comprehensive and timely input from the Navy and other stakeholders that is based on rigorous reporting out from the Navy and the researchers doing the work. Further, the Navy is pursuing many of the topics that the commenter identifies, either through the Navy monitoring required under the MMPA and ESA, or through Navy-funded research programs (ONR and LMR). We are confident that the monitoring conducted by the Navy satisfies the requirements of the MMPA.

The Navy established the Strategic Planning Process under the marine species monitoring program to help structure the evaluation and prioritization of projects for funding. Section 5.1.2.2.1.3 (Strategic Planning Process) of the AFTT FEIS/OEIS provides a brief overview of the Strategic Planning Process. More detail, including the current intermediate scientific objectives, is available on the monitoring portal as well as in the Strategic Planning Process report. The Navy's evaluation and prioritization process is driven largely by a standard set of criteria that help the steering committee evaluate how well a potential project would address the primary objectives of the monitoring program. NMFS has opportunities to provide input regarding the Navy's intermediate scientific objectives as well as providing feedback on individual projects through the annual program review meeting and annual report. For additional information, please visit: *https://www.navymarinespeciesmonitoring.us/about/strategic-planning-process/.*

Details on the Navy's involvement with future research will continue to be developed and refined by Navy and NMFS through the consultation and adaptive management processes, which regularly considers and evaluates the development and use of new science and technologies for Navy applications. The Navy has indicated that it will continue to be a leader in funding of research to better understand the potential impacts of Navy training and testing activities and to operate with the least possible impacts while meeting training and testing requirements.

- Individual-level behavioral-response studies—In addition to the Navy's marine species monitoring program investments for individual-level behavioral-response studies, the Office of Naval Research Marine Mammals and Biology program and the Navy's Living Marine Resources program continue to heavily invest in this topic. For example, the following studies are currently being funded.
- The Southern California Behavioral Response Study (Principal Investigators: John Calambokidis and Brandon Southall).
- Cuvier's Beaked Whale and Fin Whale Behavior During Military Sonar Operations: Using Medium-term Tag Technology to Develop Empirical Risk Functions (Principal Investigators: Greg Schorr and Erin Falcone).
- 3S3—Behavioral responses of sperm whales to naval sonar (Principal Investigators: Petter Kvadsheim and Frans-Peter Lam).
- Measuring the effect of range on the behavioral response of marine mammals through the use of Navy sonar (Principal Investigators: Stephanie Watwood and Greg Schorr).
- Behavioral response evaluations employing robust baselines and actual Navy training (BREVE) (Principal Investigators: Steve Martin, Tyler Helble, Len Thomas).
- Integrating remote sensing methods to measure baseline behavior and responses of social delphinids to Navy sonar (Principal Investigators: Brandon Southall, John Calambokidis, John Durban).

2. DTAGS to characterize social communication between individuals of a species or stock, including mothers and calves—The Navy has funded a variety of projects that are collecting data that can be used to study social interactions amongst individuals. Examples of these projects include:

- Southern California Behavioral Response Study (Principal Investigators: John Calambokidis and Brandon Southall).
- Tagging and Tracking of Endangered NARW in Florida Waters (Principal Investigators: Doug Nowacek and Susan Parks). This project involves the use of DTAGs, and data regarding the tagged individual and group are collected in association with the tagging event. In addition to the vocalization data that is being collected on the DTAGs, data is collected on individual and group behaviors that are observed, including between mother/calf pairs when applicable. The Navy will continue to collect this type of data when possible.
- Integrating remote sensing methods to measure baseline behavior and responses of social delphinids to Navy sonar (Principal Investigators: Brandon Southall, John Calambokidis, John Durban).
- Acoustic Behavior of NARW (*Eubalaena glacialis*) Mother-Calf Pairs (Principal Investigators: Susan E. Parks and Sofie Van Parijs). The long-term goal of this project is to quantify the behavior of mother-calf pairs from the NARW to determine (a) why mothers and calves are more susceptible to collisions with vessels and, (b) the vocal behavior of this critical life stage to assess the effectiveness of passive acoustic monitoring to detect mother-calf pairs in important habitat areas (see *https://www.onr.navy.mil/reports/FY15/mbparks.pdf*).
- Social Ecology and Group Cohesion in Pilot Whales and Their Responses to Playback of Anthropogenic and Natural Sounds (Principal Investigator: Frants H. Jensen). This project investigates the social ecology and cohesion of long-finned pilot whales as part of a broad multi-investigator research program that seeks to understand how cetaceans are affected by mid-frequency sonar and other sources of anthropogenic noise (see *https://www.onr.navy.mil/reports/FY15/mbjensen.pdf*).

3. Unmanned Aerial Vehicles to assess marine mammal behavior before, during, and after Navy training and testing activities (*e.g.,* swim speed and direction, group cohesion)—Studies that use unmanned aerial vehicles to assess marine mammal behaviors and body condition are being funded by the Office of Naval Research Marine Mammals and Biology program. Although the technology shows promise, the field limitations associated with the use of

this technology has hindered the useful application in behavioral response studies in association with Navy training and testing events. For safety, research vessels cannot remain in close proximity to Navy vessels during Navy training or testing events, so battery life of the unmanned aerial vehicles has been an issue. However, as the technology improves, the Navy will continue to assess the applicability of this technology for the Navy's research and monitoring programs. An example project is Integrating Remote Sensing Methods to Measure Baseline Behavior and Responses of Social Delphinids to Navy sonar (Principal Investigators: Brandon Southall, John Calambokidis, and John Durban).

4. NMFS asked the Navy to expand funding to explore the utility of other, simpler modeling methods that could provide at least an indicator of population-level effects, even if each of the behavioral and physiological mechanisms are not fully characterized—The Office of Naval Research Marine Mammals and Biology program has invested in the Population Consequences of Disturbance (PCoD) model, which provides a theoretical framework and the types of data that would be needed to assess population level impacts. Although the process is complicated and many species are data poor, this work has provided a foundation for the type of data that is needed. Therefore, in the future, relevant data that is needed for improving the analytical approaches for population level consequences resulting from disturbances will be collected during projects funded by the Navy's marine species monitoring program. General population level trend analysis is conducted by NMFS through its SARs and regulatory determinations. The Navy's analysis of effects to populations (species and stocks) of all potentially exposed marine species, including marine mammals and sea turtles, is based on the best available science as discussed in Sections 3.7 (Marine Mammals) and 3.8 (Reptiles) of the AFTT FEIS/OEIS. PCoD models, similar to many fisheries stock assessment models, once developed will be powerful analytical tools when mature. However, currently they are dependent on too many unknown factors for these types of models to produce a reliable answer.

As discussed in the *Monitoring* section of this final rule, the Navy's marine species monitoring program typically supports 10–15 projects in the Atlantic at any given time. Current projects cover a range of species and topics from collecting baseline data on occurrence and distribution, to tracking whales and sea turtles, to conducting behavioral response studies on beaked whales and pilot whales. The Navy's marine species monitoring web portal provides details on past and current monitoring projects, including technical reports, publications, presentations, and access to available data and can be found at: *https://www.navymarinespeciesmonitoring.us/regions/atlantic/current-projects/*. A list of the monitoring studies that the Navy is currently planning under this rule are listed at the bottom of the *Monitoring* section of this final rule.

Negligible Impact Determination

General

Comment 53: A Commenter commented that NMFS' analytical approach is not transparent. NMFS applied both qualitative and quantitative analyses to inform its negligible impact determination. In general, NMFS has based negligible impact determinations associated with incidental take authorizations on abundance estimates provided either in its SARs or other more recent published literature. For the AFTT proposed rule, NMFS used the average population estimate as determined by the Navy's density models across all seasons from Roberts *et al.* (2016) rather than abundance estimates from either the SARs or published literature. For some species, NMFS indicated that it had apportioned the takes at the species or population level based on takes predicted at higher taxonomic levels. However, NMFS did not specify for which species/populations this method was used or the assumptions made. NMFS also did not specify how it determined the actual ''population'' size given that the densities differ on orders of kilometers. Interpolation or smoothing, and potentially extrapolation, of data likely would be necessary to achieve NMFS' intended goal—it is unclear whether any such methods were implemented.

In addition, it is unclear whether NMFS used data from Mannocci *et al.* (2017) in a similar manner to the Roberts *et al.* (2016) data, which informed abundance estimates for the majority of species within the U.S. EEZ. Furthermore, NMFS did not specify how it determined the proportion of total takes that would occur beyond the U.S. EEZ. Presumably, that was based on modeling assumptions and model-estimated takes provided by the Navy, but this is not certain. Moreover, the ''instances'' of the specific types of taking (*i.e.,* mortality, Level A and B harassment) do not match the total takes ''inside and outside the U.S. EEZ'' in Tables 72–77 or those take estimates in Tables 39–41. It appears the ''instances'' of take columns were based on only those takes in the U.S. EEZ rather than the entire AFTT Study Area. Sperm whales, for example, have 3,880 takes that presumably would occur outside the U.S. EEZ and were not enumerated in the ''instances'' of take columns. Thus, it is unclear what types of takes those constitute. Given that the negligible impact determination is based on the total taking in the entire study area, NMFS should have partitioned the takes in the ''instances'' of take columns in Tables 72–77 for all activities that occur within and beyond the U.S. EEZ.

Response: NMFS has added explanation in the *Analysis and Negligible Impact Determination* section to better describe the take-specific analysis for each stock, species, or group, as appropriate. As described in the footnotes, the Navy abundances referenced in the tables in the *Analysis and Negligible Impact Determination* section, both in and outside of the U.S. EEZ, are a reflection of summing the densities that are used to calculate take for each species as described in the *Estimated Take of Marine Mammals* section (*i.e.,* including Roberts *et al.* and/or Mannocci *et al.* where appropriate), which means using Roberts *et al.* (2016), where available (inside the U.S EEZ), and Mannocci *et al.* (2017) outside the U.S. EEZ, as the commenter suggests. NMFS acknowledges that there were a few small errors in the take numbers in the proposed rule; however, they have been corrected (*i.e.,* the take totals in Tables 39, 40, and 41 for a given stock now equal the ''in and outside the U.S. EEZ'' take totals in Tables 72–77) and the minor changes do not affect the analysis or determinations in the rule.

Comment 54: A Commenter asserts that NMFS assumes that it is unlikely any particular subset of a stock would be taken over more than a few sequential days—*i.e.,* where repeated takes of individuals are likely to occur, they are more likely to result from non-sequential exposures from different activities, and marine mammals are not predicted to be taken for more than a few days in a row, at most. Yet NMFS presents no details of the Navy's training and testing activities in support of this position. The Commenter cites to the fact that the Navy reuses certain geographic areas regularly for some specific exercises as a reason that repeat exposures are likely to be sequential.

Response: The Commenter ignores the fact that marine mammals still move

around (some for long distances), and even if they are resident and Navy activities are geographically concentrated, it does not naturally follow that their exposures to these activities are necessarily temporally concentrated.

In addition, NMFS' analyses do not uniformly assume that where repeated takes are likely to occur, they are more likely to result from non-sequential exposures. NMFS negligible impact analyses suggest that individuals of some stocks are likely to be taken across sequential days, while others are not. Multiple factors are taken into consideration in predicting the relative likelihood that repeated takes of an individual will occur sequentially, including the approximate predicted number of takes to an individual within a year and the manner in which the activities overlap the species range. For example, if the number of average takes per individual is less than two, the entire species range is contained within the AFTT Study Area, and that range includes a migratory pathway that moves through an area dense with training and testing activities (*e.g.,* NARW), it is reasonably likely that every or almost every individual gets taken on at least one day. This means that there are relatively few takes left to distribute. There is no reason to think (based on species movement and activities) that these takes would all accrue to a few animals, or that the takes would occur on sequential days. In other words, even if activities occur in focused areas, it is highly unlikely that individual animals (*e.g.,* NARW) are staying in those areas, especially given how limited activities are in the areas that animals (*e.g.,* NARW) aggregate due to the mitigation. Alternately, if the average number of takes per animal is notably higher (either altogether or in a limited area such as the U.S. EEZ), such as 18 for beaked whales, it follows that some number of individuals are likely actually taken at an even higher number, and the higher that number, the higher the probability that when spread across the years, some days will be sequential. NMFS addresses these differences in our negligible impact analyses.

Comment 55: A Commenter states that NMFS must consider new information for sperm whales in the GOMEX prior to authorizing take for the AFTT specified activities, particularly because of the five reported stranded sperm whale calves in the Gulf since October 2016. The Commenter asserts that NMFS must protect the Mississippi Canyon that provides year-round sperm whale habitat. The Commenter also states that NMFS should ensure heightened protection for this area for sperm whales as well as Bryde's whales and Cuvier's beaked whales that are vulnerable to harm from military activities.

Response: NMFS considered the sperm whale information provided by the commenter in its negligible impact determination. There have been six documented sperm whales strandings in the GOMEX between 2016 and 2018. Five sperm whales stranded in 2016, 1 whale in 2017, and zero whales in 2018. Based on the examination data that was available (the condition of the whale ranged from fresh dead to moderate/advanced decomposition to mummified/skeletal) there were four whales where findings of human interaction could not be determined. Of the two whales that remained, one whale showed evidence of a fishery interaction, and the other showed no evidence of human interaction. NMFS' SERO requested a consultation with the Working Group on Marine Mammal Unusual Mortality Events about the elevated 2016 sperm whale strandings, but the Working Group determined the data did not qualify as a UME at that time. The Working Group noted that the current number of four strandings for the year was only at the upper limit of the 10 year average, that there was a very low total number of strandings in general in the region, and the animals were stranding during months that they would be expected, and therefore the findings did not meet the UME criteria. The SERO and our Southeast Fisheries Science Center will continue to coordinate with the Working Group for sharing of histopathology results and formulation of hypotheses.

Separately, and as described in more detail elsewhere in the rule, after additional discussion with NMFS, the Navy withdrew its request for mortal take by vessel strike for sperm whale (GOMEX stock) due to the following considerations that showed that vessel strike of a whale from this stock is unlikely: (1) The lower number of Navy steaming days in the GOMEX; (2) that there have been no vessel strikes of any large whales since 2009 per the SAR and no Navy strikes of any large whales since 1995 (based on our records) in the GOMEX; (3) the lower abundance of sperm whales in the GOMEX, and (4) the Navy's adherence to Marine Species Awareness Training and adoption of additional mitigation measures. NMFS concurs that the strike of sperm whales in the GOMEX is unlikely and has not authorized mortal take. Further, nearly the entire important sperm whale habitat (Mississippi Canyon) is included in the GOMEX Planning Awareness Mitigation Areas. As stated in this final rule and the AFTT FEIS/OEIS, the Navy is not planning to conduct any MTEs in the GOMEX.

Cumulative and Aggregate Effects

Comment 56: A Commenter commented that NMFS failed to adequately assess the aggregate effects of all of the Navy's activities included in the rule. The Commenter alleges that NMFS' lack of analysis of these aggregate impacts, which is essential to any negligible impact determination, represents a glaring omission from the proposed rule. Further, they assert that the agency assumes that all of the Navy's estimated impacts would not affect individuals or populations through repeated activity—even though the takes anticipated each year would affect the same populations and, indeed, would admittedly involve extensive use of some of the same biogeographic areas. While NMFS states that Level B behavioral harassment (aside from those caused by masking effects) involves a stress response that may contribute to an animal's allostatic load, it assumes without further analysis that any such impacts would be insignificant. The commenter states that both statements are factually insupportable given the lack of any population analysis or quantitative assessment of long-term effects in the proposed rule and the numerous deficiencies in the thresholds and modeling that NMFS has adopted from the Navy.

Response: We respond to the aggregate effect comment here, and address the consideration of impacts from other activities in the response to Comment 57 immediately below.

NMFS did analyze the aggregate effects of mortality, injury, masking, energetic costs, stress, hearing loss, and behavioral harassment from the Navy's activities in reaching the negligible impact determinations. Significant additional discussion has been added to the *Analysis and Negligible Impact Determination* section of the final rule to better explain the agency's analysis and how the potential for aggregate or cumulative effects on individuals relate to the overall negligible impact determination for each species or stock.

In our analysis, NMFS fully considers the potential for aggregate effects from all Navy activities. We also consider UMEs and previous environmental impacts (*i.e.,* DWH oil spill) to inform the baseline levels of both individual health and susceptibility to additional stressors, as well as stock status. Further, the species and stock-specific assessments in the *Analysis and*

Negligible Impact Determination section (which have been updated and expanded) pull together and address the combined mortality, injury, behavioral harassment, and other effects of the aggregate AFTT activities (and in consideration of applicable mitigation) as well as other information that supports our determinations that the Navy activities will not adversely affect any species or stocks via impacts on rates of recruitment or survival. We refer the reader to the *Analysis and Negligible Impact Determination* section for this analysis.

Comment 57: Some commenters asserted that in reaching our MMPA findings, NMFS did not adequately consider the cumulative impacts of the Navy's activities when combined with the effects of other non-Navy activities. A Commenter adds that NMFS needs to include consideration of the most up-to-date information on NARW, humpback whales, and sperm whales, including UMEs, deaths, and recent strandings.

Response: The preamble for NMFS' implementing regulations under section 101(a)(5) (54 FR 40338; September 29, 1989) explains in responses to comments that the impacts from other past and ongoing anthropogenic activities are to be incorporated into the negligible impact analysis via their impacts on the environmental baseline. Consistent with that direction, NMFS here has factored into its negligible impact analyses the impacts of other past and ongoing anthropogenic activities via their impacts on the baseline (*e.g.,* as reflected in the density/distribution and status of the species, population size and growth rate, and other relevant stressors (such as incidental mortality in commercial fisheries, UMEs, or oil spills)). See the *Analysis and Negligible Impact Determination* section of this rule.

Also, as described further in the *Analysis and Negligible Impact Determination* section of the final rule, NMFS evaluated the impacts of AFTT authorized mortality on the affected stocks in consideration of other anticipated human-caused mortality, including the mortality predicted in the SARs for other activities along with other NMFS-permitted mortality (*i.e.,* authorized as part of the Northeast Fisheries Science Center (NEFSC) rule), using multiple factors, including Potential Biological Removal (PBR). As described in more detail in the *Analysis and Negligible Impact Determination* section, PBR was designed to identify the maximum number of animals that may be removed from a stock (not including natural mortalities) while allowing that stock to reach or maintain its optimum sustainable population (OSP) and is also helpful in informing whether mortality will adversely affect annual rates of recruitment or survival in the context of a section 101(a)(5)(A).

In addition, NMFS did consider the most up-to-date information on the three large whale species referenced by the commenter, along with the other potentially affected species and stocks. See the relevant sections of the final rule for extensive discussion on the effects of UMEs, deaths, recent strandings, and other factors that are affecting, or have the potential to affect, the species and stocks that will also be affected by the Navy's activities.

Our 1989 final rule for the MMPA implementing regulations also addressed public comments regarding cumulative effects from future, unrelated activities. There we stated that such effects are not considered in making findings under section 101(a)(5) concerning negligible impact. We indicated that NMFS would consider cumulative effects that are reasonably foreseeable when preparing a NEPA analysis and also that reasonably foreseeable cumulative effects would be considered under section 7 of the ESA for ESA-listed species.

We recognize the potential for cumulative impacts, and that the aggregate impacts of the Navy's training and testing activities will be greater than the impacts of any one particular activity. The direct aggregate impacts of the Navy's training and testing activities were addressed through the associated NEPA analyses in the AFTT FEIS/OEIS (with NMFS as a cooperating agency), which addressed the impacts of a maximum amount of activities, and which NMFS has adopted as the basis for its Record of Decision for the issuance of the final rule and LOAs.

In order to meet the responsibility to analyze cumulative effects under NEPA, the Navy, in cooperation with NMFS, evaluated the cumulative effects of the incremental impact of its proposed action when added to other past, present, and future actions (as well as the effects of climate change), against the appropriate resources and regulatory baselines. The Navy used the best available science and a comprehensive review of past, present, and reasonably foreseeable actions to develop its Cumulative Impacts analysis. This analysis is contained in Chapter 4 of the AFTT FEIS/OIES. As required under NEPA, the level and scope of the analysis is commensurate with the scope of potential impacts of the action and the extent and character of the potentially-impacted resources (*e.g.,* the geographic boundaries for cumulative impacts analysis for some resources are expanded to include activities outside the AFTT Study Area that might impact migratory or wide-ranging animals), as reflected in the resource-specific discussions in Chapter 3 (Affected Environment and Environmental consequences) of the AFTT FEIS/OEIS. The AFTT FEIS/OEIS considered the proposed training and testing activities alongside other actions in the region whose impacts may be additive to those of the proposed training and testing. Past and present actions are also included in the analytical process as part of the affected environmental baseline conditions presented in Chapter 3 of the AFTT FEIS/OEIS. The Navy has done so in accordance with 1997 Council on Environmental Quality (CEQ) guidance. Per the guidance, a qualitative approach and best professional judgment are appropriate where precise measurements are not available. Where precise measurements and/or methodologies were available they were used. Guidance from CEQ states it ''is not practical to analyze cumulative effects of an action on the universe; the list of environmental effects must focus on those that are truly meaningful.'' Further, the U.S. EPA has reviewed the AFTT FEIS/OEIS and rated the document as LO—lack of objections—which means it has not identified any environmental impact requiring substantive changes to the proposal. Information on the NEPA analysis is provided in Section 4.1.1 (Determination of Significance). Lastly, all of the potential effects on marine mammals from Navy training and testing were analyzed in Section 3.7 (Affected Environment and Environmental Consequences—Marine mammals) of the AFTT FEIS/OEIS. Based on the best available science, it was determined that population-level impacts would not occur.

Comment 58: A Commenter cites to the status and trajectory of NARWs and asserts that the negligible impact finding is unsupported for this species specifically. The commenter asserts that the negligible impact analysis must take into account all of the baseline activities that are known to have contributed to the species' decline, as well as other reasonably foreseeable activities (*e.g.,* five seismic surveys planned for the Atlantic in the near future) that would affect the same populations impacted by the Navy's activities. The Commenter also cites to the number of Level B harassment takes (585) included in the proposed rule to support their assertions. To satisfy the negligible impact requirement for NARWs, the

Commenter asserts that NMFS must revise its impacts analysis and incorporate additional mitigation, such as those recommended in section II of Commenter's letter.

Response: The analysis for NARW in the final rule has been updated and expanded since the proposed rule and more clearly addresses the pertinent points the commenter raises. See also the responses above for how NMFS took into account other activities that have or may contribute to the species' status (*Comments and Responses* 35, 36, 40, 44, and 45). In addition, since publication of the proposed rule, the Navy has removed an exercise that would have occurred in the Northeast, decreasing estimated takes by approximately 20 percent to 471. Further, the Navy has expanded the NE NARW Mitigation Area (and its associated protections) to match the updated NARW ESA-designated critical habitat and further added a requirement not to conduct MTEs in the Gulf of Maine Planning Awareness Area. Both of these mitigation measures further reduce impacts to NARW in important feeding areas. Given all of this, and as described in more detail in the *Analysis and Negligible Impact Determination* section of the rule, any individual NARW is likely to be disturbed at a low-moderate level on no more than a few likely non-sequential days per year, and not in biologically important areas. Even given the fact that some of the affected individuals may already have compromised health, there is nothing to suggest that such a low magnitude and severity of effects would result in impacts on reproduction or survival of any individual. For these reasons, we determined that the expected take will have a negligible impact on NARW.

NEPA

Comment 59: A Commenter comments that NMFS cannot rely on the Navy's AFTT FEIS/OEIS to fulfill its obligations under NEPA because the Purpose and Need is too narrow and does not support NMFS' MMPA action, and therefore the AFTT FEIS/OEIS does not explore a reasonable range of alternatives.

Response: The proposed action at issue is the Navy's proposal to conduct training activities in the AFTT Study Area. NMFS is a cooperating agency for that proposed action, as it has jurisdiction by law and special expertise over marine resources impacted by the proposed action including marine mammals and federally listed threatened and endangered species. Consistent with the regulations published by the Council on Environmental Quality (CEQ), it is common and sound NEPA practice for NOAA to adopt a lead agency's NEPA analysis when, after independent review, NOAA determines the document to be sufficient in accordance with 40 CFR 1506.3. Specifically here, NOAA must be satisfied that the AFTT EIS/OEIS adequately addresses the impacts of issuing the MMPA incidental take authorization and that NOAA's comments and concerns have been adequately addressed. There is no requirement in CEQ regulations that NMFS, as a cooperating agency, issue a separate purpose and need statement in order to ensure adequacy and sufficiency for adoption. Nevertheless, the Navy, in coordination with NMFS, has clarified the statement of Purpose and Need in the AFTT FEIS/OEIS to more explicitly acknowledge NMFS' action of issuing an MMPA incidental take authorization. NMFS also clarified how its regulatory role under the MMPA related to Navy's activities. NMFS' early participation in the NEPA process and role in shaping and informing analyses using its special expertise ensured that the analysis in the AFTT FEIS/OEIS is sufficient for purposes of NMFS' own NEPA obligations related to its issuance of an Incidental Take Authorization under the MMPA.

Regarding the alternatives, NMFS' early involvement in development of the AFTT DEIS/OEIS and role in evaluating the effects of incidental take under the MMPA ensured that the AFTT DEIS/OEIS would include adequate analysis of a reasonable range of alternatives. The AFTT FEIS/OEIS includes a No Action Alternative specifically to address what could happen if NMFS did not issue an MMPA authorization. The other two Alternatives address two action options that the Navy could potentially pursue while also meeting their mandated Title 10 training and testing responsibilities. More importantly, these alternatives fully analyze a comprehensive variety of mitigation measures. This mitigation analysis supported NMFS' evaluation of our options in potentially issuing an MMPA authorization, which, if the authorization may be issued, primarily revolves around the appropriate mitigation to prescribe. This approach to evaluating a reasonable range of alternatives is consistent with NMFS policy and practice for issuing MMPA incidental take authorizations. NOAA has independently reviewed and evaluated the AFTT EIS/OEIS, including the purpose and need statement and range of alternatives, and determined that the Navy's AFTT FEIS/OEIS fully satisfies NMFS' NEPA obligations related to its decision to issue the MMPA final rule and associated Letters of Authorization, and we have adopted it.

Use of NMFS' Acoustic Technical Guidance

Comment 60: A Commenter does not agree with the Navy's use of NMFS 2016 Acoustic Technical Guidance (NMFS, 2016) for purposes of evaluating potential auditory injury. The Commenter claims that (1) NOAA is considering rescinding or revising the Acoustic Technical Guidance (2) NMFS' use of the guidance conflicts with Executive Order (E.O.) 13795 (''Implementing an America-First Offshore Energy Strategy''); (2) Several industry groups have identified Data Quality flaws in the Acoustic Technical guidance; (3) the Commenter has also identified significant Data Quality flaws in the Acoustic Technical Guidance; and (4) NMFS and/or Navy's continued use of the Acoustic Technical Guidance violates Information Quality Act (IQA) guidelines. Regarding the IQA, the Commenter states that NMFS does not have an Office of Management and Budget (OMB)-approved Information Collection Request (ICR) associated with the guidance, and is therefore violating the IQA.

Response: NMFS disagrees that use of the Acoustic Technical Guidance results in any of the claims listed by the Commenter. NMFS is not considering rescinding the Acoustic Technical Guidance. First, the use of the Acoustic Technical Guidance does not conflict with Executive Order 13795. Section 10 of the Executive Order called for a review of the technical guidance as follows: ''The Secretary of Commerce shall review for consistency with the policy set forth in Section 2 of this order and, after consultation with the appropriate Federal agencies, take all steps permitted by law to rescind or revise that guidance, if appropriate.'' To assist the Secretary in the review of the Acoustic Technical Guidance, NMFS solicited public comment via a 45-day public comment period (82 FR 24950; May 31, 2017) and hosted an interagency consultation meeting with representatives from ten federal agencies (September 25, 2017). NMFS received 62 comments directly related to the 2016 Acoustic Technical Guidance. Comments were submitted by federal agencies (Bureau of Ocean Energy Management (BOEM), the Navy, the Marine Mammal Commission), oil and gas industry representatives, Members of Congress, subject matter experts, NGOs, a foreign statutory

advisory group, a regulatory advocacy group, and members of the public. Most of the comments (85 percent) recommended no changes to the Acoustic Technical Guidance, and no public commenter suggested rescinding the Acoustic Technical Guidance. The U.S. Navy, the Marine Mammal Commission, Members of Congress, and subject matter experts expressed support for the Acoustic Technical Guidance thresholds and weighting functions as reflecting the best available science. The remaining comments (15 percent) focused on additional scientific publications for consideration or recommended revisions to improve implementation of the Acoustic Technical Guidance. All public comments received during this review can be found at *www.regulations.gov*. At the September 25, 2017, Federal Interagency Consultation, *none* of the federal agencies recommended rescinding the Acoustic Technical Guidance. Federal agencies were supportive of the Acoustic Technical Guidance thresholds and auditory weighting functions and the science behind their derivation and were appreciative of the opportunity to provide input. Comments received at the meeting focused on improvements to implementation of the Acoustic Technical Guidance and recommendations for future working group discussions to address implementation of the Acoustic Technical Guidance based on any new scientific information as it becomes available.

NMFS has already released a revised 2018 Acoustic Technical Guidance document (June 21, 2018) as a result of the review under E.O. 13795 (see *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance*), and the thresholds and weighting functions in the revised document (2018 Acoustic Technical Guidance) are identical to those in the 2016 Acoustic Technical Guidance. Thus, the revised version does not change the analysis already completed by the Navy, which relied on the 2016 version. Additional information on the review process under Executive Order 13795 can be found in Appendix C of the Acoustic Technical Guidance.

In addition, NMFS did comply with the OMB Peer Review Bulletin and IQA Guidelines in development of the technical guidance. The Acoustic Technical Guidance was classified as a Highly Influential Scientific Assessment and, as such, underwent three independent peer reviews, at three different stages in its development, including a follow-up to one of the peer reviews, prior to its dissemination by NMFS. In addition, there were three separate public comment periods. Responses to public comments were provided in a previous **Federal Register** notice (81 FR 51694; August 4, 2016). Detailed information on the peer reviews and public comment periods conducted during development of the Acoustic Technical Guidance are included as an appendix to the Acoustic Technical Guidance.

The Commenter is incorrect in their assumption that the Acoustic Technical Guidance is only based on non-impulsive Navy sonar and that it is radically different from impulsive sound like seismic air guns used in the oil and gas industry. The Commenter is also incorrect in stating that the application of the Acoustic Technical Guidance cannot practically be used to regulate seismic and other impulsive sounds sources and that explosives, like those used by the Navy, are not subject to the Acoustic Technical Guidance, but instead to a completely different explosive risk guidance. While it is true that there are less marine mammal TTS onset data available for impulsive sources compared to non-impulsive sources, the Acoustic Technical Guidance impulsive thresholds are specifically derived from data from two impulsive sources: (1) A seismic water gun (Finneran *et al.,* 2002) and (2) a single air gun exposure (Lucke *et al.,* 2009) (*i.e.,* these sources are more similar to those used by the oil and gas industry than tactical sonar or tonal signals). For the evaluation of PTS onset, underwater explosives are subject to the same impulsive thresholds from the Acoustic Technical Guidance as other impulsive sources, such as seismic air guns or impact pile drivers (*i.e.,* they do not have a separate set of criteria for potential impacts on hearing). Underwater explosives do have additional thresholds based on their potential to induce lung or gastrointestinal injury via exposure to shock waves, which are based on net explosive weight, as well as charge depth and animal mass.

Regarding the comment that industry impulsive sound would be more appropriately assessed and regulated through Navy's explosive risk guidance than through the Acoustic Technical Guidance, we disagree. Please see our comments above regarding explosives. Overall, the Acoustic Technical Guidance is a scientific tool that assists in impact assessments and explicitly states that while it can inform regulatory decisions, it in no way directly mandates any specific regulatory decisions, actions, or mitigations. Discretion is left to regulators to interpret the best way to use this best available information.

Last, regarding the Paperwork Reduction Act, there is no collection of information requirement associated with the Acoustic Technical Guidance. Rather, NMFS information collection for Applications and Reporting Requirements for Incidental Taking of Marine Mammals by Specified Activities Under the Marine Mammal Protection Act, OMB control number 0648–0151, was recently renewed and fully considers any potential additional time required as a result of using the Acoustic Technical Guidance, which is included in the estimated burden hours.

Description of Marine Mammals and Their Habitat in the Area of the Specified Activities

Marine mammal species and their associated stocks that have the potential to occur in the AFTT Study Area are presented in Table 12 along with an abundance estimate, an associated coefficient of variation value, and best/minimum abundance estimates. Some marine mammal species, such as manatees, are not managed by NMFS, but by the U.S. Fish and Wildlife Service and therefore not discussed below. The Navy anticipates the take of individuals of 39 marine mammal species by Level A and B harassment incidental to training and testing activities from the use of sonar and other transducers, in-water detonations, air guns, and impact pile driving/vibratory extraction. In addition, the Navy requested authorization for nine serious injuries or mortalities of four marine mammal stocks during ship shock trials, and three takes by serious injury or mortality from vessel strikes over the five-year period. One marine mammal species, the NARW, has critical habitat designated under the ESA in the AFTT Study Area (described below).

The species carried forward for analysis are those likely to be found in the AFTT Study Area based on the most recent data available, and do not include stocks or species that may have once inhabited or transited the area but have not been sighted in recent years and therefore are extremely unlikely to occur in the AFTT Study Area (*e.g.,* species which were extirpated because of factors such as nineteenth and twentieth century commercial exploitation).

The species not carried forward for analysis include the bowhead whale, beluga whale, and narwhal as these would be considered extralimital

species and are not part of the AFTT seasonal species assemblage. Bowhead whales are likely to be found only in the Labrador Current open ocean area, even if in 2012 and 2014, the same bowhead whale was observed in Cape Cod Bay, which represents the southernmost record of this species in the western North Atlantic. In June 2014, a beluga whale was observed in several bays and inlets of Rhode Island and Massachusetts (Swaintek, 2014). This sighting likely represents a single extralimital beluga whale occurrence in the Northeast United States Continental Shelf Large Marine Ecosystem. There is no stock of narwhal that occurs in the U.S. EEZ in the Atlantic Ocean; however, populations from Hudson Strait and Davis Strait may extend into the AFTT Study Area at its northwest extreme. However, narwhals prefer cold Arctic waters and those wintering in Hudson Strait occur in smaller numbers. For these reasons, the likelihood of any Navy activities encountering and having any effect on any of these three species is so slight as to be unlikely; therefore, these species do not require further analysis.

Additionally, for multiple bottlenose dolphin stocks, there was no potential for overlap with any stressors from Navy activities and therefore there would be no adverse effects (or takes), in which case, those stocks were not considered further. Specifically, with the exception of the Mississippi Sound, Lake Borgne, Bay Boudreau stock of bottlenose dolphins (which is addressed in the *Analysis and Negligible Impact Determination* section below), there is no potential for overlap of any Navy stressor with any other Northern GOMEX Bay, Sound, and Estuary stocks. Also, the following bottlenose dolphin stocks for the Atlantic do not have any potential for overlap with Navy activity stressors (or take), and therefore are not considered further: Northern South Carolina Estuarine System, Charleston Estuarine System, Northern Georgia/Southern South Carolina Estuarine System, Central Georgia Estuarine System, Southern Georgia Estuarine System, Biscayne Bay, and Florida Bay stocks. For the same reason, bottlenose dolphins off of Puerto Rico and the U.S. Virgin Islands were also not considered further. We note that in NMFS' draft 2018 SARs (made available since the proposed rule was published), NMFS has further delineated stocks within the Northern GOMEX Bay, Sound, and Estuary stocks since the 2017 SAR and the Navy's application. However, the Mississippi Sound, Lake Borgne, Bay Boudreau stock of bottlenose dolphins remains the same, and the fact that no Navy stressors overlap any of the other stocks remains accurate, so our analysis of these stocks is unchanged. NMFS is in the process of writing individual SARs for each of the 31 Northern GOMEX Bay, Sound, and Estuary stocks. To date, six have been completed (including the Mississippi Sound, Lake Borgne, Bay Boudreau stock).We presented a detailed discussion of marine mammals and their occurrence in the planned action area, inclusive of important marine mammal habitat (*e.g.,* critical habitat), BIAs, national marine sanctuaries, and UMEs in our **Federal Register** notice of proposed rulemaking (83 FR 10954; March 13, 2018); please see that proposed rule or the Navy's application for more information. There have been no changes to important marine mammal habitat, BIAs, National Marine Sanctuaries, or ESA-designated critical habitat since the issuance of the proposed rule; therefore, they are not discussed further (though we note that NARW ESA-designated critical habitat was updated in 2016, since the last Navy AFTT rule, and some of the discussion in the rule references that). Additional information on UMEs has become available and is discussed following Table 12.

Table 12. Marine mammals with the potential to occur within the AFTT Study Area.

Common Name	*Scientific Name*[1]	*Stock*[2]	*ESA/MMPA Status*[3]	*Stock Abundance*[4] *Best / Minimum Population*	*Occurrence in AFTT Study Area*[5]		
					Open Ocean	*Large Marine Ecosystems*	*Inland Waters*
Order Cetacea							
Suborder Mysticeti (baleen whales)							
Family Balaenidae (right whales)							
Bowhead whale	*Balaena mysticetus*	Eastern Canada-West Greenland	Endangered, strategic, depleted	7,660 (4,500-11,100)[6]	Labrador Current	Newfoundland-Labrador Shelf, West Greenland Shelf, Northeast U.S. Continental Shelf	NA
North Atlantic right whale	*Eubalaena glacialis*	Western	Endangered, strategic, depleted	451 (0) / 445	Gulf Stream, Labrador Current, North Atlantic Gyre	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf, Gulf of Mexico (extralimital)	NA
Family Balaenopteridae (rorquals)							
Blue whale	*Balaenoptera musculus*	Western North Atlantic (Gulf of St. Lawrence)	Endangered, strategic, depleted	Unknown / 440[11]	Gulf Stream, North Atlantic Gyre, Labrador Current	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf, Southeast U.S. Continental Shelf, Caribbean Sea, and Gulf of Mexico (strandings only)	NA
Bryde's whale	*Balaenoptera brydei/edeni*	Northern Gulf of Mexico	Planned Endangered, strategic	33 (1.07) / 16	Gulf Stream, North Atlantic Gyre	Gulf of Mexico	NA

Fin whale	*Balaenoptera physalus*	Western North Atlantic	Endangered, strategic, depleted	1,618 (0. 33) / 1,234	Gulf Stream, North Atlantic Gyre, Labrador Current	Caribbean Sea, Gulf of Mexico, Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
		West Greenland	Endangered, strategic, depleted	4,468 (1,343-14,871)[9]	Labrador Current	West Greenland Shelf	NA
		Gulf of St. Lawrence	Endangered, strategic, depleted	328 (306-350)[10]		Newfoundland-Labrador Shelf, Scotian Shelf	NA
Humpback whale	*Megaptera novaeangliae*	Gulf of Maine	NA	896 (0) / 896	Gulf Stream, North Atlantic Gyre, Labrador Current	Gulf of Mexico, Caribbean Sea, Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
Minke whale	*Balaenoptera acutorostrata*	Canadian Eastern Coastal	NA	2,591 (0.81) / 1,425	Gulf Stream, North Atlantic Gyre, Labrador Current	Caribbean Sea, Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
		West Greenland[7]	NA	16,609 (7,172-38,461) / NA [7]	Labrador Current	West Greenland Shelf	NA
Sei whale	*Balaenoptera borealis*	Nova Scotia	Endangered, strategic, depleted	357 (0.52) / 236	Gulf Stream, North Atlantic Gyre	Gulf of Mexico, Caribbean Sea, Southeast Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
		Labrador Sea	Endangered, strategic, depleted	Unknown[8]	Labrador Current	Newfoundland-Labrador Shelf, West Greenland Shelf	NA
Family Physeteridae (sperm whale)							
Suborder Odontoceti (toothed whales)							

Sperm whale	*Physeter macrocephalus*	North Atlantic	Endangered, strategic, depleted	2,288 (0.28) / 1,815	Gulf Stream, North Atlantic Gyre, Labrador Current	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf, Caribbean Sea	NA
		Northern Gulf of Mexico	Endangered, strategic, depleted	763 (0.38) / 560	NA	Gulf of Mexico	NA
		Puerto Rico and U.S. Virgin Islands	Endangered, strategic, depleted	Unknown	North Atlantic Gyre	Caribbean Sea	NA
Family Kogiidae (sperm whales)							
Pygmy and dwarf sperm whales	*Kogia breviceps* and *Kogia sima*	Western North Atlantic	NA	3,785 (0.47) / 2,598[12]	Gulf Stream, North Atlantic Gyre	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf, Caribbean Sea	NA
		Northern Gulf of Mexico	NA	186 (1.04) / 90[12]	NA	Gulf of Mexico, Caribbean Sea	NA
Family Monodontidae (beluga whale and narwhal)							
Beluga whale	*Delphinapterus leucas*	Eastern High Arctic/Baffin Bay[13]	NA	21,213 (10,985–32,619) [13]	Labrador Current	West Greenland Shelf	NA
		West Greenland[14]	NA	10,595 (4.904–24,650) [14]	NA	West Greenland Shelf	NA
Narwhal	*Monodon monoceros*	NA[15]	NA	NA[15]	NA	Newfoundland-Labrador Shelf, West Greenland Shelf	NA
Family Ziphiidae (beaked whales)							
Blainville's beaked whale	*Mesoplodon densirostris*	Western North Atlantic[16]	NA	7,092 (0.54) / 4,632[17]	Gulf Stream, North Atlantic Gyre, Labrador Current	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
		Northern Gulf of Mexico	NA	149 (0.91) / 77[18]	NA	Gulf of Mexico, Caribbean Sea	NA

Cuvier's beaked whale	*Ziphius cavirostris*	Western North Atlantic[16]	NA	6,532 (0.32) / 5,021	Gulf Stream, North Atlantic Gyre	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
		Northern Gulf of Mexico[16]	NA	74 (1.04) / 36	NA	Gulf of Mexico, Caribbean Sea	NA
		Puerto Rico and U.S. Virgin Islands	Strategic	Unknown	NA	Caribbean Sea	NA
Gervais' beaked whale	*Mesoplodon europaeus*	Western North Atlantic[16]	NA	7,092 (0.54) / 4,632 [17]	Gulf Stream, North Atlantic Gyre	Southeast U.S. Continental Shelf, Northeast United States Continental Shelf	NA
		Northern Gulf of Mexico[16]	NA	149 (0.91) / 77 [18]	Gulf Stream, North Atlantic Gyre	Gulf of Mexico, Caribbean Sea	NA
Northern bottlenose whale	*Hyperoodon ampullatus*	Western North Atlantic	NA	Unknown	Gulf Stream, North Atlantic Gyre, Labrador Current	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
Sowerby's beaked whale	*Mesoplodon bidens*	Western North Atlantic[16]	NA	7,092 (0.54) / 4,632 [17]	Gulf Stream, North Atlantic Gyre	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
True's beaked whale	*Mesoplodon mirus*	Western North Atlantic[16]	NA	7,092 (0.54) / 4,632 [17]	Gulf Stream, North Atlantic Gyre	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
Family Delphinidae (dolphins)							
Atlantic spotted dolphin	*Stenella frontalis*	Western North Atlantic[16]	NA	44,715 (0.43) / 31,610	Gulf Stream	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf	NA
		Northern Gulf of Mexico	NA	Unknown	NA	Gulf of Mexico, Caribbean Sea	NA

		Puerto Rico and U.S. Virgin Islands	Strategic	Unknown	NA	Caribbean Sea	NA
Atlantic white-sided dolphin	*Lagenorhynchus acutus*	Western North Atlantic	NA	48,819 (0.61) / 30,403	Gulf Steam, Labrador Current	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
Clymene dolphin	*Stenella clymene*	Western North Atlantic[16]	NA	Unknown	Gulf Stream	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf	NA
		Northern Gulf of Mexico[16]	NA	129 (1.0) / 64	NA	Gulf of Mexico, Caribbean Sea	NA
Common bottlenose dolphin	*Tursiops truncatus*	Western North Atlantic Offshore[19]	Strategic, depleted	77,532 (0.40) / 56,053	Gulf Stream, North Atlantic Gyre	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf	NA
		Western North Atlantic Northern Migratory Coastal[20]	NA	6,639 (0.41) / 4,759	NA	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf	Long Island Sound, Sandy Hook Bay, Lower Chesapeake Bay, James River, Elizabeth River
		Western North Atlantic Southern Migratory Coastal[20]	Strategic, depleted	3,751 (0.06) / 2,353	NA	Southeast U.S. Continental Shelf	Lower Chesapeake Bay, James River, Elizabeth River, Beaufort Inlet, Cape Fear River, Kings Bay, St. Johns River
		Western North Atlantic South Carolina/Georgia Coastal[20]	Strategic, depleted	6,027 (0.34) / 4,569	NA	Southeast U.S. Continental Shelf	Kings Bay, St. Johns River
		Northern North Carolina Estuarine System[20]	Strategic	823 (0.06) / 782	NA	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf	Beaufort Inlet, Cape Fear River
		Southern North Carolina Estuarine System[20]	Strategic	Unknown	NA	Southeast U.S. Continental Shelf	Beaufort Inlet, Cape Fear River
		Northern South Carolina Estuarine System[20]	Strategic	Unknown	NA	Southeast U.S. Continental Shelf	NA

		Charleston Estuarine System[20]	Strategic	Unknown	NA	Southeast U.S. Continental Shelf	NA
Common bottlenose dolphin (continued)	*Tursiops truncatus*	Northern Georgia/ Southern South Carolina Estuarine System[20]	Strategic	Unknown	NA	Southeast U.S. Continental Shelf	NA
		Central Georgia Estuarine System[20]	Strategic	192 (0.04) / 185	NA	Southeast U.S. Continental Shelf	NA
		Southern Georgia Estuarine System[20]	Strategic	194 (0.05) / 185	NA	Southeast U.S. Continental Shelf	Kings Bay, St. Johns River
		Western North Atlantic Northern Florida Coastal[20]	Strategic, depleted	877 (0.49) / 595	NA	Southeast U.S. Continental Shelf	Kings Bay, St. Johns River
		Jacksonville Estuarine System[20]	Strategic	Unknown	NA	Southeast U.S. Continental Shelf	Kings Bay, St. Johns River
		Western North Atlantic Central Florida Coastal[20]	Strategic, depleted	1,218 (0.35) / 913	NA	Southeast U.S. Continental Shelf	Port Canaveral
		Indian River Lagoon Estuarine System[20]	Strategic	Unknown	NA	Southeast U.S. Continental Shelf	Port Canaveral
		Biscayne Bay[16]	Strategic	Unknown	NA	Southeast U.S. Continental Shelf	NA
		Florida Bay[16]	NA	Unknown	NA	Gulf of Mexico	NA
		Northern Gulf of Mexico Continental Shelf[20]	Na	51,192 (0.10) / 46,926	NA	Gulf of Mexico	NA
		Gulf of Mexico Eastern Coastal[20]	NA	12,388 (0.13) / 11,110	NA	Gulf of Mexico	NA
		Gulf of Mexico Northern Coastal[20]	NA	7,185 (0.21) / 6,044	NA	Gulf of Mexico	St. Andrew Bay, Pascagoula River
		Gulf of Mexico Western Coastal[20]	NA	20,161 (0.17) / 17,491	NA	Gulf of Mexico	Corpus Christi Bay, Galveston Bay

Northern Gulf of Mexico Oceanic[20]	NA	5,806 (0.39) / 4,230	NA	Gulf of Mexico	NA
Laguna Madre	Strategic	80 (1.57) / Unknown	NA	Gulf of Mexico	NA
Nueces Bay/Corpus Christi Bay	Strategic	58 (0.61) / Unknown	NA	Gulf of Mexico	NA
Copano Bay/Aransas Bay/San Antonio Bay/Redfish Bay/Espiritu Santo Bay	Strategic	55 (0.82) / Unknown	NA	Gulf of Mexico	NA
Matagorda Bay/Tres Palacios Bay/Lavaca Bay	Strategic	61 (0.45) / Unknown	NA	Gulf of Mexico	NA
West Bay	NA	48 (0.03) / 46	NA	Gulf of Mexico	NA
Galveston Bay/East Bay/Trinity Bay	Strategic	152 (0.43) / Unknown	NA	Gulf of Mexico	NA
Sabine Lake	Strategic	0	NA	Gulf of Mexico	NA
Calcasieu Lake	Strategic	0	NA	Gulf of Mexico	NA
Vermilion Bay/West Cote Blanche Bay/Atchafalaya Bay	Strategic	0	NA	Gulf of Mexico	NA
Terrebonne Bay/Timbalier Bay	NA	3,870 (0.15) / 3,426	NA	Gulf of Mexico	NA
Barataria Bay Estuarine System[20]	Strategic	2,306 (0.09) / 2,138	NA	Gulf of Mexico	NA
Mississippi River Delta	Strategic	332 (0.93) / 170	NA	Gulf of Mexico	NA
Mississippi Sound, Lake Borgne, Bay Boudreau[20]	Strategic	3,046 (0.06) / 2,896	NA	Gulf of Mexico	NA
Mobile Bay/Bonsecour Bay	Strategic	122 (0.34) / Unknown	NA	Gulf of Mexico	NA
Perdido Bay	Strategic	0	NA	Gulf of Mexico	NA
Pensacola Bay/East Bay	Strategic	33 (0.80) / Unknown	NA	Gulf of Mexico	NA
Choctawhatchee	Strategic	179 (0.04) /	NA	Gulf of Mexico	NA

		Bay		Unknown			
		St. Andrew Bay	Strategic	124 (0.57) / Unknown	NA	Gulf of Mexico	NA
		St. Joseph Bay[20]	Strategic	152 (0.08) / Unknown	NA	Gulf of Mexico	NA
		St. Vincent Sound/Apalachicola Bay/St. George Sound	Strategic	439 (0.14) / Unknown	NA	Gulf of Mexico	NA
		Apalachee Bay	Strategic	491 (0.39) / Unknown	NA	Gulf of Mexico	NA
		Waccasassa Bay/Withlacoochee Bay/Crystal Bay	Strategic	Unknown	NA	Gulf of Mexico	NA
		St. Joseph Sound/Clearwater Harbor	Strategic	Unknown	NA	Gulf of Mexico	NA
		Tampa Bay	Strategic	Unknown	NA	Gulf of Mexico	NA
		Sarasota Bay/Little Sarasota Bay	Strategic	158 (0.27) / 126	NA	Gulf of Mexico	NA
		Pine Island Sound/Charlotte Harbor/Gasparilla Sound/Lemon Bay	Strategic	826 (0.09) / Unknown	NA	Gulf of Mexico	NA
		Caloosahatchee River	Strategic	0	NA	Gulf of Mexico	NA
		Estero Bay	Strategic	Unknown	NA	Gulf of Mexico	NA
		Chokoloskee Bay/Ten Thousand Islands/Gullivan Bay	Strategic	Unknown	NA	Gulf of Mexico	NA
		Whitewater Bay	Strategic	Unknown	NA	Gulf of Mexico	NA
		Florida Keys (Bahia Honda to Key West)	Strategic	Unknown	NA	Gulf of Mexico	NA
		Puerto Rico and U.S. Virgin Islands	Strategic	Unknown	NA	Caribbean Sea	NA
False killer whale	*Pseudorca crassidens*	Western North Atlantic[22]	Strategic	442 (1.06) / 212	NA	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf	NA

		Northern Gulf of Mexico[16]	NA	Unknown	NA	Gulf of Mexico, Caribbean Sea	NA
Fraser's dolphin	*Lagenodelphis hosei*	Western North Atlantic[23]	NA	Unknown	Gulf Stream	Northeast U.S. Continental Shelf, Southeast U.S. Continental Shelf	NA
		Northern Gulf of Mexico[16]	NA	Unknown	NA	Gulf of Mexico, Caribbean Sea	NA
Killer Whale	*Orcinus orca*	Western North Atlantic[22]	NA	Unknown	Gulf Stream, North Atlantic Gyre, Labrador Current	Southeast U.S. Continental Shelf, Northeast United States Continental Shelf, Scotian Shelf, Newfoundland – Labrador Shelf	NA
		Northern Gulf of Mexico[16]	NA	28 (1.02) / 14	NA	Gulf of Mexico, Caribbean Sea	NA
Long-finned pilot whale	*Globicephala melas*	Western North Atlantic	NA	5,636 (0.63) / 3,464	Gulf Stream	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
Melon-headed Whale	*Peponocephala electra*	Western North Atlantic[23]	NA	Unknown	Gulf Stream, North Atlantic Gyre	Southeast U.S. Continental Shelf	NA
		Northern Gulf of Mexico[16]	NA	2,235 (0.75) / 1,274	NA	Gulf of Mexico, Caribbean Sea	NA
Pantropical spotted-dolphin	*Stenella attenuate*	Western North Atlantic[16]	NA	3,333 (0.91) / 1,733	Gulf Stream	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf	NA
		Northern Gulf of Mexico[22]	NA	50,880 (0.27) / 40,699	NA	Gulf of Mexico, Caribbean Sea	NA
Pygmy Killer Whales	*Feresa attenuata*	Western North Atlantic[16]	NA	Unknown	Gulf Stream, North Atlantic Gyre	Southeast U.S. Continental Shelf	NA
		Northern Gulf of Mexico[16]	NA	152 (1.02) / 75	NA	Gulf of Mexico, Caribbean Sea	NA

Risso's dolphin	*Grampus griseus*	Western North Atlantic	NA	18,250 (0.46) / 12,619	Gulf Stream, North Atlantic Gyre	Southeast U.S. Continental Shelf, Northeast United States Continental Shelf, Scotian Shelf, Newfoundland – Labrador Shelf	NA
		Northern Gulf of Mexico	NA	2,442 (0.57) / 1,563	NA	Gulf of Mexico, Caribbean Sea	NA
Rough-toothed dolphin	*Steno bredanensis*	Western North Atlantic[16]	NA	136 (1.00) / 67	Gulf Stream, North Atlantic Gyre	Caribbean Sea Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf	NA
		Northern Gulf of Mexico	NA	624 (0.99) / 311	NA	Gulf of Mexico, Caribbean Sea	NA
Short-finned pilot whale	*Globicephala macrorhynchus*	Western North Atlantic	NA	28,924 (0.24) / 23,637	NA	Northeast Continental Shelf, Southeast U.S. Continental Shelf	NA
		Northern Gulf of Mexico[22]	NA	2,415 (0.66) / 1,456	NA	Gulf of Mexico, Caribbean Sea	NA
		Puerto Rico and U.S. Virgin Islands	Strategic	Unknown	NA	Caribbean Sea	NA
Spinner dolphin	*Stenella longirostris*	Western North Atlantic[16]	NA	Unknown	Gulf Stream, North Atlantic Gyre	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf	NA
		Northern Gulf of Mexico[16]	NA	11,441 (0.83) / 6,221	NA	Gulf of Mexico, Caribbean Sea	NA
		Puerto Rico and U.S. Virgin Islands	Strategic	Unknown	NA	Caribbean Sea	NA
Striped dolphin	*Stenella coeruleoalba*	Western North Atlantic[16]	NA	54,807 (0.30) / 42,804	Gulf Stream	Northeast U.S. Continental Shelf, Scotian Shelf	NA
		Northern Gulf of Mexico[16]	NA	1,849 (0.77) / 1,041	NA	Gulf of Mexico, Caribbean Sea	NA
Short-beaked common dolphin	*Delphinus delphis*	Western North Atlantic	NA	70,184 (0.28) / 55,690	Gulf Stream	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
White-beaked dolphin	*Lagenorhynchus albirostris*	Western North Atlantic[23]	NA	2,003 (0.94) / 1,023	Labrador Current	Northeast U.S. Continental Shelf, Scotian Shelf,	NA

						Newfoundland-Labrador Shelf	
Family Phocoenidae (porpoises)							
Harbor porpoise	*Phocoena*	Gulf of Maine/Bay of Fundy	NA	79,883 (0.32) / 61,415	NA	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	Narragansett Bay, Rhode Island Sound, Block Island Sound, Buzzards Bay, Vineyard Sound, Long Island Sound, Piscataqua River, Thames River, Kennebec River
		Gulf of St. Lawrence[24]	NA	Unknown[24]	Labrador Current	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
		Newfoundland[25]	NA	Unknown[25]	Labrador Current	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
		Greenland[26]	NA	Unknown[26]	Labrador Current	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf, West Greenland Shelf	NA
Order Carnivora							
Suborder Pinnipedia							
Family Phocidae (true seals)							

Gray seal	*Halichoerus grypus*	Western North Atlantic	NA	27,131 (0.19) / 23,158	NA	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	Narragansett Bay, Rhode Island Sound, Block Island Sound, Buzzards Bay, Vineyard Sound, Long Island Sound, Piscataqua River, Thames River, Kennebeck River
Harbor seal	*Phoca vitulina*	Western North Atlantic	NA	75,834 (0.15) / 66,884	NA	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	Chesapeake Bay, Narragansett Bay, Rhode Island Sound, Block Island Sound, Buzzards Bay, Vineyard Sound, Long Island Sound, Piscataqua River, Thames River, Kennebeck River
Harp seal	*Pagophilus groenlandicus*	Western North Atlantic	NA	Unknown	NA	Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf	NA
Hooded seal	*Cystophora cristata*	Western North Atlantic	NA	Unknown	NA	Southeast U.S. Continental Shelf, Northeast U.S. Continental Shelf, Scotian Shelf, Newfoundland-Labrador Shelf, West Greenland Shelf	Narragansett Bay, Rhode Island Sound, Block Island Sound, Buzzards Bay, Vineyard Sound, Long Island Sound, Piscataqua River, Thames River, Kennebec River

Notes: CV: coefficient of variation; ESA: Endangered Species Act; MMPA: Marine Mammal Protection Act; NA: not applicable

[1]Taxonomy follows (Committee on Taxonomy, 2016)

[2] Stock designations for the U.S. EEZ and abundance estimates are from Atlantic and Gulf of Mexico SARS prepared by NMFS *(Hayes et al.*, 2017) and the draft 2018 SARs, unless specifically noted.

[3] Populations or stocks defined by the MMPA as "strategic" for one of the following reasons: (1) the level of direct human-caused mortality exceeds the potential biological removal level; (2) based on the best available scientific information, numbers are declining and species are likely to be listed as threatened species under the ESA within the foreseeable future; (3) species are listed as threatened or endangered under the ESA; (4) species are designated as depleted under the MMPA.
[4] Stock abundance, CV, and minimum population are numbers provided by the Stock Assessment Reports *(Hayes et al.*, 2017). The stock abundance is an estimate of the number of animals within the stock. The CV is a statistical metric used as an indicator of the uncertainty in the abundance estimate. The minimum population estimate is either a direct count (*e.g.*, pinnipeds on land) or the lower 20th percentile of a statistical abundance estimate.
[5] Occurrence in the AFTT Study Area includes open ocean areas—Labrador Current, North Atlantic Gyre, Gulf Stream, and coastal/shelf waters of seven large marine ecosystems—West Greenland Shelf, Newfoundland-Labrador Shelf, Scotian Shelf, and Northeast U.S. Continental Shelf, Southeast U.S. Continental Shelf, Caribbean Sea, Gulf of Mexico, and inland waters of Kennebec River, Piscataqua River, Thames River, Narragansett Bay, Rhode Island Sound, Block Island Sound, Buzzards Bay, Vineyard Sound, Long Island Sound, Sandy Hook Bay, Lower Chesapeake Bay, James River, Elizabeth River, Beaufort Inlet, Cape Fear River, Kings Bay, St. Johns River, Port Canaveral, St. Andrew Bay, Pascagoula River, Sabine Lake, Corpus Christi Bay, and Galveston Bay.
[6] The bowhead whale population off the West Coast of Greenland is not managed by NMFS and, therefore, does not have an associated Stock Assessment Report. Abundance and 95 percent highest density interval were presented in (Frasier *et al.*, 2015).
[7] The West Greenland stock of minke whales is not managed by NMFS and, therefore, does not have an associated Stock Assessment Report. Abundance and 95 percent confidence interval were presented in (Heide-Jørgensen *et al.*, 2010).
[8] The Labrador Sea stock of sei whales is not managed by NMFS and, therefore, does not have an associated Stock Assessment Report. Information was obtained in (Prieto *et al.*, 2014).
[9] The West Greenland stock of fin whales is not managed by NMFS and, therefore, does not have an associated Stock Assessment Report. Abundance and 95 percent confidence interval were presented in (Heide-Jørgensen *et al.*, 2010).
[10] The Gulf of St. Lawrence stock of fin whales is not managed by NMFS and, therefore, does not have an associated Stock Assessment Report. Abundance and 95 percent confidence interval were presented in (Ramp *et al.*, 2014).
[11] Photo identification catalogue count of 440 recognizable blue whale individuals from the Gulf of St. Lawrence is considered a minimum population estimate for the western North Atlantic stock (Waring *et al.*, 2010).
[12] Estimates include both the pygmy and dwarf sperm whales in the western North Atlantic (Waring *et al*., 2014) and the northern Gulf of Mexico (Waring *et al.*, 2013).
[13] Beluga whales in the Atlantic are not managed by NMFS and have no associated Stock Assessment Report. Abundance and 95 percent confidence interval for the
Eastern High Arctic/Baffin Bay stock were presented in (Innes e*t al*., 2002).
[14] Beluga whales in the Atlantic are not managed by NMFS and have no associated Stock Assessment Report. Abundance and 95 percent confidence interval for the
West Greenland stock were presented in (Heide-Jørgensen *et al*., 2009).
[15] NA = Not applicable. Narwhals in the Atlantic are not managed by NMFS and have no associated Stock Assessment Report.
[16] Estimates for these western North Atlantic stocks are from Waring *et al*. (2014) and the northern Gulf of Mexico stock are from (Waring *et al*., 2013) as applicable.
[17] Estimate includes undifferentiated Mesoplodon species.
[18] Estimate includes Gervais' and Blainville's beaked whales.
[19] Estimate may include sightings of the coastal form.
[20] Estimates for these Gulf of Mexico stocks are from SARs
[21] NMFS is in the process of writing individual stock assessment reports for each of the 32 bay, sound, and estuary stocks.
[22] Estimates for these stocks are from Waring *et al*., (2015).
[23] Estimates for these western North Atlantic stocks are from (Waring *et al*., 2007).
[24] Harbor porpoise in the Gulf of St. Lawrence are not managed by NMFS and have no associated Stock Assessment Report.
[25] Harbor porpoise in Newfoundland are not managed by NMFS and have no associated Stock Assessment Report.
[26] Harbor porpoise in Greenland are not managed by NMFS and have no associated Stock Assessment Report.

A UME is defined under section 410(6) of the MMPA as a stranding that is unexpected; involves a significant die-off of any marine mammal population; and demands immediate response. From 1991 to the present, there have been 36 formally recognized UMEs affecting marine mammals along the Atlantic Coast and the GOMEX involving species under NMFS' jurisdiction. Two additional UME's have been declared in 2018 since publication of the proposed rule that inform our analysis: The Northeast Pinniped UME (harbor and gray seals) in the Atlantic and the Southwest Florida Bottlenose dolphin UME in the GOMEX. The NARW, humpback whale, and minke whale UMEs on the Atlantic Coast are still active and involve ongoing investigations. The impacts to Barataria Bay bottlenose dolphins from the expired UME (discussed in the proposed rule) associated with the DWH oil spill in the GOMEX are thought to be persistent and continue to inform population analyses. The other UMEs expired several years ago and little is known about how the effects of those events might be appropriately applied to an impact assessment several years later. The five UMEs that could inform the current analysis are discussed below.

NARW UME

Since June 7, 2017, elevated mortalities of NARW have been documented. To date, a total of 19 confirmed dead stranded NARW (12 in Canada; 7 in the United States), and five live whale entanglements in Canada have been observed, predominantly in the Gulf of St. Lawrence region of Canada and around the Cape Cod area of Massachusetts. Historically (2006–2016), the annual average for dead NARW strandings in Canada and the United States combined is 3.8 whales per year. This event was declared a UME and is under investigation. Full necropsy examinations have been conducted on 11 of the 19 whales and final results from the examinations are pending. Necropsy results from seven of the Canadian whales suggest mortalities of four whales were compatible with blunt trauma likely caused by vessel collision and two mortalities were confirmed from chronic entanglement in fishing gear (Daoust *et al.,* 2017; M. Hardy personal communication to D. Fauquier on October 5, 2017; Meyer-Gutbrod *et al.,* 2018; Pettis *et al.,* 2017a). The seventh whale was too decomposed to determine the cause of mortality, but some observations in this animal suggested blunt trauma. Limited samples from another whale suggest

acute death (Daoust *et al.,* 2018). Daoust *et al.* (2018) also concluded there were no oil and gas seismic surveys authorized in the months prior to or during the period over which these mortalities occurred, as well as no blasting or major marine development projects. All of the NARW that stranded in the United States that are part of the UME had been significantly decomposed at the time of stranding, and investigations have been limited. Navy was consulted as to sonar use and they confirmed none was used in the vicinity of any of the strandings.

As part of the UME process, an independent team of scientists (Investigative Team) was assembled to coordinate with the Working Group on Marine Mammal Unusual Mortality Events to review the data collected, sample future whales that strand and to determine the next steps for the investigation. For more information on this UME, please refer to *https://www.fisheries.noaa.gov/national/marine-life-distress/2017-2018-north-atlantic-right-whale-unusual-mortality-event.*

While data are not yet available to statistically estimate the population's trend beyond 2015, three lines of evidence indicate the population is still in decline. First, calving rates in 2016, 2017, and 2018 were low. Only five new calves were documented in 2017 (Pettis *et al.,* 2017a), well below the number needed to compensate for expected mortalities (Pace *et al.,* 2017), and no new calves were reported for 2018. Long-term photographic identification data indicate new calves rarely go undetected, so these years likely represent a continuation of the low calving rates that began in 2012 (Kraus *et al.,* 2007; Pace *et al.,* 2017). Second, as noted above, the preliminary abundance estimate for 2016 is 451 individuals, down approximately 1.5 percent from 458 in 2015. Third, since June 2017, at least 19 NARWs have died in what has been declared an UME as discussed above, and at least one calf died prior to this in April 2017 (Meyer-Gutbrod *et al.,* 2018; NMFS 2017).

Humpback Whale UME Along the Atlantic Coast

Since January 2016, elevated mortalities of humpback whales along the Atlantic coast from Maine through Florida have occurred. As of August 29, 2018 a total of 81 humpback strandings have occurred (26, 33, and 22 whales in 2016, 2017, and 2018 respectively). As of April 2017, partial or full necropsy examinations were conducted on 20 cases, or approximately half of the 42 strandings (at that time). Of the 20 whales examined, 10 had evidence of blunt force trauma or pre-mortem propeller wounds indicative of vessel strike, which is over six times above the 16-year average of 1.5 whales showing signs of vessel strike in this region. Vessel strikes were documented for stranded humpback whales in Virginia (3), New York (3), Delaware (2), Massachusetts (1) and New Hampshire (1). NOAA, in coordination with our stranding network partners, continues to investigate the recent mortalities, environmental conditions, and population monitoring to better understand the recent humpback whale mortalities. At this time, vessel parameters (including size) are not known for each vessel-whale collision that lead to the death of the whales. Therefore, NOAA considers all sizes of vessels to be risks for whale species in highly trafficked areas. The Navy has investigated potential strikes and confirmed that it had none. This investigation is ongoing. Please refer to *http://www.nmfs.noaa.gov/pr/health/mmume/2017humpbackatlanticume.html* for more information on this UME.

Minke Whale UME Along the Atlantic Coast

Since January 2017, elevated mortalities of minke whale along the Atlantic coast from Maine through South Carolina have occurred. As of September 9, 2018, a total of 43 strandings have occurred (27 and 16 whales in 2017 and 2018, respectively). As of February 16, 2018 full or partial necropsy examinations were conducted on over 60 percent of the whales. Preliminary findings in several of the whales have shown evidence of human interactions, primarily fisheries interactions, or infectious disease. These findings are not consistent across all of the whales examined, and final diagnostic results are still pending for many of the cases. This investigation is ongoing. Please refer to *https://www.fisheries.noaa.gov/national/marine-life-distress/2017-2018-minke-whale-unusual-mortality-event-along-atlantic-coast* for more information on this UME.

Northeast Pinniped UME Along the Atlantic Coast

Since July 2018, elevated numbers of harbor seal and gray seal mortalities have occurred across Maine, New Hampshire and Massachusetts. As of September 25, 2018, a total of 1,036 seal strandings have been confirmed. Full or partial necropsy examinations have been conducted on many of the seals and samples have been collected for testing. Based on testing conducted so far, the main pathogen found in the seals is phocine distemper virus. While initially detected in some animals, there is not strong evidence that avian influenza virus is a cause of this UME. This investigation is ongoing. Please refer to *https://www.fisheries.noaa.gov/new-england-mid-atlantic/marine-life-distress/2018-pinniped-unusual-mortality-event-along-northeast* for more information on this UME.

Southwest Florida Bottlenose Dolphin UME Along the GOMEX

Since July 2018, elevated bottlenose dolphin mortalities have occurred along the Southwest coast of Florida including Collier, Lee, Charlotte, Sarasota, Manatee, Hillsborough, and Pinellas counties. As of September 27, 2018, 65 dolphins have been confirmed stranded in this event. Our stranding network partners have conducted full or partial necropsy examinations on several dolphins, with positive results for the red tide toxin (brevetoxin) indicating this UME is related to the severe bloom of a red tide that has been ongoing since November 2017. This investigation is ongoing. Please refer to *https://www.fisheries.noaa.gov/southeast/marine-life-distress/2018-bottlenose-dolphin-unusual-mortality-event-southwest-florida* for more information on this UME.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

We provided a summary and discussion of the potential effects of the specified activity on marine mammals and their habitat in our **Federal Register** notice of proposed rulemaking (83 FR 10954; March 13, 2018). In the *Potential Effects of Specified Activities on Marine Mammals and Their Habitat* section of the proposed rule, NMFS provided a description of the ways marine mammals may be affected by these activities in the form of serious injury or mortality, physical trauma, sensory impairment (permanent and temporary threshold shifts and acoustic masking), physiological responses (particular stress responses), behavioral disturbance, or habitat effects. Therefore, we do not reprint the information here but refer the reader to that document. For additional summary and discussion of recent scientific studies not included in the proposed rulemaking, we direct the reader to the AFTT FEIS/OEIS (Chapter 3, Section 3.7 *Marine Mammals, http://www.aftteis.com/*), which NMFS participated in the development of via our cooperating agency status and adopted to meet our NEPA

requirements. We highlight several studies below, but direct the reader to the AFTT FEIS/OEIS for a full compilation. As noted above, NMFS has reviewed and accepted the Navy's compilation and interpretation of the best available science contained in the AFTT FEIS/OEIS. More specifically, we have independently reviewed the more recent studies that were not included in NMFS' proposed rule and have concluded that the descriptions and interpretations of those studies are accurate. Importantly, we note that none of the newer information highlighted here or in the AFTT FEIS/OEIS affects our analysis in a manner that changes our determinations under the MMPA.

The Acoustic Technical Guidance (NMFS 2018), which was used in the assessment of effects for this action, compiled, interpreted, and synthesized the best available scientific information for noise-induced hearing effects for marine mammals to derive updated thresholds for assessing the impacts of noise on marine mammal hearing. New data on killer whale hearing (Branstetter *et al.,* 2017), harbor porpoise hearing (Kastelein *et al.,* 2017a), harbor porpoise TS in response to airguns (Kastelein *et al.,* 2017b) and mid-frequency sonar (Kastelein *et al.,* 2017c), and harbor seal TS in response to pile-driving sounds (Kastelein *et al.,* 2018) are consistent with data included and thresholds presented in the Acoustic Technical Guidance.

Recent studies with captive odontocete species (bottlenose dolphin, harbor porpoise, beluga, and false killer whale) have observed increases in hearing threshold levels when individuals received a warning sound prior to exposure to a relatively loud sound (Nachtigall and Supin, 2013, 2015, Nachtigall *et al.,* 2016a,b,c, Finneran, 2018, Nachtigall *et al.,* 2018). These studies suggest that captive animals have a mechanism to reduce hearing sensitivity prior to impending loud sounds. Hearing change was observed to be frequency dependent and Finneran (2018) suggests hearing attenuation occurs within the cochlea or auditory nerve. Based on these observations on captive odontocetes, the authors suggest that wild animals may have a mechanism to self-mitigate the impacts of noise exposure by dampening their hearing during prolonged exposures of loud sound, or if conditioned to anticipate intense sounds (Finneran, 2018, Nachtigall *at al.,* 2018).

Recent reviews have synthesized data from experimental studies examining marine mammal behavioral response to anthropogenic sound, and have documented large variances in individual behavioral responses to anthropogenic sound both within and among marine mammal species. These reviews highlight the importance of the exposure context (*e.g.,* behavioral state, presence of other animals and social relationships, prey abundance, distance to source, presence of vessels, environmental parameters, etc.) in determining or predicting a behavioral response. As described in the Proposed Rule, in a review of experimental field studies to measure behavioral responses of cetaceans to sonar, Southall *et al.* (2016) observed that some individuals of different species display clear yet varied responses (some of which have negative implications), while others appear to tolerate high levels. Results from the studies they investigated demonstrate that responses are highly variable and may not be fully predictable with simple acoustic exposure metrics (*e.g.,* received sound level). Rather, differences among species and individuals along with contextual aspects of exposure (*e.g.,* behavioral state) appear to affect response probability (Southall *et al.,* 2016). Dunlop *et al.* (2018) combined data from the BRAHSS (Behavioural Response of Australian Humpback whales to Seismic Surveys) studies designed to examine the behavioral responses of migrating humpback whales to various seismic array sources to develop a dose-response model. The model accounted for other variables such as presence of the vessel, array towpath relative to the migration, and social and environmental parameters. Authors observed that whales were more likely to avoid the airgun or array (defined by increasing their distance from the source) when they were exposed to sounds greater than 130 dB re 1 $\mu Pa^2 \cdot s$ and they were within 4 km of the source (Dunlop *et al.,* 2018). At sound exposure levels of 150–155 dB re 1 $\mu Pa^2 \cdot s$ and less than 2.5 km from the source the model predicted a 50% probability of response (Dunlop *et al.* 2018). However, it was not possible to estimate the maximum response threshold as at the highest received levels of 160–170 dB re 1 $\mu Pa^2 \cdot s$) a small number of whales moving rapidly and close to the source did not exhibit an avoidance response as defined by the study (Dunlop *et al.,* 2018).

Estimated Take of Marine Mammals

This section indicates the number of takes that NMFS is authorizing, which are based on the amount of take that NMFS anticipates could occur or is likely to occur, depending on the type of take and the methods used to estimate it, as described in detail below. NMFS coordinated closely with the Navy in the development of their incidental take application, and with one limited exception, agrees that the methods the Navy put forth in their application to estimate take (including the model, thresholds, and density estimates), and the resulting numbers being authorized, are appropriate and based on the best available science. As noted elsewhere, additional discussion and subsequent analysis led both NMFS and the Navy, in coordination, to conclude that different take estimates for serious injury or mortality were appropriate, and where those numbers differ from the Navy's application or our proposed rule, NMFS has explicitly described our rationale and indicated what we consider an appropriate number of takes.

Takes are predominantly in the form of harassment, but a small number of serious injuries or mortalities are also authorized. For military readiness activities, the MMPA defines ''harassment'' as: (i) Any act that injures or has the significant potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) Any act that disturbs or is likely to disturb a marine mammal or marine mammal stock in the wild by causing disruption of natural behavioral patterns, including, but not limited to, migration, surfacing, nursing, breeding, feeding, or sheltering, to a point where such behavioral patterns are abandoned or significantly altered (Level B harassment).

Authorized takes would primarily be in the form of Level B harassment, as use of the acoustic and explosive sources (*i.e.,* sonar, air guns, pile driving, explosives) is more likely to result in the disruption of natural behavioral patterns to a point where they are abandoned or significantly altered (as defined specifically at the beginning of this section, but referred to generally as behavioral disruption) or TTS for marine mammals than other forms of take. There is also the potential for Level A harassment, however, in the form of auditory injury and/or tissue damage (latter from explosives only) to result from exposure to the sound sources utilized in training and testing activities. Lastly, a limited number of serious injuries or mortalities could occur for four species of mid-frequency cetaceans during ship shock trials and three serious injuries or mortalities total (over the five-year period) of mysticetes (except for blue whales) and North Atlantic sperm whales could occur through vessel collisions. Although we analyze the impacts of these potential serious injuries or mortalities that are

authorized, the required mitigation and monitoring measures are expected to minimize the likelihood that ship strike or these high level explosive exposures (and the associated serious injury or mortality) actually occur.

Generally speaking, for acoustic impacts, we estimate the amount and type of harassment by considering: (1) Acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be taken by Level B harassment (in this case, as defined in the military readiness definition of Level B harassment included above) or incur some degree of temporary or permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day or event; (3) the density or occurrence of marine mammals within these ensonified areas; and (4) and the number of days of activities or events. Below, we describe these components in more detail and present the take estimate.

Acoustic Thresholds

Using the best available science, NMFS, in coordination with the Navy, has established acoustic thresholds that identify the most appropriate received level of underwater sound above which marine mammals exposed to these sound sources could be reasonably expected to experience a disruption in behavior patterns to a point where they are abandoned or significantly altered, or to incur TTS (equated to Level B harassment) or PTS of some degree (equated to Level A harassment).

Thresholds have also been developed to identify the pressure levels above which animals may incur non-auditory injury from exposure to pressure waves from explosive detonation.

Despite the quickly evolving science, there are still challenges in quantifying expected behavioral responses that qualify as Level B harassment, especially where the goal is to use one or two predictable indicators (*e.g.,* received level and distance) to predict responses that are also driven by additional factors that cannot be easily incorporated into the thresholds (*e.g.,* context). So, while the new Level B behavioral harassment thresholds have been refined here to better consider the best available science (*e.g.,* incorporating both received level and distance), they also still, accordingly, have some built-in conservative choices to address the challenge noted. For example, while duration of observed responses in the data are now considered in the thresholds, some of the responses that are informing take thresholds are of a very short duration, such that it is possible some of these responses might not always rise to the level of disrupting behavior patterns to a point where they are abandoned or significantly altered. In summary, we believe these Level B behavioral harassment thresholds are the most appropriate method for predicting Level B behavioral harassment given the best available science and the associated uncertainty. We describe the application of this Level B behavioral harassment threshold as identifying the ''maximum number of instances in which marine mammals could be reasonably expected to experience a disruption in behavior patterns to a point where they are abandoned or significantly altered.''

Hearing Impairment (TTS/PTS and Tissues Damage and Mortality)

Non-Impulsive and Impulsive

NMFS' Acoustic Technical Guidance (NMFS, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). The Acoustic Technical Guidance also identifies criteria to predict TTS, which is not considered injury and falls into the Level B harassment category. The Navy's planned activity includes the use of non-impulsive (sonar, vibratory pile driving/removal) and impulsive (explosives, air guns, impact pile driving) sources.

These thresholds (Tables 13–14) were developed by compiling and synthesizing the best available science and soliciting input multiple times from both the public and peer reviewers. The references, analysis, and methodology used in the development of the thresholds are described in Acoustic Technical Guidance, which may be accessed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance.*

TABLE 13—ACOUSTIC THRESHOLDS IDENTIFYING THE ONSET OF TTS AND PTS FOR NON-IMPULSIVE SOUND SOURCES BY FUNCTIONAL HEARING GROUP

Functional hearing group	Non-impulsive	
	TTS threshold SEL (weighted)	PTS threshold SEL (weighted)
Low-Frequency Cetaceans	179	199
Mid-Frequency Cetaceans	178	198
High-Frequency Cetaceans	153	173
Phocid Pinnipeds (Underwater)	181	201

Note: SEL thresholds in dB re 1 μPa^2s.

Based on the best available science, the Navy (in coordination with NMFS) used the acoustic and pressure thresholds indicated in Table 14 to predict the onset of TTS, PTS, tissue damage, and mortality for explosives (impulsive) and other impulsive sound sources.

TABLE 14—ONSET OF TTS, PTS, TISSUE DAMAGE, AND MORTALITY THRESHOLDS FOR MARINE MAMMALS FOR EXPLOSIVES AND OTHER IMPULSIVE SOURCES

Functional hearing group	Species	Onset TTS	Onset PTS	Mean onset slight GI tract injury	Mean onset slight lung injury	Mean onset mortality
Low-frequency cetaceans	All mysticetes	168 dB SEL (weighted) or 213 dB Peak SPL.	183 dB SEL (weighted) or 219 dB Peak SPL.	237 dB Peak SPL.	Equation 1	Equation 2.

TABLE 14—ONSET OF TTS, PTS, TISSUE DAMAGE, AND MORTALITY THRESHOLDS FOR MARINE MAMMALS FOR EXPLOSIVES AND OTHER IMPULSIVE SOURCES—Continued

Functional hearing group	Species	Onset TTS	Onset PTS	Mean onset slight GI tract injury	Mean onset slight lung injury	Mean onset mortality
Mid-frequency cetaceans	Most delphinids, medium and large toothed whales.	170 dB SEL (weighted) or 224 dB Peak SPL.	185 dB SEL (weighted) or 230 dB Peak SPL.	237 dB Peak SPL.		
High-frequency cetaceans ...	Porpoises and Kogia spp.	140 dB SEL (weighted) or 196 dB Peak SPL.	155 dB SEL (weighted) or 202 dB Peak SPL.	237 dB Peak SPL.		
Phocidae	Harbor, Gray, Bearded, Harp, Hooded, and Ringed seals.	170 dB SEL (weighted) or 212 dB Peak SPL.	185 dB SEL (weighted) or 218 dB Peak SPL.	237 dB Peak SPL.		

Notes:
Equation 1: $47.5M^{1/3}$ $(1+[D_{Rm}/10.1])^{1/6}$ Pa-sec.
Equation 2: $103M^{1/3}$ $(1+[D_{Rm}/10.1])^{1/6}$ Pa-sec.
M = mass of the animals in kg.
D_{Rm} = depth of the receiver (animal) in meters.
SPL = sound pressure level.

Impulsive—Air Guns and Impact Pile Driving

Impact pile driving produces impulsive noise; therefore, the criteria used to assess the onset of TTS and PTS are identical to those used for air guns, as well as explosives (see Table 14 above) (see Hearing Loss from Air guns in Chapter 6, Section 6.4.3.1, Methods for Analyzing Impacts from Air guns in the Navy's rulemaking/LOA application). Refer to the *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Impacts to Marine Mammals and Sea Turtles technical report* (U.S. Department of the Navy, 2017d) for detailed information on how the criteria and thresholds were derived.

Non-Impulsive—Sonar and Vibratory Pile Driving/Removal

Vibratory pile removal (that will be used during the ELCAS) creates continuous non-impulsive noise at low source levels for a short duration. Therefore, the criteria used to assess the onset of TTS and PTS due to exposure to sonars (non-impulsive, see Table 13 above) are also used to assess auditory impacts to marine mammals from vibratory pile driving (see Hearing Loss from Sonar and Other Transducers in Chapter 6, Section 6.4.2.1, Methods for Analyzing Impacts from Sonars and Other Transducers in the Navy's rulemaking/LOA application). Refer to the *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Impacts to Marine Mammals and Sea Turtles technical report* (U.S. Department of the Navy, 2017d) for detailed information on how the criteria and thresholds were derived. Non-auditory injury (*i.e.,* other than PTS) and mortality from sonar and other transducers is so unlikely as to be discountable under normal conditions for the reasons explained in the proposed rule under *Potential Effects of Specified Activities on Marine Mammals and Their Habitat* section—*Acoustically Mediated Bubble Growth and Other Pressure-related Injury* and is therefore not considered further in this analysis.

Behavioral Harassment

Though significantly driven by received level, the onset of Level B harassment by behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source (*e.g.,* frequency, predictability, duty cycle), the environment (*e.g.,* bathymetry), and the receiving animals (hearing, motivation, experience, demography, behavioral context) and can be difficult to predict (Southall *et al.,* 2007, Ellison *et al.,* 2011). Based on what the available science indicates and the practical need to use thresholds based on a factor, or factors, that are both predictable and measurable for most activities, NMFS uses generalized acoustic thresholds based primarily on received level (and distance in some cases) to estimate the onset of Level B behavioral harassment.

Air Guns and Pile Driving

For air guns and pile driving, NMFS predicts that marine mammals are likely to be taken by Level B behavioral harassment when exposed to underwater anthropogenic noise above received levels of 120 dB re 1 μPa (rms) for continuous (*e.g.,* vibratory pile-driving, drilling) and above 160 dB re 1 μPa (rms) for non-explosive impulsive (*e.g.,* seismic air guns) or intermittent (*e.g.,* scientific sonar) sources. To estimate Level B behavioral harassment from air guns, the existing NMFS Level B harassment threshold of 160 dB re 1 μPa (rms) is used. The root mean square calculation for air guns is based on the duration defined by 90 percent of the cumulative energy in the impulse.

The existing NMFS Level B harassment thresholds were also applied to estimate Level B behavioral harassment from impact and vibratory pile driving (Table 15).

TABLE 15—PILE DRIVING LEVEL B HARASSMENT THRESHOLDS USED IN THIS ANALYSIS TO PREDICT BEHAVIORAL RESPONSES FROM MARINE MAMMALS

Pile driving criteria (SPL, dB re 1 μPa) Level B harassment threshold	
Underwater vibratory (dB rms)	Underwater impact (dB rms)
120	160

Notes: Root mean square calculation for impact pile driving is based on the duration defined by 90 percent of the cumulative energy in the impulse. Root mean square for vibratory pile driving is calculated based on a representative time series long enough to capture the variation in levels, usually on the order of a few seconds.
dB: decibel; dB re 1 μPa: decibel referenced to 1 micropascal; rms: root mean square.

Sonar

As noted, the Navy coordinated with NMFS to propose Level B behavioral harassment thresholds specific to their military readiness activities utilizing active sonar. The way the criteria were derived is discussed in detail in the *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Impacts to Marine Mammals and Sea Turtles Technical Report* (U.S. Department of the Navy, 2017d). Developing the new Level B harassment behavioral criteria involved multiple steps. All peer-reviewed published behavioral response studies conducted both in the field and on captive animals were examined in order to understand the breadth of behavioral responses of marine mammals to sonar and other transducers. NMFS has carefully reviewed the Navy's proposed Level B behavioral thresholds and establishment of cutoff distances for the species, and agrees that it is the best available science and is the appropriate method to use at this time for determining impacts to marine mammals from sonar and other transducers and calculating take and to support the determinations made in the proposed rule.

As noted above, marine mammal responses to sound (some of which are considered disturbances that rise to the level of a take) are highly variable and context specific, *i.e.,* they are affected by differences in acoustic conditions; differences between species and populations; differences in gender, age, reproductive status, or social behavior; or other prior experience of the individuals. This means that there is support for considering alternative approaches for estimating Level B behavioral harassment. Although the statutory definition of Level B harassment for military readiness activities means that a natural behavior pattern of a marine mammal is significantly altered or abandoned, the current state of science for determining those thresholds is somewhat unsettled.

In its analysis of impacts associated with sonar acoustic sources (which was coordinated with NMFS), the Navy proposed an updated conservative approach that likely overestimates the number of takes by Level B harassment due to behavioral disturbance and response. Many of the behavioral responses identified using the Navy's quantitative analysis are most likely to be of moderate severity as described in the Southall *et al.,* 2007 behavioral response severity scale. These ''moderate'' severity responses were considered significant if they were sustained for the duration of the exposure or longer. Within the Navy's quantitative analysis, many reactions are predicted from exposure to sound that may exceed an animal's Level B behavioral harassment threshold for only a single exposure (a few seconds) to several minutes, and it is likely that some of the resulting estimated behavioral responses that are counted as Level B harassment would not constitute ''significantly altering or abandoning natural behavioral patterns.'' The Navy and NMFS have used the best available science to address the challenging differentiation between significant and non-significant behavioral reactions (*i.e.,* whether the behavior has been abandoned or significantly altered such that it qualifies as harassment), but have erred on the cautious side where uncertainty exists (*e.g.,* counting these lower duration reactions as take), which likely results in some degree of overestimation of Level B behavioral harassment. We consider application of this Level B behavioral harassment threshold, therefore, as identifying the maximum number of instances in which marine mammals could be reasonably expected to experience a disruption in behavior patterns to a point where they are abandoned or significantly altered (*i.e.,* Level B harassment). Because this is the most appropriate method for estimating Level B harassment given the best available science and uncertainty on the topic, it is these numbers of Level B harassment by behavioral disturbance that are analyzed in the *Analysis and Negligible Impact Determination* section.

In the Navy's acoustic impact analyses during Phase II, the likelihood of Level B behavioral harassment in response to sonar and other transducers was based on a probabilistic function (termed a behavioral response function—BRF), that related the likelihood (*i.e.,* probability) of a behavioral response (at the level of a Level B harassment) to the received SPL. The BRF was used to estimate the percentage of an exposed population that is likely to exhibit Level B harassment due to altered behaviors or behavioral disturbance at a given received SPL. This BRF relied on the assumption that sound poses a negligible risk to marine mammals if they are exposed to SPL below a certain ''basement'' value. Above the basement exposure SPL, the probability of a response increased with increasing SPL. Two BRFs were used in Navy acoustic impact analyses: BRF1 for mysticetes and BRF2 for other species. BRFs were not used for harbor porpoises and beaked whales during Phase II analyses. Instead, step functions at SPLs of 120 dB re 1 µPa and 140 dB re 1 µPa were used for harbor porpoises and beaked whales, respectively, as thresholds to predict Level B harassment by behavioral disturbance.

Developing the new Level B behavioral harassment criteria for Phase III involved multiple steps: All available behavioral response studies conducted both in the field and on captive animals were examined to understand the breadth of behavioral responses of marine mammals to sonar and other transducers. Marine mammal species were placed into behavioral criteria groups based on their known or suspected behavioral sensitivities to sound. In most cases these divisions were driven by taxonomic classifications (*e.g.,* mysticetes, pinnipeds). The data from the behavioral studies were analyzed by looking for significant responses, or lack thereof, for each experimental session.

The Navy used cutoff distances beyond which the potential of significant behavioral responses (and therefore Level B harassment) is considered to be unlikely (see Table 16 below). For animals within the cutoff distance, a behavioral response function based on a received SPL as presented in Chapter 3, Section 3.1.0 of the Navy's rulemaking/LOA application was used to predict the probability of a potential significant behavioral response. For training and testing events that contain multiple platforms or tactical sonar sources that exceed 215 dB re 1 µPa @ 1 m, this cutoff distance is substantially increased (*i.e.,* doubled) from values derived from the literature. The use of multiple platforms and intense sound sources are factors that probably increase responsiveness in marine mammals overall. There are currently few behavioral observations under these circumstances; therefore, the Navy conservatively predicted significant behavioral responses that would rise to Level B harassment at further ranges as shown in Table 16, versus less intense events.

TABLE 16—CUTOFF DISTANCES FOR MODERATE SOURCE LEVEL, SINGLE PLATFORM TRAINING AND TESTING EVENTS AND FOR ALL OTHER EVENTS WITH MULTIPLE PLATFORMS OR SONAR WITH SOURCE LEVELS AT OR EXCEEDING 215 dB RE 1 μPa @1 m

Criteria group	Moderate SL/ single platform cutoff distance (km)	High SL/ multi-platform cutoff distance (km)
Odontocetes	10	20
Pinnipeds	5	10
Mysticetes and Manatees	10	20
Beaked Whales	25	50
Harbor Porpoise	20	40

Notes: dB re 1 μPa @1 m: decibels referenced to 1 micropascal at 1 meter; km: kilometer; SL: source level.

The information currently available regarding harbor porpoises suggests a very low threshold level of response for both captive and wild animals. Threshold levels at which both captive (Kastelein *et al.,* 2000; Kastelein *et al.,* 2005) and wild harbor porpoises (Johnston, 2002) responded to sound (*e.g.,* acoustic harassment devices, acoustic deterrent devices, or other non-impulsive sound sources) are very low, approximately 120 dB re 1 μPa. Therefore, a SPL of 120 dB re 1 μPa was used in the analysis as a threshold for predicting Level B behavioral harassment in harbor porpoises.

The range to received sound levels in 6-dB steps from five representative sonar bins and the percentage of animals that may be taken by Level B harassment under each behavioral response function (or step function in the case of the harbor porpoise) are shown in Table 17 through Table 21. Cells are shaded if the mean range value for the specified received level exceeds the distance cutoff range for a particular hearing group and therefore are not included in the estimated take. See Chapter 6, Section 6.4.2.1.1 (Methods for Analyzing Impacts from Sonars and Other Transducers) of the Navy's rulemaking/LOA application for further details on the derivation and use of the behavioral response functions, thresholds, and the cutoff distances to identify takes by Level B harassment, which were coordinated with NMFS. Table 17 illustrates the maximum likely takes (maximum number of instances in which marine mammals would be reasonably expected to experience a disruption in behavior patterns to a point where they are abandoned or significantly altered) for LFAS. As noted previously, NMFS carefully reviewed, and contributed to, Navy's proposed level B behavioral harassment thresholds and cutoff distances for the species, and agrees that these methods represent the best available science at this time for determining impacts to marine mammals from sonar and other transducers.

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Table 17. Ranges to an Estimated Level B Behavioral Harassment Takes for Sonar Bin LF5 over a Representative Range of Environments within the AFTT Study Area.

Received Level (dB re 1 µPa)	*Mean Range (m) with minimum to maximum values in parentheses*	*Probability of Level B Behavioral Harassment*				
		Odontocetes	*Mysticetes*	*Pinnipeds*	*Beaked Whales*	*Harbor Porpoises*
178	1 (0—1)	97%	59%	92%	100%	100%
172	2 (1—2)	91%	30%	76%	99%	100%
166	4 (1—6)	78%	20%	48%	97%	100%
160	10 (1—13)	58%	18%	27%	93%	100%
154	21 (1—25)	40%	17%	18%	83%	100%
148	46 (1—60)	29%	16%	16%	66%	100%
142	104 (1—140)	25%	13%	15%	45%	100%
136	242 (120—430)	23%	9%	15%	28%	100%
130	573 (320—1,275)	20%	5%	15%	18%	100%
124	1,268 (550—2,775)	17%	2%	14%	14%	100%
118	2,733 (800—6,525)	12%	1%	13%	12%	0%
112	5,820 (1,025—18,275)	6%	0%	9%	11%	0%
106	13,341 (1,275—54,525)	3%	0%	5%	11%	0%
100	31,026 (2,025—100,000*)	1%	0%	2%	8%	0%

* Indicates maximum range of acoustic model, a distance of approximately 100 kilometers from the sound source.
Notes: Cells are shaded if the mean range value for the specified received level exceeds the distance cutoff range for a particular hearing group. Any impacts within the cutoff range for a criteria group are included in the estimated impacts. Cut-off ranges in this table are for activities with high source levels and/or multiple platforms (see Table 16 for behavioral cut-off distances).
dB re 1 µPa2 - s: decibels referenced to 1 micropascal squared second; m: meters

Table 18 through Table 20 enumerate the maximum likely takes for MFAS.

Table 18. Ranges to an Estimated Level B Behavioral Harassment Takes for Sonar Bin MF1 over a Representative Range of Environments within the AFTT Study Area.

Received Level (dB re 1 µPa)	*Mean Range (m) with minimum to maximum values in parentheses*	*Probability of Level B Behavioral Harassment*				
		Odontocetes	*Mysticetes*	*Pinnipeds*	*Beaked Whales*	*Harbor Porpoises*
196	109 (100—150)	100%	100%	100%	100%	100%
190	257 (220—370)	100%	98%	99%	100%	100%
184	573 (400—1,000)	99%	88%	98%	100%	100%
178	1,235 (725—3,525)	97%	59%	92%	100%	100%
172	3,007 (875—9,775)	91%	30%	76%	99%	100%
166	6,511 (925—19,525)	78%	20%	48%	97%	100%
160	11,644 (975—36,275)	58%	18%	27%	93%	100%
154	18,012 (975—60,775)	40%	17%	18%	83%	100%
148	26,037 (1,000—77,525)	29%	16%	16%	66%	100%
142	33,377 (1,000—100,000*)	25%	13%	15%	45%	100%
136	41,099 (1,025—100,000*)	23%	9%	15%	28%	100%
130	46,618 (3,275—100,000*)	20%	5%	15%	18%	100%
124	50,173 (3,525—100,000*)	17%	2%	14%	14%	100%
118	52,982 (3,775—100,000*)	12%	1%	13%	12%	0%
112	56,337 (4,275—100,000*)	6%	0%	9%	11%	0%
106	60,505 (4,275—100,000*)	3%	0%	5%	11%	0%
100	62,833 (4,525—100,000*)	1%	0%	2%	8%	0%

* Indicates maximum range of acoustic model, a distance of approximately 100 kilometers from the sound source.

Notes: Cells are shaded if the mean range value for the specified received level exceeds the distance cutoff range for a particular hearing group. Any impacts within the cutoff range for a criteria group are included in the estimated impacts. Cut-off ranges in this table are for activities with high source levels and/or multiple platforms (see Table 16 for behavioral cut-off distances). dB re 1 μPa^2 - s: decibels referenced to 1 micropascal squared second; m: meters

Table 19. Ranges to an Estimated Level B Behavioral Harassment Takes for Sonar Bin MF4 over a Representative Range of Environments within the AFTT Study Area.

Received Level (dB re 1 µPa)	*Mean Range (m) with minimum to maximum values in parentheses*	*Probability of Level B Behavioral Harassment*				
		Odontocetes	*Mysticetes*	*Pinnipeds*	*Beaked Whales*	*Harbor Porpoises*
196	8 (1—10)	100%	100%	100%	100%	100%
190	17 (1—21)	100%	98%	99%	100%	100%
184	35 (1—40)	99%	88%	98%	100%	100%
178	71 (1—95)	97%	59%	92%	100%	100%
172	156 (110—410)	91%	30%	76%	99%	100%
166	431 (280—1,275)	78%	20%	48%	97%	100%
160	948 (490—3,525)	58%	18%	27%	93%	100%
154	1,937 (750—10,025)	40%	17%	18%	83%	100%
148	3,725 (1,025—20,525)	29%	16%	16%	66%	100%
142	7,084 (1,525—38,525)	25%	13%	15%	45%	100%
136	11,325 (1,775—56,275)	23%	9%	15%	28%	100%
130	16,884 (1,775—74,275)	20%	5%	15%	18%	100%
124	24,033 (2,275—80,775)	17%	2%	14%	14%	100%
118	31,950 (2,275—100,000*)	12%	1%	13%	12%	0%
112	37,663 (2,525—100,000*)	6%	0%	9%	11%	0%
106	41,436 (2,775—100,000*)	3%	0%	5%	11%	0%
100	44,352 (2,775—100,000*)	1%	0%	2%	8%	0%

* Indicates maximum range of acoustic model, a distance of approximately 100 kilometers from the sound source.

Notes: Cells are shaded if the mean range value for the specified received level exceeds the distance cutoff range for a particular hearing group. Any impacts within the cutoff range for a criteria group are included in the estimated impacts. Cut-off ranges in this table are for activities with high source levels and/or multiple platforms (see Table 16 for behavioral cut-off distances). dB re 1 μPa^2 - s: decibels referenced to 1 micropascal squared second; m: meters

Table 20. Ranges to an Estimated Level B Behavioral Harassment Takes for Sonar Bin MF5 over a Representative Range of Environments within the AFTT Study Area.

Received Level (dB re 1 µPa)	*Mean Range (m) with minimum to maximum values in parentheses*	*Probability of Level B Behavioral Harassment*				
		Odontocetes	*Mysticetes*	*Pinnipeds*	*Beaked Whales*	*Harbor Porpoises*
190	2 (1—3)	100%	98%	99%	100%	100%
184	4 (1—9)	99%	88%	98%	100%	100%
178	14 (1—18)	97%	59%	92%	100%	100%
172	29 (1—35)	91%	30%	76%	99%	100%
166	61 (1—80)	78%	20%	48%	97%	100%
160	141 (1—400)	58%	18%	27%	93%	100%
154	346 (1—1,000)	40%	17%	18%	83%	100%
148	762 (420—2,525)	29%	16%	16%	66%	100%
142	1,561 (675—5,525)	25%	13%	15%	45%	100%
136	2,947 (1,025—10,775)	23%	9%	15%	28%	100%
130	5,035 (1,025—17,275)	20%	5%	15%	18%	100%
124	7,409 (1,275—22,525)	17%	2%	14%	14%	100%
118	10,340 (1,525—29,525)	12%	1%	13%	12%	0%
112	13,229 (1,525—38,025)	6%	0%	9%	11%	0%
106	16,487 (1,525—46,025)	3%	0%	5%	11%	0%
100	20,510 (1,775—60,525)	1%	0%	2%	8%	0%

Notes: Cells are shaded if the mean range value for the specified received level exceeds the distance cutoff range for a particular hearing group. Any impacts within the cutoff range for a criteria group are included in the estimated impacts. Cut-off ranges in this table are for activities with high source levels and/or multiple platforms (see Table 16 for behavioral cut-off distances). dB re 1 μPa^2 - s: decibels referenced to 1 micropascal squared second; m: meter

Table 21. Ranges to an Estimated Level B Behavioral Harassment Takes for Sonar Bin HF4 over a Representative Range of Environments within the AFTT Study Area.

Received Level (dB re 1 µPa)	*Mean Range (m) with minimum to maximum values in parentheses*	*Probability of Level B Behavioral Harassment*				
		Odontocetes	*Mysticetes*	*Pinnipeds*	*Beaked Whales*	*Harbor Porpoises*
196	3 (1—6)	100%	100%	100%	100%	100%
190	8 (1—14)	100%	98%	99%	100%	100%
184	18 (1—35)	99%	88%	98%	100%	100%
178	37 (1—100)	97%	59%	92%	100%	100%
172	78 (1—300)	91%	30%	76%	99%	100%
166	167 (1—725)	78%	20%	48%	97%	100%
160	322 (25—1,525)	58%	18%	27%	93%	100%
154	555 (45—3,775)	40%	17%	18%	83%	100%
148	867 (70—6,775)	29%	16%	16%	66%	100%
142	1,233 (150—12,775)	25%	13%	15%	45%	100%
136	1,695 (260—20,025)	23%	9%	15%	28%	100%
130	2,210 (470—29,275)	20%	5%	15%	18%	100%
124	2,792 (650—40,775)	17%	2%	14%	14%	100%
118	3,421 (950—49,775)	12%	1%	13%	12%	0%
112	4,109 (1,025—49,775)	6%	0%	9%	11%	0%
106	4,798 (1,275—49,775)	3%	0%	5%	11%	0%
100	5,540 (1,275—49,775)	1%	0%	2%	8%	0%

Notes: dB re 1 μPa^2 - s: decibels referenced to 1 micropascal squared second; m: meters

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Explosives

Phase III explosive criteria for Level B behavioral harassment thresholds for marine mammals is the hearing groups' TTS threshold minus 5 dB (see Table 22 and Table 14 for the TTS thresholds for explosives) for events that contain multiple impulses from explosives underwater. This was the same approach as taken in Phase II for explosive analysis. See the *Criteria and Thresholds for U.S. Navy Acoustic and Explosive Impacts to Marine Mammals and Sea Turtles Technical Report* (U.S. Department of the Navy, 2017d) for detailed information on how the criteria and thresholds were derived. NMFS continues to concur that this approach is the best available science for determining impacts to marine mammals from explosives.

TABLE 22—PHASE III LEVEL B BEHAVIORAL HARASSMENT THRESHOLDS FOR EXPLOSIVES FOR MARINE MAMMALS

Medium	Functional hearing group	SEL (weighted)
Underwater	LF	163
Underwater	MF	165
Underwater	HF	135

TABLE 22—PHASE III LEVEL B BEHAVIORAL HARASSMENT THRESHOLDS FOR EXPLOSIVES FOR MARINE MAMMALS—Continued

Medium	Functional hearing group	SEL (weighted)
Underwater	PW	165

Note: Weighted SEL thresholds in dB re 1 μPa^2s underwater.

Navy's Acoustic Effects Model

Sonar and Other Transducers and Explosives

The Navy's Acoustic Effects Model calculates sound energy propagation from sonar and other transducers and explosives during naval activities and the sound received by animat dosimeters. Animat dosimeters are virtual representations of marine mammals distributed in the area around the modeled naval activity and each dosimeter records its individual sound ''dose.'' The model bases the distribution of animats over the AFTT Study Area on the density values in the *Navy Marine Species Density Database* and distributes animats in the water column proportional to the known time that species spend at varying depths.

The model accounts for environmental variability of sound propagation in both distance and depth when computing the received sound level on the animats. The model conducts a statistical analysis based on multiple model runs to compute the estimated effects on animals. The number of animats that exceed the thresholds for effects is tallied to provide an estimate of the number of marine mammals that could be affected.

Assumptions in the Navy model intentionally err on the side of overestimation when there are unknowns. Naval activities are modeled as though they would occur regardless of proximity to marine mammals, meaning that no mitigation is considered (*i.e.,* no power down or shut down modeled) and without any avoidance of the activity by the animal. The final step of the quantitative analysis of acoustic effects is to consider the implementation of mitigation and the possibility that marine mammals would avoid continued or repeated sound exposures. For more information on this process, see the discussion in the *Take Requests* subsection below. Many explosions from ordnance such as bombs and missiles actually occur upon impact with above-water targets. However, for this analysis, sources such as these were modeled as exploding underwater. This overestimates the amount of explosive and acoustic energy entering the water.

The model estimates the impacts caused by individual training and testing exercises. During any individual modeled event, impacts to individual animats are considered over 24-hour periods. The animats do not represent actual animals, but rather they represent a distribution of animals based on density and abundance data, which allows for a statistical analysis of the number of instances that marine mammals may be exposed to sound levels resulting in an effect. Therefore, the model estimates the number of instances in which an effect threshold was exceeded over the course of a year, but does not estimate the number of individual marine mammals that may be impacted over a year *(i.e.,* some marine mammals could be impacted several times, while others would not experience any impact). A detailed explanation of the Navy's Acoustic Effects Model is provided in the technical report *Quantitative Analysis for Estimating Acoustic and Explosive Impacts to Marine Mammals and Sea Turtles* (U.S. Department of the Navy, 2017a).

Air Guns and Pile Driving

The Navy's quantitative analysis estimates the sound and energy received by marine mammals distributed in the area around planned Navy activities involving air guns. See the technical report titled *Quantitative Analysis for Estimating Acoustic and Explosive Impacts to Marine Mammals and Sea Turtles* (U.S. Department of the Navy, 2017a) for additional details. Underwater noise effects from pile driving and vibratory pile extraction were modeled using actual measures of impact pile driving and vibratory removal during construction of an ELCAS (Illingworth and Rodkin, 2015, 2016). A conservative estimate of spreading loss of sound in shallow coastal waters (*i.e.,* transmission loss = 16.5*Log10 [radius]) was applied based on spreading loss observed in actual measurements. Inputs used in the model are provided in Chapter 1, Section 1.4.1.3 (Pile Driving) of the Navy's rulemaking/LOA application, including source levels; the number of strikes required to drive a pile and the duration of vibratory removal per pile; the number of piles driven or removed per day; and the number of days of pile driving and removal.

Range to Effects

The following section provides range to effects for sonar and other active acoustic sources as well as explosives to specific acoustic thresholds determined using the Navy Acoustic Effects Model. Marine mammals exposed within these ranges for the shown duration are predicted to experience the associated effect. Range to effects is important information in not only predicting acoustic impacts, but also in verifying the accuracy of model results against real-world situations and determining adequate mitigation ranges to avoid higher level effects, especially physiological effects to marine mammals.

Sonar

The range to received sound levels in 6-dB steps from 5 representative sonar bins and the percentage of the total number of animals that may exhibit a significant behavioral response (and therefore Level B harassment) under each behavioral response function (or step function in the case of the harbor porpoise) are shown in Table 17 through Table 21 above, respectively. See Chapter 6, Section 6.4.2.1 (Methods for Analyzing Impacts from Sonars and Other Transducers) of the Navy's rulemaking/LOA application for additional details on the derivation and use of the behavioral response functions, thresholds, and the cutoff distances that are used to identify Level B behavioral harassment.

The ranges to the PTS for 5 representative sonar systems for an exposure of 30 seconds is shown in Table 23 relative to the marine mammal's functional hearing group. This period (30 seconds) was chosen based on examining the maximum amount of time a marine mammal would realistically be exposed to levels that could cause the onset of PTS based on platform (*e.g.,* ship) speed and a nominal animal swim speed of approximately 1.5 m per second. The ranges provided in the table include the average range to PTS, as well as the range from the minimum to the maximum distance at which PTS is possible for each hearing group.

TABLE 23—RANGE TO PERMANENT THRESHOLD SHIFT (METERS) FOR FIVE REPRESENTATIVE SONAR SYSTEMS

Functional hearing group	Approximate PTS (30 seconds) ranges (meters) [1]				
	Sonar bin LF5 (low frequency sources <180 dB source level)	Sonar bin MF1 (e.g., SQS–53 ASW hull mounted sonar)	Sonar bin MF4 (e.g., AQS–22 ASW Dipping Sonar)	Sonar bin MF5 (e.g., SSQ–62 ASW Sonobuoy)	Sonar bin HF4 (e.g., SQS–20 Mine Hunting Sonar)
Low-frequency Cetaceans	0 (0–0)	66 (65–80)	15 (15–18)	0 (0–0)	0 (0–0)
Mid-frequency Cetaceans	0 (0–0)	16 (16–16)	3 (3–3)	0 (0–0)	1 (0–2)
High-frequency Cetaceans	0 (0–0)	192 (170–270)	31 (30–40)	9 (8–13)	34 (20–85)
Phocid Seals	0 (0–0)	46 (45–55)	11 (11–13)	0 (0–0)	0 (0–0)

[1] PTS ranges extend from the sonar or other active acoustic sound source to the indicated distance. The average range to PTS is provided as well as the range from the estimated minimum to the maximum range to PTS in parenthesis.

Notes: ASW: Anti-submarine warfare; HF: High frequency; LF: Low frequency; MF: Mid-frequency; PTS: Permanent threshold shift; NA: Not applicable because there is no overlap between species and sound source.

The tables below illustrate the range to TTS for 1, 30, 60, and 120 seconds from five representative sonar systems (see Table 24 through Table 28).

TABLE 24—RANGES TO TEMPORARY THRESHOLD SHIFT (METERS) FOR SONAR BIN LF5 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE AFTT STUDY AREA

Functional hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin LF5 (low frequency sources <180 dB source level)			
	1 second	30 seconds	60 seconds	120 seconds
Low-frequency Cetaceans	4 (0–5)	4 (0–5)	4 (0–5)	4 (0–5)
Mid-frequency Cetaceans	222 (200–310)	222 (200–310)	331 (280–525)	424 (340–800)
High-frequency Cetaceans	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)
Phocid Seals	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)

[1] Ranges to TTS represent the model predictions in different areas and seasons within the Study Area. The zone in which animals are expected to suffer TTS extend from onset-PTS to the distance indicated. The average range to TTS is provided as well as the range from the estimated minimum to the maximum range to TTS in parenthesis. **Notes:** Ranges for 1-sec and 30-sec periods are identical for Bin MF1 because this system nominally pings every 50 seconds, therefore these periods encompass only a single ping. PTS: Permanent threshold shift; TTS: Temporary threshold shift.

TABLE 25—RANGES TO TEMPORARY THRESHOLD SHIFT (METERS) FOR SONAR BIN MF1 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE AFTT STUDY AREA

Functional hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin MF1 (e.g., SQS–53 ASW hull mounted sonar)			
	1 second	30 seconds	60 seconds	120 seconds
Low-frequency Cetaceans	1111 (650–2775)	1111 (650–2775)	1655 (800–3775)	2160 (900–6525)
Mid-frequency Cetaceans	222 (200–310)	222 (200–310)	331 (280–525)	424 (340–800)
High-frequency Cetaceans	3001 (1275–8275)	3001 (1275–8275)	4803 (1525–13525)	6016 (1525–16775)
Phocid Seals	784 (575–1275)	784 (575–1275)	1211 (850–3025)	1505 (1025–3775)

[1] Ranges to TTS represent the model predictions in different areas and seasons within the Study Area. The zone in which animals are expected to suffer TTS extend from onset-PTS to the distance indicated. The average range to TTS is provided as well as the range from the estimated minimum to the maximum range to TTS in parenthesis.

Notes: Ranges for 1-sec and 30-sec periods are identical for Bin MF1 because this system nominally pings every 50 seconds, therefore these periods encompass only a single ping. ASW: Anti-submarine warfare; MF: Mid-frequency; PTS: Permanent threshold shift; TTS: Temporary threshold shift.

TABLE 26—RANGES TO TEMPORARY THRESHOLD SHIFT (METERS) FOR SONAR BIN MF4 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE AFTT STUDY AREA

Functional hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin MF4 (e.g., AQS–22 ASW Dipping Sonar)			
	1 second	30 seconds	60 seconds	120 seconds
Low-frequency Cetaceans	89 (85–120)	175 (160–280)	262 (220–575)	429 (330–875)
Mid-frequency Cetaceans	22 (22–25)	36 (35–45)	51 (45–60)	72 (70–95)
High-frequency Cetaceans	270 (220–575)	546 (410–1025)	729 (525–1525)	1107 (600–2275)
Phocid Seals	67 (65–90)	119 (110–180)	171 (150–260)	296 (240–700)

[1] Ranges to TTS represent the model predictions in different areas and seasons within the Study Area. The zone in which animals are expected to suffer TTS extend from onset-PTS to the distance indicated. The average range to TTS is provided as well as the range from the estimated minimum to the maximum range to TTS in parenthesis.
Notes: ASW: Anti-submarine warfare; MF: Mid-frequency; PTS: Permanent threshold shift; TTS: Temporary threshold shift.

TABLE 27—RANGES TO TEMPORARY THRESHOLD SHIFT (METERS) FOR SONAR BIN MF5 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE AFTT STUDY AREA

Functional hearing group	Approximate TTS ranges (meters) [1]			
	Sonar bin MF5 (e.g., SSQ–62 ASW Sonobuoy)			
	1 second	30 seconds	60 seconds	120 seconds
Low-frequency Cetaceans	11 (0–14)	11 (0–14)	16 (0–20)	23 (0–25)
Mid-frequency Cetaceans	5 (0–10)	5 (0–10)	12 (0–15)	17 (0–22)
High-frequency Cetaceans	122 (110–320)	122 (110–320)	187 (150–525)	286 (210–750)
Phocid Seals	9 (8–13)	9 (8–13)	15 (14–18)	22 (21–25)

[1] Ranges to TTS represent the model predictions in different areas and seasons within the Study Area. The zone in which animals are expected to suffer TTS extend from onset-PTS to the distance indicated. The average range to TTS is provided as well as the range from the estimated minimum to the maximum range to TTS in parenthesis.
Notes: ASW: Anti-submarine warfare; MF: Mid-frequency; PTS: Permanent threshold shift; TTS: Temporary threshold shift.

TABLE 28—RANGES TO TEMPORARY THRESHOLD SHIFT (METERS) FOR SONAR BIN HF4 OVER A REPRESENTATIVE RANGE OF ENVIRONMENTS WITHIN THE AFTT STUDY AREA

Functional hearing group	Approximate TTS ranges (Meters) [1]			
	Sonar bin HF4 (e.g., SQS–20 Mine Hunting Sonar)			
	1 second	30 seconds	60 seconds	120 seconds
Low-frequency Cetaceans	1 (0–3)	3 (0–5)	5 (0–7)	7 (0–12)
Mid-frequency Cetaceans	10 (7–17)	19 (11–35)	27 (17–60)	39 (22–100)
High-frequency Cetaceans	242 (100–975)	395 (170–1775)	524 (230–2775)	655 (300–4275)
Phocid Seals	2 (0–5)	5 (0–8)	8 (5–13)	12 (8–20)

[1] Ranges to TTS represent the model predictions in different areas and seasons within the Study Area. The zone in which animals are expected to suffer TTS extend from onset-PTS to the distance indicated. The average range to TTS is provided as well as the range from the estimated minimum to the maximum range to TTS in parenthesis.
Notes: HF: High frequency; PTS: Permanent threshold shift; TTS: Temporary threshold shift.

Explosives

The following section provides the range (distance) over which specific physiological or behavioral effects are expected to occur based on the explosive criteria (see Chapter 6, Section 6.5.2.1.1 of the Navy's rulemaking/LOA application and the Navy's technical report *Criteria and Thresholds Used to Estimate Impacts to Marine Mammals from Explosives*) and the explosive propagation calculations

from the Navy Acoustic Effects Model (see Chapter 6, Section 6.5.2.1.3, Navy Acoustic Effects Model of the Navy's rulemaking/LOA application). The range to effects are shown for a range of explosive bins, from E1 (up to 0.25 lb net explosive weight) to E17 (up to 58,000 lb net explosive weight) (Tables 29 through 34). Ranges are determined by modeling the distance that noise from an explosion would need to propagate to reach exposure level thresholds specific to a hearing group that would cause behavioral response (to the degree of Level B behavioral harassment), TTS, PTS, and non-auditory injury. Ranges are provided for a representative source depth and cluster size for each bin. For events with multiple explosions, sound from successive explosions can be expected to accumulate and increase the range to the onset of an impact based on SEL thresholds. Ranges to non-auditory injury and mortality are shown in Tables 33 and 34, respectively. Range to effects is important information in not only predicting impacts from explosives, but also in verifying the accuracy of model results against real-world situations and determining adequate mitigation ranges to avoid higher level effects, especially physiological effects to marine mammals. For additional information on how ranges to impacts from explosions were estimated, see the technical report *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing* (U.S. Navy, 2017b).

Table 29 shows the minimum, average, and maximum ranges to onset of auditory and likely behavioral effects that rise to the level of Level B harassment for high-frequency cetaceans based on the developed thresholds.

TABLE 29—SEL-BASED RANGES (METERS) TO ONSET PTS, ONSET TTS, AND LEVEL B BEHAVIORAL HARASSMENT FOR HIGH-FREQUENCY CETACEANS

Range to effects for explosives: high frequency cetaceans [1]					
Bin	Source depth (m)	Cluster size	PTS	TTS	Behavioral
E1	0.1	1	446 (180–975)	1,512 (525–3,775)	2,591 (800–6,775)
		20	1,289 (440–3,025)	4,527 (1,275–10,775)	6,650 (1,525–16,525)
E2	0.1	1	503 (200–1,025)	1,865 (600–3,775)	3,559 (1,025–6,775)
		2	623 (250–1,275)	2,606 (750–5,275)	4,743 (1,275–8,525)
E3	18.25	1	865 (525–2,525)	3,707 (1,025–6,775)	5,879 (1,775–10,025)
		50	4,484 (1,275–7,775)	10,610 (2,275–19,775)	13,817 (2,275–27,025)
E4	15	1	1,576 (1,025–2,275)	6,588 (4,525–8,775)	9,744 (7,275–13,025)
		5	3,314 (2,275–4,525)	10,312 (7,525–14,775)	14,200 (9,775–20,025)
	19.8	2	1,262 (975–2,025)	4,708 (1,775–7,525)	6,618 (2,025–11,525)
	198	2	1,355 (875–2,775)	4,900 (2,525–8,275)	6,686 (3,025–11,275)
E5	0.1	25	3,342 (925–8,025)	8,880 (1,275–20,525)	11,832 (1,525–25,025)
E6	0.1	1	1,204 (550–3,275)	4,507 (1,275–10,775)	6,755 (1,525–16,525)
	30	1	2,442 (1,525–5,025)	7,631 (4,525–10,775)	10,503 (4,775–15,025)
E7	15	1	3,317 (2,525–4,525)	10,122 (7,775–13,275)	13,872 (9,775–17,775)
E8	0.1	1	1,883 (675–4,525)	6,404 (1,525–14,525)	9,001 (1,525–19,775)
	45.75	1	2,442 (1,025–5,525)	7,079 (2,025–12,275)	9,462 (2,275–17,025)
	305	1	3,008 (2,025–4,025)	9,008 (6,025–10,775)	12,032 (8,525–14,525)
E9	0.1	1	2,210 (800–4,775)	6,088 (1,525–13,275)	8,299 (1,525–19,025)
E10	0.1	1	2,960 (875–7,275)	8,424 (1,525–19,275)	11,380 (1,525–24,275)
E11	18.5	1	4,827 (1,525–8,775)	11,231 (2,525–20,025)	14,667 (2,525–26,775)
	45.75	1	3,893 (1,525–7,525)	9,320 (2,275–17,025)	12,118 (2,525–21,525)
E12	0.1	1	3,046 (1,275–6,775)	7,722 (1,525–18,775)	10,218 (2,025–22,525)
E16	61	1	5,190 (2,275–9,775)	7,851 (3,525–19,525)	9,643 (3,775–25,775)
E17	61	1	6,173 (2,525–12,025)	11,071 (3,775–29,275)	13,574 (4,025–37,775)

[1] Distances in meters (m). Average distance is shown with the minimum and maximum distances due to varying propagation environments in parentheses.

Table 30 shows the minimum, average, and maximum ranges to onset of auditory and likely behavioral effects that rise to the level of a take for mid-frequency cetaceans based on the developed thresholds.

TABLE 30—SEL-BASED RANGES (METERS) TO ONSET PTS, ONSET TTS, AND LEVEL B BEHAVIORAL HARASSMENT FOR MID-FREQUENCY CETACEANS

Range to effects for explosives: mid-frequency cetaceans [1]					
Bin	Source depth (m)	Cluster size	PTS	TTS	Behavioral
E1	0.1	1	26 (25–50)	139 (95–370)	218 (120–550)
		20	113 (80–290)	539 (210–1,025)	754 (270–1,525)
E2	0.1	1	35 (30–45)	184 (100–300)	276 (130–490)
		2	51 (40–70)	251 (120–430)	365 (160–700)
E3	18.25	1	40 (35–45)	236 (190–800)	388 (280–1,275)
		50	304 (230–1,025)	1,615 (750–3,275)	2,424 (925–5,025)
E4	15	1	74 (60–100)	522 (440–750)	813 (650–1,025)
		5	192 (140–260)	1,055 (875–1,525)	1,631 (1,275–2,525)
	19.8	2	69 (65–70)	380 (330–470)	665 (550–750)
	198	2	48 (0–55)	307 (260–380)	504 (430–700)
E5	0.1	25	391 (170–850)	1,292 (470–3,275)	1,820 (575–5,025)
E6	0.1	1	116 (90–290)	536 (310–1,025)	742 (380–1,525)
	30	1	110 (85–310)	862 (600–2,275)	1,281 (975–3,275)
E7	15	1	201 (190–220)	1,067 (1,025–1,275)	1,601 (1,275–2,025)
E8	0.1	1	204 (150–500)	802 (400–1,525)	1,064 (470–2,275)
	45.75	1	133 (120–200)	828 (525–2,025)	1,273 (775–2,775)
	305	1	58 (0–110)	656 (550–750)	1,019 (900–1,025)

TABLE 30—SEL-BASED RANGES (METERS) TO ONSET PTS, ONSET TTS, AND LEVEL B BEHAVIORAL HARASSMENT FOR MID-FREQUENCY CETACEANS—Continued

Range to effects for explosives: mid-frequency cetaceans [1]					
Bin	Source depth (m)	Cluster size	PTS	TTS	Behavioral
E9	0.1	1	241 (200–370)	946 (450–1,525)	1,279 (500–2,275)
E10	0.1	1	339 (230–750)	1,125 (490–2,525)	1,558 (550–4,775)
E11	18.5	1	361 (230–750)	1,744 (800–3,775)	2,597 (925–5,025)
	45.75	1	289 (230–825)	1,544 (800–3,275)	2,298 (925–5,025)
E12	0.1	1	382 (270–550)	1,312 (525–2,775)	1,767 (600–4,275)
E16	61	1	885 (650–1,775)	3,056 (1,275–5,025)	3,689 (1,525–6,525)
E17	61	1	1,398 (925–2,275)	3,738 (1,525–6,775)	4,835 (1,775–9,275)

[1] Distances in meters (m). Average distance is shown with the minimum and maximum distances due to varying propagation environments in parentheses.

Table 31 shows the minimum, average, and maximum ranges to onset of auditory and likely behavioral effects that rise to the level of a take for low-frequency cetaceans based on the developed thresholds.

TABLE 31—SEL-BASED RANGES (METERS) TO ONSET PTS, ONSET TTS, AND LEVEL B BEHAVIORAL HARASSMENT FOR LOW-FREQUENCY CETACEANS

Range to effects for explosives: low frequency cetaceans [1]					
Bin	Source depth (m)	Cluster size	PTS	TTS	Behavioral
E1	0.1	1	54 (45–80)	259 (130–390)	137 (90–210)
		20	211 (110–320)	787 (340–1,525)	487 (210–775)
E2	0.1	1	64 (55–75)	264 (150–400)	154 (100–220)
		2	87 (70–110)	339 (190–500)	203 (120–300)
E3	18.25	1	211 (190–390)	1,182 (600–2,525)	588 (410–1,275)
		50	1,450 (675–3,275)	8,920 (1,525–24,275)	4,671 (1,025–10,775)
E4	15	1	424 (380–550)	3,308 (2,275–4,775)	1,426 (1,025–2,275)
		5	1,091 (950–1,525)	6,261 (3,775–9,525)	3,661 (2,525–5,275)
	19.8	2	375 (350–400)	1,770 (1,275–3,025)	1,003 (725–1,275)
	198	2	308 (280–380)	2,275 (1,275–3,525)	1,092 (850–2,275)
E5	0.1	25	701 (300–1,525)	4,827 (750–29,275)	1,962 (575–22,525)
E6	0.1	1	280 (150–450)	1,018 (460–7,275)	601 (300–1,525)
	30	1	824 (525–1,275)	4,431 (2,025–7,775)	2,334 (1,275–4,275)
E7	15	1	1,928 (1,775–2,275)	8,803 (6,025–14,275)	4,942 (3,525–6,525)
E8	0.1	1	486 (220–1,000)	3,059 (575–20,525)	1,087 (440–7,775)
	45.75	1	1,233 (675–3,025)	7,447 (1,275–19,025)	3,633 (1,000–9,025)
	305	1	937 (875–975)	6,540 (3,025–12,025)	3,888 (2,025–6,525)
E9	0.1	1	655 (310–1,275)	2,900 (650–31,025)	1,364 (500–8,525)
E10	0.1	1	786 (340–7,275)	7,546 (725–49,025)	3,289 (550–26,525)
E11	18.5	1	3,705 (925–8,775)	16,488 (2,275–40,275)	9,489 (1,775–22,775)
	45.75	1	3,133 (925–8,275)	16,365 (1,775–50,275)	8,701 (1,275–23,775)
E12	0.1	1	985 (400–6,025)	7,096 (800–72,775)	2,658 (625–46,525)
E16	61	1	10,155 (2,025–21,525)	35,790 (18,025–69,775)	25,946 (14,025–58,775)
E17	61	1	17,464 (8,275–39,525)	47,402 (21,025–93,275)	34,095 (16,275–86,275)

[1] Distances in meters (m). Average distance is shown with the minimum and maximum distances due to varying propagation environments in parentheses.

Table 32 shows the minimum, average, and maximum ranges to onset of auditory and likely behavioral effects that rise to the level of take for phocids based on the developed thresholds.

TABLE 32—SEL-BASED RANGES (METERS) TO ONSET PTS, ONSET TTS, LEVEL B BEHAVIORAL HARASSMENT AND FOR PHOCIDS

Range to effects for explosives: phocids [1]					
Bin	Source depth (m)	Cluster size	PTS	TTS	Behavioral
E1	0.1	1	50 (45–85)	242 (120–470)	360 (160–650)
		20	197 (110–380)	792 (300–1,275)	1,066 (410–2,275)
E2	0.1	1	65 (55–85)	267 (140–430)	378 (190–675)
		2	85 (65–100)	345 (180–575)	476 (230–875)
E3	18.25	1	121 (110–220)	689 (500–1,525)	1,074 (725–2,525)
		50	859 (600–2,025)	4,880 (1,525–10,525)	7,064 (1,775–16,275)
E4	15	1	213 (190–260)	1,246 (1,025–1,775)	2,006 (1,525–3,025)
		5	505 (450–600)	2,933 (2,275–4,275)	4,529 (3,275–6,775)
	19.8	2	214 (210–220)	1,083 (900–2,025)	1,559 (1,025–2,525)
	198	2	156 (150–180)	1,141 (825–2,275)	2,076 (1,275–3,525)
E5	0.1	25	615 (250–1,025)	2,209 (850–9,775)	3,488 (1,025–15,275)
E6	0.1	1	210 (160–380)	796 (480–1,275)	1,040 (600–3,275)
	30	1	359 (280–625)	1,821 (1,275–2,775)	2,786 (1,775–4,275)
E7	15	1	557 (525–650)	3,435 (2,775–4,525)	5,095 (3,775–6,775)

TABLE 32—SEL-BASED RANGES (METERS) TO ONSET PTS, ONSET TTS, LEVEL B BEHAVIORAL HARASSMENT AND FOR PHOCIDS—Continued

Range to effects for explosives: phocids [1]					
Bin	Source depth (m)	Cluster size	PTS	TTS	Behavioral
E8	0.1	1	346 (230–600)	1,136 (625–4,025)	1,708 (850–6,025)
	45.75	1	469 (380–1,025)	2,555 (1,275–6,025)	3,804 (1,525–9,775)
	305	1	322 (310–330)	3,222 (1,775–4,525)	4,186 (2,275–5,775)
E9	0.1	1	441 (330–575)	1,466 (825–5,775)	2,142 (950–9,775)
E10	0.1	1	539 (350–900)	1,914 (875–8,525)	3,137 (1,025–15,025)
E11	18.5	1	1,026 (700–2,025)	5,796 (1,525–12,775)	8,525 (1,775–19,775)
	45.75	1	993 (675–2,275)	4,835 (1,525–13,525)	7,337 (1,775–18,775)
E12	0.1	1	651 (420–900)	2,249 (950–11,025)	3,349 (1,275–16,025)
E16	61	1	2,935 (1,775–5,025)	6,451 (2,275–16,275)	10,619 (3,275–24,025)
E17	61	1	3,583 (1,775–7,525)	12,031 (3,275–29,275)	18,396 (7,275–41,025)

[1] Distances in meters (m). Average distance is shown with the minimum and maximum distances due to varying propagation environments in parentheses.

Table 33 below shows the minimum, average, and maximum ranges due to varying propagation conditions to non-auditory injury as a function of animal mass and explosive bin (*i.e.,* net explosive weight). Ranges to gastrointestinal tract injury typically exceed ranges to slight lung injury; therefore, the maximum range to effect is not mass-dependent. Animals within these water volumes would be expected to receive minor injuries at the outer ranges, increasing to more substantial injuries, and finally mortality as an animal approaches the detonation point.

TABLE 33—RANGES [1] TO 50 PERCENT NON-AUDITORY INJURY RISK FOR ALL MARINE MAMMAL HEARING GROUPS

Bin	Range (m)
E1	22 (22–35)
E2	25 (25–30)
E3	46 (35–75)
E4	63 (0–130)
E5	75 (55–130)
E6	97 (65–390)
E7	232 (200–270)
E8	170 (0–490)
E9	215 (100–430)
E10	251 (110–700)
E11	604 (400–2,525)
E12	436 (130–1,025)

TABLE 33—RANGES [1] TO 50 PERCENT NON-AUDITORY INJURY RISK FOR ALL MARINE MAMMAL HEARING GROUPS—Continued

Bin	Range (m)
E16	1,844 (925–3,025)
E17	3,649 (1,000–14,025)

[1] Distances in meters (m). Average distance is shown with the minimum and maximum distances due to varying propagation environments in parentheses. Modeled ranges based on peak pressure for a single explosion generally exceed the modeled ranges based on impulse (related to animal mass and depth).

Ranges to mortality, based on animal mass, are show in Table 34 below.

TABLE 34—RANGES [1] TO 50 PERCENT MORTALITY RISK FOR ALL MARINE MAMMAL HEARING GROUPS AS A FUNCTION OF ANIMAL MASS

Range to effects for air guns [1] for 10 pulses (m)					
Hearing group	PTS (SEL)	PTS (Peak SPL)	TTS (SEL)	TTS (Peak SPL)	Behavioral [2]
High-Frequency Cetacean	0 (0–0)	15 (15–15)	0 (0–0)	25 (25–25)	700 (250–1,025)
Low-Frequency Cetacean ..	13 (12–13)	2 (2–2)	72 (70–80)	4 (4–4)	685 (170–1,025)
Mid-Frequency Cetacean ...	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)	680 (160–2,275)
Phocids	0 (0–0)	2 (2–2)	3 (3–3)	4 (4–4)	708 (220–1,025)

[1] Average distance (m) to PTS, TTS, and behavioral thresholds are depicted above the minimum and maximum distances which are in parentheses. PTS and TTS values depict the range produced by SEL and Peak SPL (as noted) hearing threshold criteria levels.
[2] Behavioral values depict the ranges produced by RMS hearing threshold criteria levels.

Air Guns

Table 35 and Table 36 present the approximate ranges in meters to PTS, TTS, and likely behavioral reactions that rise to the level of take for air guns for 10 and 100 pulses, respectively. Ranges are specific to the AFTT Study Area and also to each marine mammal hearing group, dependent upon their criteria and the specific locations where animals from the hearing groups and the airgun activities could overlap. Small air guns (12–60 in3) would be fired pierside at the Naval Undersea Warfare Center Division, Newport Testing Range, and at off-shore locations typically in the Northeast, Virginia Capes, and GOMEX Range Complexes. Single, small air guns lack the peak pressures that could cause non-auditory injury (see Finneran et al., (2015)); therefore, potential impacts could include PTS, TTS, and/or Level B behavioral harassment.

TABLE 35—RANGE TO EFFECTS (METERS) FROM AIR GUNS FOR 10 PULSES

Range to effects for air guns [1] for 10 pulses (m)					
Hearing group	PTS (SEL)	PTS (Peak SPL)	TTS (SEL)	TTS (Peak SPL)	Behavioral [2]
High-Frequency Cetacean	0 (0–0)	15 (15–15)	0 (0–0)	25 (25–25)	700 (250–1,025)
Low-Frequency Cetacean	13 (12–13)	2 (2–2)	72 (70–80)	4 (4–4)	685 (170–1,025)

TABLE 35—RANGE TO EFFECTS (METERS) FROM AIR GUNS FOR 10 PULSES—Continued

Range to effects for air guns [1] for 10 pulses (m)					
Hearing group	PTS (SEL)	PTS (Peak SPL)	TTS (SEL)	TTS (Peak SPL)	Behavioral [2]
Mid-Frequency Cetacean	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)	680 (160–2,275)
Phocids	0 (0–0)	2 (2–2)	3 (3–3)	4 (4–4)	708 (220–1,025)

[1] Average distance (m) to PTS, TTS, and behavioral thresholds are depicted above the minimum and maximum distances which are in parentheses. PTS and TTS values depict the range produced by SEL and Peak SPL (as noted) hearing threshold criteria levels.
[2] Behavioral values depict the ranges produced by RMS hearing threshold criteria levels.

TABLE 36—RANGE TO EFFECTS FROM AIR GUNS FOR 100 PULSES

Range to effects for air guns [1] for 100 pulses (m)					
Hearing group	PTS (SEL)	PTS (Peak SPL)	TTS (SEL)	TTS (Peak SPL)	Behavioral [2]
High-Frequency Cetacean	4 (4–4)	40 (40–40)	48 (45–50)	66 (65–70)	2,546 (1,025–5,525)
Low-Frequency Cetacean	122 (120–130)	3 (3–3)	871 (600–1,275)	13 (12–13)	2,546 (1,025–5,525)
Mid-Frequency Cetacean	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)	2,546 (1,025–5,525)
Phocids	3 (2–3)	3 (3–3)	25 (25–25)	14 (14–15)	2,546 (1,025–5,525)

[1] Average distance (m) to PTS, TTS, and behavioral thresholds are depicted above the minimum and maximum distances which are in parentheses. PTS and TTS values depict the range produced by SEL and Peak SPL (as noted) hearing threshold criteria levels.
[2] Behavioral values depict the ranges produced by RMS hearing threshold criteria levels.

Pile Driving

Table 37 and Table 38 present the approximate ranges in meters to PTS, TTS, and likely behavioral responses that rise to the level of take for impact pile driving and vibratory pile removal, respectively. Non-auditory injury is not predicted for pile driving activities.

TABLE 37—AVERAGE RANGES TO EFFECTS (METERS) FROM IMPACT PILE DRIVING

Hearing group	PTS (m)	TTS (m)	Behavioral (m)
Low-frequency Cetaceans	65	529	870
Mid-frequency Cetaceans	2	16	870
High-frequency Cetaceans	65	529	870
Phocids	19	151	870

Notes: PTS: Permanent threshold shift; TTS: Temporary threshold shift.

TABLE 38—AVERAGE RANGES TO EFFECTS (METERS) FROM VIBRATORY PILE EXTRACTION

Hearing group	PTS (m)	TTS (m)	Behavioral (m)
Low-frequency Cetaceans	0	3	376
Mid-frequency Cetaceans	0	4	376
High-frequency Cetaceans	7	116	376
Phocids	0	2	376

Notes: PTS: Permanent threshold shift; TTS: Temporary threshold shift.

Marine Mammal Density

A quantitative analysis of impacts on a species or stock requires data on their abundance and distribution that may be affected by anthropogenic activities in the potentially impacted area. The most appropriate metric for this type of analysis is density, which is the number of animals present per unit area. Marine species density estimation requires a significant amount of effort to both collect and analyze data to produce a reasonable estimate. Unlike surveys for terrestrial wildlife, many marine species spend much of their time submerged, and are not easily observed. In order to collect enough sighting data to make reasonable density estimates, multiple observations are required, often in areas that are not easily accessible (*e.g.,* far offshore). Ideally, marine mammal species sighting data would be collected for the specific area and time period *(e.g.,* season) of interest and density estimates derived accordingly. However, in many places, poor weather conditions and high sea states prohibit the completion of comprehensive visual surveys.

For most cetacean species, abundance is estimated using line-transect surveys or mark-recapture studies (*e.g.,* Barlow, 2010, Barlow and Forney, 2007, Calambokidis *et al.,* 2008). The result provides one single density estimate value for each species across broad geographic areas. This is the general approach applied in estimating cetacean abundance in the NMFS' SARs. Although the single value provides a good average estimate of abundance (total number of individuals) for a specified area, it does not provide information on the species distribution or concentrations within that area, and it does not estimate density for other timeframes or seasons that were not

surveyed. More recently, habitat modeling has been used to estimate cetacean densities (Barlow *et al.,* 2009; Becker *et al.,* 2010, 2012a, b, c, 2014, 2016; Ferguson *et al.,* 2006a; Forney *et al.,* 2012, 2015; Redfern *et al.,* 2006). These models estimate cetacean density as a continuous function of habitat variables (*e.g.,* sea surface temperature, seafloor depth, etc.) and thus allow predictions of cetacean densities on finer spatial scales than traditional line-transect or mark recapture analyses and for areas that have not been surveyed. Within the geographic area that was modeled, densities can be predicted wherever these habitat variables can be measured or estimated.

To characterize the marine species density for large areas such as the AFTT Study Area, the Navy compiled data from several sources. The Navy developed a protocol to select the best available data sources based on species, area, and time (season). The resulting Geographic Information System database called the Navy Marine Species Density Database includes seasonal density values for every marine mammal species present within the AFTT Study Area. This database is described in the technical report titled *U.S. Navy Marine Species Density Database Phase III for the Atlantic Fleet Training and Testing Area* (U.S. Department of the Navy, 2017), hereafter referred to as the density technical report.

A variety of density data and density models are needed in order to develop a density database that encompasses the entirety of the AFTT Study Area. Because this data is collected using different methods with varying amounts of accuracy and uncertainty, the Navy has developed a model hierarchy to ensure the most accurate data is used when available. The density technical report describes these models in detail and provides detailed explanations of the models applied to each species density estimate. The below list describes possible models in order of preference.

1. Spatial density models (see Roberts *et al.* (2016)) are preferred and used when available because they provide an estimate with the least amount of uncertainty by deriving estimates for divided segments of the sampling area. These models (see Becker *et al.,* 2016; Forney *et al.,* 2015) predict spatial variability of animal presence based on habitat variables (*e.g.,* sea surface temperature, seafloor depth, etc.). This model is developed for areas, species, and, when available, specific timeframes (months or seasons) with sufficient survey data; therefore, this model cannot be used for species with low numbers of sightings. In the AFTT Study Area, this model is available for certain species along the East Coast to the offshore extent of available survey data and in the GOMEX.

2. Design-based density models predict animal density based on survey data. Like spatial density models, they are applied to areas with survey data. Design-based density models may be stratified, in which a density is predicted for each sub-region of a survey area, allowing for better prediction of species distribution across the density model area. In the AFTT Study Area, stratified density models are used for certain species on both the East Coast and the GOMEX. In addition, a few species' stratified density models are applied to areas east of regions with available survey data and cover a substantial portion of the Atlantic Ocean portion of the AFTT Study Area.

3. Extrapolative models are used in areas where there is insufficient or no survey data. These models use a limited set of environmental variables to predict possible species densities based on environmental observations during actual marine mammal surveys (see Mannocci *et al.* (2017)). In the AFTT Study Area, extrapolative models are typically used east of regions with available survey data and cover a substantial portion of the Atlantic Ocean of the AFTT Study Area. Because some unsurveyed areas have oceanographic conditions that are very different from surveyed areas (*e.g.,* the Labrador Sea and North Atlantic gyre) and some species models rely on a very limited data set, the predictions of some species' extrapolative density models and some regions of certain species' extrapolative density models are considered highly speculative. Extrapolative models are not used in the GOMEX.

4. Existing Relative Environmental Suitability models include a high degree of uncertainty, but are applied when no other model is available.

When interpreting the results of the quantitative analysis, as described in the density technical report (U.S. Department of the Navy, 2017), ''it is important to consider that even the best estimate of marine species density is really a model representation of the values of concentration where these animals might occur. Each model is limited to the variables and assumptions considered by the original data source provider. No mathematical model representation of any biological population is perfect and with regards to marine species biodiversity, any single model method will not completely explain the actual distribution and abundance of marine mammal species. It is expected that there would be anomalies in the results that need to be evaluated, with independent information for each case, to support if we might accept or reject a model or portions of the model.''

The Navy's estimate of abundance (based on the density estimates used) in the AFTT Study Area may differ from population abundances estimated in the NMFS' SARs in some cases for a variety of reasons. Models may predict different population abundances for many reasons. The models may be based on different data sets or different temporal predictions may be made. The SARs are often based on single years of NMFS surveys, whereas the models used by the Navy generally include multiple years of survey data from NMFS, the Navy, and other sources. To present a single, best estimate, the SARs often use a single season survey where they have the best spatial coverage (generally summer). Navy models often use predictions for multiple seasons, where appropriate for the species, even when survey coverage in non-summer seasons is limited, to characterize impacts over multiple seasons as Navy activities may occur in any season. Predictions may be made for different spatial extents. Many different, but equally valid, habitat and density modeling techniques exist and these can also be the cause of differences in population predictions. Differences in population estimates may be caused by a combination of these factors. Even similar estimates should be interpreted with caution and differences in models fully understood before drawing conclusions.

These factors and others described in the Density Technical Report should be considered when examining the estimated impact numbers in comparison to current population abundance information for any given species or stock. For a detailed description of the density and assumptions made for each species, see the Density Technical Report.

NMFS coordinated with the Navy in the development of its take estimates and concurs that the Navy's approach for density appropriately utilizes the best available science. Later, in the *Analysis and Negligible Impact Determination* section, we assess how the estimated take numbers compare to stock abundance in order to better understand the potential number of individuals impacted—and the rationale for which abundance estimate is used is included there.

Take Requests

The AFTT FEIS/OEIS considered all training and testing activities proposed to occur in the AFTT Study Area that have the potential to result in the MMPA defined take of marine mammals. The Navy determined that the three stressors below could result in the incidental taking of marine mammals. NMFS has reviewed the Navy's data and analysis and determined that it is complete and accurate and agrees that the following stressors have the potential to result in takes of marine mammals from the Navy's planned activities.

- Acoustics (sonar and other transducers; air guns; pile driving/extraction).
- Explosives (explosive shock wave and sound).
- Physical Disturbance and Strike (vessel strike).

NMFS reviewed and agrees with the Navy's conclusion that acoustic and explosive sources have the potential to result in incidental takes of marine mammals by harassment, serious injury, or mortality. NMFS carefully reviewed the Navy's analysis and conducted its own analysis of vessel strikes, determining that the likelihood of any particular species of large whale being struck is quite low. Nonetheless, NMFS agrees that vessel strikes have the potential to result in incidental take from serious injury or mortality for certain species of large whales and the Navy has specifically requested coverage for these species. Therefore, the likelihood of vessel strikes, and later the effects of the incidental take that is being authorized, has been fully analyzed and is described below.

The quantitative analysis process used for the AFTT FEIS/OEIS and the Navy's take request in the rulemaking/LOA application to estimate potential exposures to marine mammals resulting from acoustic and explosive stressors is detailed in the technical report titled *Quantitative Analysis for Estimating Acoustic and Explosive Impacts to Marine Mammals and Sea Turtles* (U.S. Department of the Navy, 2017a). The Navy Acoustic Effects Model estimates acoustic and explosive effects without taking mitigation into account; therefore, the model overestimates predicted impacts on marine mammals within mitigation zones. To account for mitigation for marine species in the take estimates, the Navy conducts a quantitative assessment of mitigation. The Navy conservatively quantifies the manner in which procedural mitigation is expected to reduce model-estimated PTS to TTS for exposures to sonar and other transducers, and reduce model-estimated mortality to injury for exposures to explosives. The extent to which the mitigation areas reduce impacts on the affected species and stocks is addressed separately in the *Analysis and Negligible Impact Determination* section.

The Navy assessed the effectiveness of its procedural mitigation measures on a per-scenario basis for four factors: (1) Species sightability, (2) a Lookout's ability to observe the range to PTS (for sonar and other transducers) and range to mortality (for explosives), (3) the portion of time when mitigation could potentially be conducted during periods of reduced daytime visibility (to include inclement weather and high sea-state) and the portion of time when mitigation could potentially be conducted at night, and (4) the ability for sound sources to be positively controlled (*e.g.,* powered down).

During the conduct of training and testing activities, there is typically at least one, if not numerous, support personnel involved in the activity (*e.g.,* range support personnel aboard a torpedo retrieval boat or support aircraft). In addition to the Lookout posted for the purpose of mitigation, these additional personnel observe for and disseminate marine species sighting information amongst the units participating in the activity whenever possible as they conduct their primary mission responsibilities. However, as a conservative approach to assigning mitigation effectiveness factors, the Navy elected to only account for the minimum number of required Lookouts used for each activity; therefore, the mitigation effectiveness factors may underestimate the likelihood that some marine mammals may be detected during activities that are supported by additional personnel who may also be observing the mitigation zone.

The Navy used the equations in the below sections to calculate the reduction in model-estimated mortality impacts due to implementing procedural mitigation.

Equation 1:

Mitigation Effectiveness = Species Sightability × Visibility × Observation Area × Positive Control

Species Sightability is the ability to detect marine mammals and is dependent on the animal's presence at the surface and the characteristics of the animal that influence its sightability. The Navy considered applicable data from the best available science to numerically approximate the sightability of marine mammals and determined that the standard ''detection probability'' referred to as g(0) is most appropriate. Visibility = 1 − sum of individual visibility reduction factors. Observation Area = portion of impact range that can be continuously observed during an event. Positive Control = positive control factor of all sound sources involving mitigation. For further details on these mitigation effectiveness factors please refer to the technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing report* (U.S. Department of the Navy, 2018).

To quantify the number of marine mammals predicted to be sighted by Lookouts during implementation of procedural mitigation in the range to injury (PTS) for sonar and other transducers, the species sightability is multiplied by the mitigation effectiveness scores and number of model-estimated PTS impacts, as shown in the equation below:

Equation 2:

Number of Animals Sighted by Lookouts = Mitigation Effectiveness × Model-Estimated Impacts

The marine mammals sighted by Lookouts during implementation of mitigation in the range to PTS, as calculated by the equation above, would avoid being exposed to these higher level impacts. The Navy corrects the category of predicted impact for the number of animals sighted within the mitigation zone (*e.g.,* shifts PTS to TTS), but does not modify the total number of animals predicted to experience impacts from the scenario.

To quantify the number of marine mammals predicted to be sighted by Lookouts during implementation of procedural mitigation in the range to mortality during events using explosives, the species sightability is multiplied by the mitigation effectiveness scores and number of model-estimated mortality impacts, as shown in equation 1 above. The marine mammals predicted to be sighted by Lookouts during implementation of procedural mitigation in the range to mortality, as calculated by the above equation 2, are predicted to avoid exposure in these ranges. The Navy corrects the category of predicted impact for the number of animals sighted within the mitigation zone, but does not modify the total number of animals predicted to experience impacts from the scenario. For example, the number of animals sighted (*i.e.,* number of animals that will avoid mortality) is first subtracted from the model-predicted mortality impacts, and then

added to the model-predicted injurious impacts.

The Navy coordinated with NMFS in the development of this quantitative method to address the effects of procedural mitigation on acoustic and explosive exposures and takes, and NMFS independently reviewed and concurs with the Navy that it is appropriate to incorporate the quantitative assessment of mitigation into the take estimates based on the best available science. For additional information on the quantitative analysis process and mitigation measures, refer to Chapter 6 (*Take Estimates for Marine Mammals*) and Chapter 11 (*Mitigation Measures*) of the Navy's rulemaking/LOA application.

In summary, we believe the Navy's methods, including the method for incorporating mitigation and avoidance, are the most appropriate methods for predicting PTS and TTS. But even with the consideration of mitigation and avoidance, given some of the more conservative components of the methodology (*e.g.,* the thresholds do not consider ear recovery between pulses), we would describe the application of these methods as identifying the maximum number of instances in which marine mammals would be reasonably expected to incur either TTS or PTS.

Authorized Take From Training Activities

For training activities, Table 39 summarizes the Navy's take request and the maximum amount and type of take by harassment that NMFS concurs is reasonably likely to occur by species or stock. Authorized mortality is addressed further down. Navy Figures 6.4–10 through 6.5–69 in Chapter 6 of the Navy's rulemaking/LOA application illustrate the comparative amounts of TTS and Level B behavioral harassment for each species, noting that if a ''taken'' animat was exposed to both TTS and Level B behavioral harassment in the model, it was recorded as a TTS.

TABLE 39—SPECIES AND STOCK-SPECIFIC TAKE FROM ALL TRAINING ACTIVITIES

Species	Stock	Annual		5-Year total	
		Level B harassment	Level A harassment	Level B harassment	Level A harassment
Suborder Mysticeti (baleen whales)					
Family Balaenidae (right whales)					
North Atlantic right whale *	Western	245	0	1,177	0
Family Balaenopteridae (roquals)					
Blue whale *	Western North Atlantic (Gulf of St. Lawrence).	26	0	121	0
Bryde's whale	Northern Gulf of Mexico	0	0	0	0
	NSD †	206	0	961	0
Minke whale	Canadian East Coast	2,425	0	11,262	0
Fin whale *	Western North Atlantic	1,498	3	7,296	14
Humpback whale	Gulf of Maine	233	1	1,116	3
Sei whale *	Nova Scotia	292	0	1,400	0
Suborder Odontoceti (toothed whales)					
Family Physeteridae (sperm whale)					
Sperm whale *	Gulf of Mexico Oceanic	24	0	119	0
	North Atlantic	14,084	0	68,839	0
Family Kogiidae (sperm whales)					
Dwarf sperm whale	Gulf of Mexico Oceanic	14	0	74	0
	Western North Atlantic	8,527	10	39,913	48
Pygmy sperm whale	Northern Gulf of Mexico	14	0	74	0
	Western North Atlantic	8,527	10	39,913	48
Family Ziphiidae (beaked whales)					
Blainville's beaked whale	Northern Gulf of Mexico	35	0	173	0
	Western North Atlantic	12,533	0	61,113	0
Cuvier's beaked whale	Northern Gulf of Mexico	34	0	172	0
	Western North Atlantic	46,402	0	226,286	0
Gervais' beaked whale	Northern Gulf of Mexico	35	0	173	0
	Western North Atlantic	12,533	0	61,113	0
Northern bottlenose whale	Western North Atlantic	1,073	0	5,360	0
Sowersby's beaked whale	Western North Atlantic	12,533	0	61,113	0
True's beaked whale	Western North Atlantic	12,533	0	61,113	0
Family Delphinidae (dolphins)					
Atlantic spotted dolphin	Northern Gulf of Mexico	951	0	4,706	0
	Western North Atlantic	117,994	9	573,622	46
Atlantic white-sided dolphin	Western North Atlantic	14,502	0	71,097	0
Bottlenose dolphin	Choctawhatchee Bay	7	0	33	0
	Gulf of Mexico Eastern Coastal	42	0	125	0

TABLE 39—SPECIES AND STOCK-SPECIFIC TAKE FROM ALL TRAINING ACTIVITIES—Continued

Species	Stock	Annual		5-Year total	
		Level B harassment	Level A harassment	Level B harassment	Level A harassment
	Gulf of Mexico Northern Coastal	219	0	1,089	0
	Gulf of Mexico Western Coastal	4,149	0	12,568	0
	Indian River Lagoon Estuarine System.	283	0	1,414	0
	Jacksonville Estuarine System	84	0	421	0
	Mississippi Sound, Lake Borgne, Bay Boudreau.	0	0	0	0
	Northern Gulf of Mexico Continental Shelf.	1,560	2	7,799	9
	Northern Gulf of Mexico Oceanic	195	0	970	0
	Northern North Carolina Estuarine System.	3,221	0	11,800	0
	Southern North Carolina Estuarine System.	0	0	0	0
	Western North Atlantic Northern Florida Coastal.	906	0	4,324	0
	Western North Atlantic Central Florida Coastal.	5,341	0	25,594	0
	Western North Atlantic Northern Migratory Coastal.	25,189	4	125,183	21
	Western North Atlantic Offshore	308,206	39	1,473,308	192
	Western North Atlantic South Carolina/Georgia Coastal.	4,328	0	20,559	0
	Western North Atlantic Southern Migratory Coastal.	12,494	2	58,061	10
Clymene dolphin	Northern Gulf of Mexico	99	0	495	0
	Western North Atlantic	69,774	3	330,027	13
False killer whale	Northern Gulf of Mexico	41	0	208	0
	Western North Atlantic	8,271	0	39,051	0
Fraser's dolphin	Northern Gulf of Mexico	59	0	298	0
	Western North Atlantic	3,929	0	18,634	0
Killer whale	Northern Gulf of Mexico	1	0	4	0
	Western North Atlantic	77	0	372	0
Long-finned pilot whale	Western North Atlantic	17,039	0	83,050	0
Melon-headed whale	Northern Gulf of Mexico	70	0	352	0
	Western North Atlantic	37,157	1	175,369	3
Pantropical spotted dolphin	Northern Gulf of Mexico	566	0	2,828	0
	Western North Atlantic	145,125	2	686,775	12
Pygmy killer whale	Northern Gulf of Mexico	16	0	84	0
	Western North Atlantic	6,483	0	30,639	0
Risso's dolphin	Northern Gulf of Mexico	39	0	197	0
	Western North Atlantic	21,034	0	100,018	0
Rough-toothed dolphin	Northern Gulf of Mexico	97	0	436	0
	Western North Atlantic	19,568	0	92,314	0
Short-beaked common dolphin	Western North Atlantic	218,144	13	1,046,193	64
Short-finned pilot whale	Northern Gulf of Mexico	36	0	179	0
	Western North Atlantic	31,357	0	150,213	0
Spinner dolphin	Northern Gulf of Mexico	228	0	1,138	0
	Western North Atlantic	73,689	1	347,347	6
Striped dolphin	Northern Gulf of Mexico	67	0	336	0
	Western North Atlantic	91,038	3	451,001	15
White-beaked dolphin	Western North Atlantic	40	0	192	0
Family Phocoenidae (porpoises)					
Harbor porpoise	Gulf of Maine/Bay of Fundy	29,789	161	147,290	802
Suborder Pinnipedia					
Family Phocidae (true seals)					
Gray seal	Western North Atlantic	1,444	0	7,173	0
Harbor seal	Western North Atlantic	2,341	0	11,632	0
Harp seal	Western North Atlantic	8,444	1	42,191	4
Hooded seal	Western North Atlantic	127	0	631	0

* ESA-listed species (all stocks) within the AFTT Study Area.
† NSD: No stock designated.

Authorized Take From Testing Activities

For testing activities other than ship shock trials, Table 40 summarizes the Navy's take request and the maximum amount and type of take by harassment that NMFS concurs is reasonably likely to occur and has authorized by species or stock. Since the proposed rule, the Navy has removed one of their testing events in the Northeast Range Complex (Undersea Warfare Testing), which decreased the number of Level B harassment takes annually for NARW by 115 takes. This change also decreased annual Level B harassment takes by approximately 200 takes for ESA-listed fin whale and 20 takes for sei whales as well as approximately 10,000 takes annually for harbor porpoise.

TABLE 40—SPECIES-SPECIFIC TAKE FROM ALL TESTING ACTIVITIES (EXCLUDING SHIP SHOCK TRIALS)

Species	Stock	Annual		5-Year total	
		Level B harassment	Level A harassment	Level B harassment	Level A harassment
Suborder Mysticeti (baleen whales)					
Family Balaenidae (right whales)					
North Atlantic right whale *	Western	224	0	1,091	0
Family Balaenopteridae (roquals)					
Blue whale *	Western North Atlantic (Gulf of St. Lawrence).	20	0	95	0
Bryde's whale	Northern Gulf of Mexico	52	0	257	0
	NSD †	125	0	614	0
Minke whale	Canadian East Coast	1,616	2	7,971	7
Fin whale *	Western North Atlantic	3,655	3	17,716	16
Humpback whale	Gulf of Maine	493	0	2,412	0
Sei whale *	Nova Scotia	482	0	2,327	0
Suborder Odontoceti (toothed whales)					
Family Physeteridae (sperm whale)					
Sperm whale *	Gulf of Mexico Oceanic	1,106	0	5,240	0
	North Atlantic	11,278	0	51,657	0
Family Kogiidae (sperm whales)					
Dwarf sperm whale	Gulf of Mexico Oceanic	727	6	3,424	27
	Western North Atlantic	4,384	14	21,159	66
Pygmy sperm whale	Northern Gulf of Mexico	727	6	3,424	27
	Western North Atlantic	4,384	14	21,159	66
Family Ziphiidae (beaked whales)					
Blainville's beaked whale	Northern Gulf of Mexico	1,392	0	6,710	0
	Western North Atlantic	10,565	0	49,647	0
Cuvier's beaked whale	Northern Gulf of Mexico	1,460	0	6,988	0
	Western North Atlantic	38,780	0	182,228	0
Gervais' beaked whale	Northern Gulf of Mexico	1,392	0	6,710	0
	Western North Atlantic	10,565	0	49,647	0
Northern bottlenose whale	Western North Atlantic	971	0	4,485	0
Sowersby's beaked whale	Western North Atlantic	10,593	0	49,764	0
True's beaked whale	Western North Atlantic	10,593	0	49,764	0
Family Delphinidae (dolphins)					
Atlantic spotted dolphin	Northern Gulf of Mexico	71,882	2	333,793	13
	Western North Atlantic	109,582	11	504,538	52
Atlantic white-sided dolphin	Western North Atlantic	31,779	1	150,062	6
Bottlenose dolphin	Choctawhatchee Bay	966	0	4,421	0
	Gulf of Mexico Eastern Coastal	0	0	0	0
	Gulf of Mexico Northern Coastal	16,258	1	76,439	5
	Gulf of Mexico Western Coastal	3,677	0	18,035	0
	Indian River Lagoon Estuarine System.	3	0	15	0
	Jacksonville Estuarine System	3	0	14	0
	Mississippi Sound, Lake Borgne, Bay Boudreau.	1	0	4	0
	Northern Gulf of Mexico Continental Shelf.	125,940	8	594,921	40
	Northern Gulf of Mexico Oceanic	14,448	1	67,244	5
	Northern North Carolina Estuarine System.	106	0	533	0

TABLE 40—SPECIES-SPECIFIC TAKE FROM ALL TESTING ACTIVITIES (EXCLUDING SHIP SHOCK TRIALS)—Continued

Species	Stock	Annual		5-Year total	
		Level B harassment	Level A harassment	Level B harassment	Level A harassment
	Southern North Carolina Estuarine System.	0	0	0	0
	Western North Atlantic Northern Florida Coastal.	329	0	1,614	0
	Western North Atlantic Central Florida Coastal.	2,272	0	10,950	0
	Western North Atlantic Northern Migratory Coastal.	11,855	3	56,321	15
	Western North Atlantic Offshore	119,880	23	566,572	116
	Western North Atlantic South Carolina/Georgia Coastal.	1,632	0	8,017	0
	Western North Atlantic Southern Migratory Coastal.	4,222	0	20,827	0
Clymene dolphin	Northern Gulf of Mexico	4,166	0	19,919	0
	Western North Atlantic	35,985	2	170,033	8
False killer whale	Northern Gulf of Mexico	1,931	0	9,118	0
	Western North Atlantic	3,766	0	17,716	0
Fraser's dolphin	Northern Gulf of Mexico	1,120	0	5,314	0
	Western North Atlantic	1,293	0	6,070	0
Killer whale	Northern Gulf of Mexico	32	0	152	0
	Western North Atlantic	42	0	188	0
Long-finned pilot whale	Western North Atlantic	20,502	2	94,694	8
Melon-headed whale	Northern Gulf of Mexico	3,059	0	14,546	0
	Western North Atlantic	16,688	1	78,545	4
Pantropical spotted dolphin	Northern Gulf of Mexico	25,929	1	121,469	4
	Western North Atlantic	77,451	4	355,889	19
Pygmy killer whale	Northern Gulf of Mexico	719	0	3,415	0
	Western North Atlantic	2,847	0	13,426	0
Risso's dolphin	Northern Gulf of Mexico	1,649	0	7,821	0
	Western North Atlantic	20,070	1	94,009	6
Rough-toothed dolphin	Northern Gulf of Mexico	3,927	0	18,493	0
	Western North Atlantic	8,765	0	41,492	0
Short-beaked common dolphin	Western North Atlantic	353,012	17	1,675,885	72
Short-finned pilot whale	Northern Gulf of Mexico	1,823	0	8,614	0
	Western North Atlantic	17,002	1	80,576	7
Spinner dolphin	Northern Gulf of Mexico	7,815	0	36,567	0
	Western North Atlantic	33,351	2	157,241	7
Striped dolphin	Northern Gulf of Mexico	2,447	0	11,703	0
	Western North Atlantic	102,047	5	465,392	23
White-beaked dolphin	Western North Atlantic	44	0	213	0
Family Phocoenidae (porpoises)					
Harbor porpoise	Gulf of Maine/Bay of Fundy	125,404	212	578,130	1,007
Suborder Pinnipedia					
Family Phocidae (true seals)					
Gray seal	Western North Atlantic	894	2	4,376	11
Harbor seal	Western North Atlantic	1,448	4	7,094	17
Harp seal	Western North Atlantic	7,850	2	38,273	12
Hooded seal	Western North Atlantic	787	0	3,805	0

* ESA–listed species (all stocks) within the AFTT Study Area.
† NSD: No stock designated.

Authorized Take From Ship Shock

The Navy's model and quantitative analysis process used for the AFTT FEIS/OEIS and in the Navy's rulemaking/LOA application to estimate exposures of marine mammals to explosives (ship shock) is detailed in the technical report titled *Quantifying Acoustic Impacts on Marine Mammals and Sea Turtles: Methods and Analytical Approach for Phase III Training and Testing* (U.S. Department of the Navy, 2017b). NMFS has reviewed the Navy's data and analysis of explosive impacts and concurs that the estimated take the Navy requested appropriately represents the maximum take by harassment that is reasonably expected to occur, as well as the potential for mortality. Table 41 summarizes the Navy's take request and the maximum amount and type of take that is reasonably expected to occur (harassment) or could potentially occur (serious injury/mortality) by species for ship shock trials under testing activities per small and large ship shock events and the summation over a five-year period. The table below displays maximum ship shock impacts to marine

mammals by species (in bold text), as well as maximum impacts on individual stocks. The maximum is derived by selecting the highest number of potential impacts across all locations and all seasons for each species/stock. Small Ship Shock trials could take place any season within the deep offshore water of the Virginia Capes Range Complex or in the spring, summer, or fall within the Jacksonville Range Complex and could occur up to three times over a five-year period. The Large Ship Shock trial could take place in the Jacksonville Range Complex during the spring, summer, or fall and during any season within the deep offshore water of the Virginia Capes Range Complex or within the GOMEX. The Large Ship Shock Trial could occur once over five years.

Navy's model and quantitative analysis process estimated serious injury/mortality of four dolphin species from ship shock trials including: Atlantic white-sided dolphin (Western North Atlantic), Pantropical spotted dolphin (Northern GOMEX), short-beaked common dolphin (Western North Atlantic), and Spinner dolphin (Northern GOMEX) (Table 41 below). For serious injury/mortality takes over the five-year period, based on the exposure estimates generated by the model and the quantitative post-modeling mitigation and avoidance adjustments, an annual average of 0.2 dolphins from each dolphin species/stock listed above (*i.e.,* for those species or stocks where 1 take could potentially occur divided by 5 years to get the annual number of mortalities/serious injuries) or 1.2 dolphins in the case of short-beaked common dolphin (*i.e.,* where 6 takes could potentially occur divided by 5 years to get the annual number of mortalities/serious injuries) is used in further analysis in the *Analysis and Negligible Impact Determination* section.

Table 41. Species Specific Take from Ship Shock Trials.

Species / Stock	*Small Ship Shock*			*Large Ship Shock*			*5-Year Total*		
	Level B Harassment	*Level A Harassment*	*Mortality*	*Level B Harassment*	*Level A Harassment*	*Mortality*	*Level B Harassment*	*Level A Harassment*	*Mortality*
Suborder Mysticeti (baleen whales)									
Family Balaenidae (right whales)									
North Atlantic right whale	**1**	**0**	**0**	**2**	**0**	**0**	**5**	**0**	**0**
Western *	1	0	0	2	0	0	5	0	0
Family Balaenopteridae (roquals)									
Blue whale	**0**	**0**	**0**	**1**	**0**	**0**	**1**	**0**	**0**
Western North Atlantic (Gulf of St. Lawrence)*	0	0	0	1	0	0	1	0	0
Bryde's whale	**3**	**0**	**0**	**6**	**1**	**0**	**15**	**1**	**0**
Northern Gulf of Mexico*	0	0	0	3	1	0	3	1	0
NSD†	3	0	0	6	0	0	15	0	0
Minke whale	**19**	**1**	**0**	**39**	**3**	**0**	**96**	**6**	**0**
Canadian East Coast	19	1	0	39	3	0	96	6	0
Fin whale	**131**	**3**	**0**	**234**	**27**	**0**	**627**	**36**	**0**
Western North Atlantic*	131	3	0	234	27	0	627	36	0
Humpback whale	**8**	**0**	**0**	**20**	**2**	**0**	**44**	**2**	**0**
Gulf of Maine	8	0	0	20	2	0	44	2	0
Sei whale	**12**	**1**	**0**	**27**	**4**	**0**	**63**	**7**	**0**
Nova Scotia*	12	1	0	27	4	0	63	7	0
Suborder Odontoceti (toothed whales)									
Family Physeteridae (sperm whale)									
Sperm whale*	**1**	**1**	**0**	**3**	**4**	**0**	**6**	**7**	**0**
Gulf of Mexico Oceanic	0	0	0	2	0	0	2	0	0
North Atlantic	1	1	0	3	4	0	6	7	0
Family Kogiidae (sperm whales)									
Dwarf sperm whale	**46**	**28**	**0**	**91**	**70**	**0**	**229**	**154**	**0**
Gulf of Mexico Oceanic	0	0	0	51	64	0	51	64	0
Western North Atlantic	46	28	0	91	70	0	229	154	0
Pygmy sperm whale	**46**	**28**	**0**	**91**	**70**	**0**	**229**	**154**	**0**

Northern Gulf of Mexico	0	0	0	51	64	0	51	64	0
Western North Atlantic	46	28	0	91	70	0	229	154	0
Family Ziphiidae (beaked whales)									
Blainville's beaked whale	**1**	**0**	**0**	**1**	**1**	**0**	**4**	**1**	**0**
Northern Gulf of Mexico	0	0	0	1	0	0	1	0	0
Western North Atlantic	1	0	0	1	1	0	4	1	0
Cuvier's beaked whale	**2**	**1**	**0**	**2**	**3**	**0**	**8**	**6**	**0**
Northern Gulf of Mexico	0	0	0	1	0	0	1	0	0
Western North Atlantic	2	1	0	2	3	0	8	6	0
Gervais' beaked whale	**1**	**0**	**0**	**1**	**1**	**0**	**4**	**1**	**0**
Northern Gulf of Mexico	0	0	0	1	0	0	1	0	0
Western North Atlantic	1	0	0	1	1	0	4	1	0
Northern bottlenose whale	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Western North Atlantic	0	0	0	0	0	0	0	0	0
Sowerby's beaked whale	**1**	**0**	**0**	**1**	**1**	**0**	**4**	**1**	**0**
Western North Atlantic	1	0	0	1	1	0	4	1	0
True's beaked whale	**1**	**0**	**0**	**1**	**1**	**0**	**4**	**1**	**0**
Western North Atlantic	1	0	0	1	1	0	4	1	0
Family Delphinidae (dolphins)									
Atlantic spotted dolphin	**6**	**4**	**0**	**8**	**12**	**0**	**26**	**24**	**0**
Northern Gulf of Mexico	0	0	0	2	1	0	2	1	0
Western North Atlantic	6	4	0	8	12	0	26	24	0
Atlantic white-sided dolphin	**1**	**1**	**0**	**3**	**9**	**1**	**6**	**12**	**1**

Western North Atlantic	1	1	0	3	9	1	6	12	1
Bottlenose dolphin	**13**	**10**	**0**	**16**	**24**	**0**	**55**	**54**	**0**
Choctawhatchee Bay	0	0	0	0	0	0	0	0	0
Gulf of Mexico Eastern Coastal	0	0	0	0	0	0	0	0	0
Gulf of Mexico Northern Coastal	0	0	0	1	1	0	1	1	0
Gulf of Mexico Western Coastal	0	0	0	0	0	0	0	0	0
Indian River Lagoon Estuarine System	0	0	0	0	0	0	0	0	0
Jacksonville Estuarine System	0	0	0	0	0	0	0	0	0
Mississippi Sound, Lake Borgne, Bay Boudreau	0	0	0	0	0	0	0	0	0
Northern Gulf of Mexico Continental Shelf	0	0	0	10	6	0	10	6	0
Northern Gulf of Mexico Oceanic	0	0	0	10	9	0	10	9	0
Northern North Carolina Estuarine System	0	0	0	0	0	0	0	0	0
Southern North Carolina Estuarine System	0	0	0	0	0	0	0	0	0
Western North Atlantic Northern Florida Coastal	0	0	0	0	0	0	0	0	0
Western North Atlantic Central Florida Coastal	0	0	0	0	0	0	0	0	0
Western North Atlantic Northern Migratory Coastal	0	0	0	0	0	0	0	0	0

Western North Atlantic Offshore	13	10	0	16	24	0	55	54	0
Western North Atlantic South Carolina/ Georgia Coastal	0	0	0	0	0	0	0	0	0
Western North Atlantic Southern Migratory Coastal	0	0	0	0	0	0	0	0	0
Clymene dolphin	**2**	**5**	**0**	**9**	**8**	**0**	**15**	**23**	**0**
Northern Gulf of Mexico	0	0	0	8	6	0	8	6	0
Western North Atlantic	2	5	0	9	8	0	15	23	0
False killer whale	**0**	**0**	**0**	**2**	**1**	**0**	**2**	**1**	**0**
Northern Gulf of Mexico	0	0	0	2	1	0	2	1	0
Western North Atlantic	0	0	0	2	0	0	2	0	0
Fraser's dolphin	**0**	**0**	**0**	**2**	**3**	**0**	**2**	**3**	**0**
Northern Gulf of Mexico	0	0	0	2	3	0	2	3	0
Western North Atlantic	0	0	0	0	0	0	0	0	0
Killer whale	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Northern Gulf of Mexico	0	0	0	0	0	0	0	0	0
Western North Atlantic	0	0	0	0	0	0	0	0	0
Long-finned pilot whale	**2**	**2**	**0**	**5**	**6**	**0**	**11**	**12**	**0**
Western North Atlantic	2	2	0	5	6	0	11	12	0
Melon-headed whale	**1**	**1**	**0**	**5**	**4**	**0**	**8**	**7**	**0**
Northern Gulf of Mexico	0	0	0	4	4	0	4	4	0
Western North Atlantic	1	1	0	5	1	0	8	4	0
Pantropical spotted dolphin	**2**	**3**	**0**	**25**	**20**	**1**	**31**	**29**	**1**

Northern Gulf of Mexico	0	0	0	25	20	1	25	20	1
Western North Atlantic	2	3	0	7	3	0	13	12	0
Pygmy killer whale	**0**	**0**	**0**	**1**	**1**	**0**	**1**	**1**	**0**
Northern Gulf of Mexico	0	0	0	1	1	0	1	1	0
Western North Atlantic	0	0	0	1	0	0	1	0	0
Risso's dolphin	**1**	**1**	**0**	**3**	**1**	**0**	**6**	**4**	**0**
Northern Gulf of Mexico	0	0	0	2	1	0	2	1	0
Western North Atlantic	1	1	0	3	1	0	6	4	0
Rough-toothed dolphin	**1**	**0**	**0**	**3**	**2**	**0**	**6**	**2**	**0**
Northern Gulf of Mexico	0	0	0	2	2	0	2	2	0
Western North Atlantic	0	0	0	0	0	0	0	0	0
Short-beaked common dolphin	**40**	**51**	**1**	**67**	**107**	**3**	**187**	**260**	**6**
Western North Atlantic	40	51	1	67	107	3	187	260	6
Short-finned pilot whale	**2**	**2**	**0**	**4**	**5**	**0**	**10**	**11**	**0**
Northern Gulf of Mexico	0	0	0	2	3	0	2	3	0
Western North Atlantic	2	2	0	4	5	0	10	11	0
Spinner dolphin	**3**	**1**	**0**	**37**	**45**	**1**	**46**	**48**	**1**
Northern Gulf of Mexico	0	0	0	37	45	1	37	45	1
Western North Atlantic	3	1	0	7	3	0	16	6	0
Striped dolphin	**4**	**8**	**0**	**10**	**12**	**0**	**22**	**36**	**0**
Northern Gulf of Mexico	0	0	0	4	3	0	4	3	0
Western North Atlantic	4	8	0	10	12	0	22	36	0
White-beaked dolphin	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**

Western North Atlantic	0	0	0	0	0	0	0	0	0
Family Phocoenidae (porpoises)									
Harbor porpoise	**43**	**41**	**0**	**120**	**81**	**0**	**249**	**204**	**0**
Gulf of Maine/Bay of Fundy	43	41	0	120	81	0	249	204	0
Suborder Pinnipedia									
Family Phocidae (true seals)									
Gray seal	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Western North Atlantic	0	0	0	0	0	0	0	0	0
Harbor seal	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Western North Atlantic	0	0	0	0	0	0	0	0	0
Harp seal	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Western North Atlantic	0	0	0	0	0	0	0	0	0
Hooded seal	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**0**
Western North Atlantic	0	0	0	0	0	0	0	0	0

Note: The table displays maximum ship shock impacts to marine mammals by species (in bold text), as well as maximum impacts on individual stocks.
* ESA-listed species' stocks within the AFTT Study Area
†NSD: No stock designated

Take From Vessel Strikes

The marine mammals most vulnerable to vessel strikes are those that spend extended periods of time at the surface in order to restore oxygen levels within their tissues after deep dives (*e.g.,* the sperm whale). In addition, some baleen whales, such as the NARW, seem generally unresponsive to vessel sound, making them more susceptible to vessel collisions (Nowacek *et al.,* 2004). These species are primarily large, slower moving whales.

Some researchers have suggested the relative risk of a vessel strike can be assessed as a function of animal density and the magnitude of vessel traffic (*e.g.,* Fonnesbeck et al. 2008; Vanderlaan *et al.,* 2008). Differences among vessel types also influence the probability of a vessel strike. The ability of any ship to detect a marine mammal and avoid a collision depends on a variety of factors, including environmental conditions, ship design, size, speed, and personnel, as well as the behavior of the animal. Vessel speed, size, and mass are all important factors in determining if injury or death of a marine mammal is likely due to a vessel strike. For large vessels, speed and angle of approach can influence the severity of a strike. For example, Vanderlaan and Taggart (2007) found that between vessel speeds of 8.6 and 15 knots, the probability that a vessel strike is lethal increases from 0.21 to 0.79. Large whales also do not have to be at the water's surface to be struck. Silber *et al.* (2010) found when a whale is below the surface (about one to two times the vessel draft), there is likely to be a pronounced propeller suction effect. This suction effect may draw the whale into the hull of the ship, increasing the probability of propeller strikes.

There are some key differences between the operation of military and non-military vessels, which make the likelihood of a military vessel striking a whale lower than some other vessels (*e.g.,* commercial merchant vessels). Key differences include: Many military ships have their bridges positioned closer to the bow, offering better visibility ahead of the ship (compared to a commercial merchant vessel).

- There are often aircraft associated with the training or testing activity (which can serve as Lookouts), which can more readily detect cetaceans in the vicinity of a vessel or ahead of a vessel's present course before crew on the vessel would be able to detect them.
- Military ships are generally more maneuverable than commercial merchant vessels, and if cetaceans are spotted in the path of the ship, could be capable of changing course more quickly.
- The crew size on military vessels is generally larger than merchant ships, allowing for stationing more trained Lookouts on the bridge. At all times when vessels are underway, trained Lookouts and bridge navigation teams are used to detect objects on the surface of the water ahead of the ship, including cetaceans. Additional Lookouts, beyond those already stationed on the bridge and on navigation teams, are positioned as Lookouts during some training events.
- When submerged, submarines are generally slow moving (to avoid detection) and therefore marine mammals at depth with a submarine are likely able to avoid collision with the submarine. When a submarine is transiting on the surface, there are Lookouts serving the same function as they do on surface ships.

Vessel strike to marine mammals is not associated with any specific training or testing activity but is rather an extremely limited and sporadic, but possible, accidental result of Navy vessel movement within the AFTT Study Area or while in transit.

There have been three recorded Navy vessel strikes of large whales in the AFTT Study Area from 2009 through 2017 (nine years), the period in which Navy began implementing effective mitigation measures to reduce the likelihood of vessel strikes. In order to

account for the accidental nature of vessel strikes to large whales in general, and the potential risk from any vessel movement within the AFTT Study Area within the five-year period, the Navy requested incidental takes based on probabilities derived from a Poisson distribution using ship strike data between 2009–2016 in the AFTT Study Area (the time period from when current mitigations were instituted until the Navy conducted the analysis for the EIS and application), and no new strikes have occurred since), as well as historical at-sea days in AFTT from 2009–2016 and estimated potential at-sea days for the period from 2018 to 2023 covered by the requested regulations. This distribution predicted the probabilities of a specific number of strikes (n=0, 1, 2, etc.) over the period from 2018 to 2023. The analysis is described in detail in Chapter 6 of the Navy's rulemaking/LOA application (and further refined in the Navy's revised ship strike analysis posted on NMFS' website *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

For the same reasons listed above describing why Navy vessel strike is comparatively unlikely, it is highly unlikely that a Navy vessel would strike a whale or dolphin without detecting it and, accordingly, NMFS is confident that the Navy's reported strikes are accurate and appropriate for use in the analysis. The Navy used those three whale strikes in their calculations to determine the number of strikes likely to result from their activities (although worldwide strike information, from all Navy activities and other strikes, was used to inform the species that may be struck) and evaluated data beginning in 2009 as that was the start of the Navy's Marine Species Awareness Training and adoption of additional mitigation measures to address ship strike, which will remain in place along with additional mitigation measures during the five years of this rule.

The probability analysis concluded that there was a 15 percent chance that zero whales would be struck by Navy vessels over the next five years, indicating an 85 percent chance that at least one whale would be struck over the next five years and a 17 percent chance of striking three whales over the five-year period. In addition, small delphinids are neither expected nor authorized to be struck by Navy vessels since: They have not been struck historically as a result of Navy AFTT activities, their smaller size and maneuverability makes a strike from a larger vessel much less likely as illustrated in worldwide ship-strike records, and the majority of the Navy's faster-moving activities are located in offshore areas where smaller delphinid densities are less. Accordingly, NMFS anticipates and authorizes takes by vessel strike of large whales only (*i.e.,* no dolphins or smaller whales) over the course of the five-year regulations from training and testing activities as discussed below.

Based on the above analysis, the Navy estimated that it has the potential to strike, and take by serious injury or mortality, up to three large whales incidental to the specified activity over the course of the five years of the AFTT regulations. Because of the number of incidents in which the struck animal has remained unidentified to species (although due to the Navy's particular measures to avoid NARW, it is unlikely that any of the three vessel strikes were of NARW), it is challenging to predict the number of the potential takes that will be of any particular species. The Navy requested incidental take authorization for up to two of any the following species in the five-year period: Humpback whale (Gulf of Maine stock), fin whale (Western North Atlantic stock), minke (Canadian East Coast stock), and sperm whale (North Atlantic stock) and one of any of the following: Sei whale (Nova Scotia stock), blue whale (Western North Atlantic stock), sperm whale (GOMEX Oceanic stock). NMFS independently reviewed this analysis and agrees that three ship strikes have at least the potential to occur and therefore the request for mortal takes of three large whales over the five-year period of the rule is reasonable based on the available strike data (three strikes by Navy over nine years) and the Navy's probability analysis. NMFS does not agree, however, that two mortal takes of any one species is likely, or that strike of either blue whales or the GOMEX stock of sperm whales is remotely likely.

In order to predict the likelihood of striking any particular species, NMFS compiled information from the latest NMFS 2018 SARs on detected annual rates of large whale serious injury and mortality from vessel collisions (Table 42 below), which represent the best available science. The annual rates of large whale serious injury and mortality from vessel collisions indicate the relative susceptibility of large whale species to vessel strike in the Atlantic Ocean and GOMEX. To calculate the relative likelihood of striking each species, we summed the annual rates of mortality and serious injury from vessel collisions, then divided each species' annual rate by this number. To estimate the percent likelihood of striking a particular species of large whale, we multiplied the relative likelihood of striking each species by the total probability of striking a whale (*i.e.,* 85 percent, as described by the Navy's probability analysis). To calculate the percent likelihood of striking a particular species of large whale twice, we squared the value estimated for the probability of striking a particular species of whale (*i.e.,* to calculate the probability of an event occurring twice, multiply the probability of the first event by the second). The analysis indicates that there is a very low percent chance of striking any particular species or stock more than once (*i.e.,* less than 7 percent chance for all species) as shown in Table 42 below and, accordingly, in the proposed rule NMFS proposed that any of the mysticete and sperm whale stocks might incur one serious injury or mortality take by vessel strike over the five-year period of the rule, except the NARW which would have zero mortality/serious injury takes because of the enhanced mitigation and the Bryde's whale, which would also have zero mortality/serious injury takes because of their low numbers and lack of previous strikes

However, based on the quantitative method above, blue whales and GOMEX sperm whales also have a zero percent chance of being struck. Following additional discussion with the Navy (after the proposed rule was published) about this quantitative analysis, the Navy's activities, and other factors—and NMFS' independent review—NMFS and the Navy agreed that vessel strike of these two stocks was highly unlikely. Accordingly, the Navy revised their request for take by serious injury or mortality to include up to one of any the following species in the five-year period: Humpback whale (Gulf of Maine stock), fin whale (Western North Atlantic stock), minke whale (Canadian East Coast stock), sperm whale (North Atlantic stock), and sei whale (Nova Scotia stock)—removing the request for GOMEX sperm whales and North Atlantic blue whales. We note that the quantitative method outlined above indicates only a very small likelihood that the Navy will strike a North Atlantic sperm whale (< 3 percent), however, the Navy has struck a sperm whale previously in the Atlantic, which points to a higher likelihood that it could occur and that an authorized mortality is appropriate. Additional discussion relevant to our determinations for North Atlantic blue

whales, GOMEX sperm whale, NARW, and Bryde's whale is included below.

In addition to the zero probability predicted by the quantitative model, there are no recent confirmed records of vessel collision mortality or serious injury to blue whales in the U.S. Atlantic EEZ, although there is one older historical record pointing to a ship strike that likely occurred outside of the U.S. Atlantic EEZ (outside of where most Navy activities occur, so less relevant) and one 1998 record of a dead 20 m (66 ft) male blue whale brought into Rhode Island waters on the bow of a tanker. The cause of death was determined to be ship strike; however, some of the injuries were difficult to explain from the necropsy. As noted previously, the Navy has been conducting Marine Species Awareness Training and implementing additional mitigation measures to protect against strikes since 2009. Therefore, given the absence of any strikes in the recent past since the Navy has implemented its current mitigation measures, the very low abundance of North Atlantic blue whales throughout the AFTT Study Area, and the very low number of two blue whales ever known to be struck in the area by any type of vessel (and not struck by Navy vessels), we believe the likelihood of the Navy hitting a blue whale is discountable.

In addition to the zero probability of hitting a sperm whale in the GOMEX predicted by the quantitative model, there have been no vessel strikes of any large whales since 2009 per the SAR and no Navy strikes of any large whales since 1995 (based on our records) in the GOMEX. Further, the Navy has comparatively fewer steaming days in the GOMEX and there is a fairly low abundance of sperm whales occurring there. As noted previously, the Navy has been conducting Marine Species Awareness Training and implementing additional mitigation measures to protect against strikes since 2009. Therefore, NMFS believes that the likelihood of the Navy hitting a GOMEX sperm whale is discountable.

Although the quantitative analysis predicts that NARWs do have a low probability of being struck one time within the five-year period when vessel strikes across all activity types (including non-Navy) are considered (10.11 percent, lower than all other stocks except North Atlantic sperm whales), when the enhanced mitigation measures (discussed below) the Navy will implement for NARWs are considered in combination with this low probability, the Navy and NMFS find that a vessel strike is highly unlikely and therefore, lethal take of NARWs was not requested and is not authorized. We further note that while there have been three strikes of unidentified whales, it is unlikely they were NARW, as one occurred in the Chesapeake Bay and observed features suggested it was most probably a humpback whale, while the other two occurred 75 and 45 nmi offshore from Cape Hatteras, beyond where NARW are expected to occur. Regarding the Bryde's whale, due to the fact that the Navy has not struck a Bryde's whale, the very low abundance numbers, and the limited Navy ship traffic that overlaps with Bryde's whale habitat, neither the Navy nor NMFS anticipate any vessel-strike takes, and none were requested or proposed for authorization. The Navy is now also limiting activities (*i.e.,* 200 hr cap on hull-mounted MFAS) and will not use explosives (except during mine warfare activities) in the Bryde's Whale Mitigation Area.

TABLE 42—ANNUAL RATES OF MORTALITY AND SERIOUS INJURY FROM VESSEL COLLISIONS COMPILED FROM NMFS 2018 SARS AND ESTIMATED PERCENT CHANCE OF STRIKING EACH LARGE WHALE SPECIES IN THE AFTT STUDY AREA OVER A FIVE-YEAR PERIOD

Species	Annual rate of M/SI * from vessel collision	Percent chance of ONE strike	Percent chance of TWO strike
Fin whale—Western North Atlantic stock	1.6	22.67	5.14
Sei whale—Nova Scotia stock	0.8	11.33	1.28
Minke whale—Canadian East Coast stock	1.4	19.83	3.93
Blue whale—Western North Atlantic stock	0	0	0
Humpback whale—Gulf of Maine stock	1.8	25.50	6.50
Sperm whale—North Atlantic stock	0.2	2.83	0.08
Sperm whale—Gulf of Mexico stock	0	0	0

In conclusion, although it is generally unlikely that any whales will be struck in a year, based on the information and analysis above (as well as the additional information regarding NARW mitigation below), NMFS anticipates that no more than three whales could be taken by serious injury or mortality over the five-year period of the rule, and that those three whales may include no more than one of any of the five following stocks (though no more than three total): Humpback whale (Gulf of Maine stock), fin whale (Western North Atlantic stock), minke (Canadian East Coast stock), sperm whale (North Atlantic stock), and sei whale (Nova Scotia stock). Accordingly, NMFS has authorized the serious injury or mortality of 0.2 whales annually from each of these species or stocks (*i.e.,* 1 take divided by 5 years to get the annual number). Below we include additional information regarding the mitigation measures that help avoid ship strike of NARW.

In addition to procedural mitigation, the Navy will implement measures in mitigation areas used by NARW for foraging, calving, and migration (see the *Mitigation Measures* section in this rule and a full analysis in Chapter 5 (Mitigation) of the AFTT FEIS/OEIS). These measures, which go above and beyond those focused on other species (*e.g.,* funding of and communication with sightings systems, implementation of speed reductions during applicable circumstances in certain areas) have helped the Navy avoid striking a NARW during training and testing activities in the past; and essentially eliminate the potential for strikes to occur during the five-year period of the rule. In particular, the mitigation pertaining to vessels, including the continued participation in and sponsoring of the Early Warning System, will help Navy vessels avoid NARW during transits and training and testing activities. The Early Warning System is a comprehensive information exchange network dedicated to reducing the risk of vessel strikes to NARW off the southeast United States from all mariners (*i.e.,* Navy and non-Navy vessels). Navy participants include the Fleet Area

Control and Surveillance Facility, Jacksonville; Commander, Naval Submarine Forces, Norfolk, Virginia; and Naval Submarine Support Command. The Navy, U.S. Coast Guard, U.S. Army Corps of Engineers, and NMFS collaboratively sponsor daily aerial surveys from December 1 through March 31 (weather permitting) to observe for NARW from the shoreline out to approximately 30–35 nmi offshore. Aerial surveyors relay sightings information to all mariners transiting within the NARW calving habitat (*e.g.,* commercial vessels, recreational boaters, and Navy ships).

In the NE NARW Mitigation Area, before all vessel transits, the Navy conducts a web query or email inquiry of NOAA's NARW Sighting Advisory System to obtain the latest NARW sightings information. Navy vessels will use the obtained sightings information to reduce potential interactions with NARW during transits and prevent ship strikes. In this mitigation area, vessels will implement speed reductions after they observe a NARW; if they are within 5 nmi of the location of a sighting reported to the NARW Sighting Advisory System within the past week; and when operating at night or during periods of reduced visibility. During transits and normal firing involving non-explosive torpedos activities, the Navy ships will maintain a speed of no more than 10 kn. During submarine target firing, ships will maintain speeds of no more than 18 kn. During vessel target firing, vessel speeds may exceed 18 kn for only brief periods of time (*e.g.,* 10–15 min). In the SE NARW Mitigation Area, before transiting or conducting training or testing activities within the mitigation area, the Navy will initiate communication with the Fleet Area Control and Surveillance Facility, Jacksonville to obtain Early Warning System NARW whale sightings data. The Fleet Area Control and Surveillance Facility, Jacksonville will advise vessels of all reported whale sightings in the vicinity to help vessels and aircraft reduce potential interactions with NARWs and prevent ship strikes. Commander Submarine Force U.S. Atlantic Fleet will coordinate any submarine activities that may require approval from the Fleet Area Control and Surveillance Facility, Jacksonville. Vessels will use the sightings information to reduce potential interactions with NARW during transits and prevent ship strikes. Vessels will also implement speed reductions after they observe a NARW, if they are within 5 nmi of a sighting reported within the past 12 hrs, or when operating in the mitigation area at night or during periods of poor visibility. To the maximum extent practicable, vessels will minimize north-south transits in the mitigation area. Finally, the Navy will broadcast awareness notification messages with NARW Dynamic Management Area information (*e.g.,* location and dates) to applicable Navy vessels operating in the vicinity of the Dynamic Management Area. The information will alert assets to the possible presence of a NARW to maintain safety of navigation and further reduce the potential for a vessel strike. Navy platforms will use the information to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation, including but not limited to, mitigation for vessel movement.

Implementation of these measures is expected to significantly reduce the probability of striking this particular species during the five-year period of the rule. Ship strikes are a fluke encounter for which the probability will never be zero for any vessel. The probability for any particular ship to strike a marine mammal is primarily a product of the ability of the ship to detect a marine mammal and the ability to effectively act to avoid it. Navy combat ships are inherently among the best at both of these because compared to large commercial vessels, they have trained Lookouts which have received specialized MMO training, and the most maneuverable ships, which means that they are more likely to sight a marine mammal and more likely to be able to maneuver to avoid it in the available time—both of which decrease the probability of striking a marine mammal below what it would have been in the absence of those abilities. In the case of the NARW, the extensive communication/detection network described above, which is in use in the areas of highest NARW occurrence and where they may be more susceptible to strike, further increases the likelihood of detecting a NARW and thereby avoiding it, which further reduces the probability of NARW strike. Further, detection of NARW in some areas/times is associated with reduced speed requirements, which in some cases may reduce the strike probability further by slightly increasing the time within which an operator has to maneuver away from a whale. Because of these additional mitigation measures combined with the already low probability that a NARW will be struck, it is extremely unlikely the Navy will strike a NARW and mortality/serious injury of a NARW from vessel strike is neither anticipated nor authorized.

Mitigation Measures

Under section 101(a)(5)(A) of the MMPA, NMFS must set forth the ''permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse 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 subsistence uses'' (''least practicable adverse impact''). NMFS does not have a regulatory definition for least practicable adverse impact. The NDAA for FY 2004 amended the MMPA as it relates to military readiness activities and the incidental take authorization process such that a determination of ''least practicable adverse impact'' shall include consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the ''military readiness activity.''

In *Conservation Council for Hawaii* v. *National Marine Fisheries Service,* 97 F. Supp.3d 1210, 1229 (D. Haw. 2015), the Court stated that NMFS ''appear[s] to think [it] satisf[ies] the statutory 'least practicable adverse impact' requirement with a 'negligible impact' finding.'' More recently, expressing similar concerns in a challenge to a U.S. Navy Operations of Surveillance Towed Array Sensor System Low Frequency Active Sonar (SURTASS LFA) incidental take rule (77 FR 50290), the Ninth Circuit Court of Appeals in *Natural Resources Defense Council (NRDC)* v. *Pritzker,* 828 F.3d 1125, 1134 (9th Cir. 2016), stated, ''[c]ompliance with the 'negligible impact' requirement does not mean there [is] compliance with the 'least practicable adverse impact' standard.'' As the Ninth Circuit noted in its opinion, however, the Court was interpreting the statute without the benefit of NMFS' formal interpretation. We state here explicitly that NMFS is in full agreement that the ''negligible impact'' and ''least practicable adverse impact'' requirements are distinct, even though both statutory standards refer to species and stocks. With that in mind, we provide further explanation of our interpretation of least practicable adverse impact, and explain what distinguishes it from the negligible impact standard. This discussion is consistent with, and expands upon, previous rules we have issued (such as the Navy Gulf of Alaska rule (82 FR 19530; April 27, 2017)).

Before NMFS can issue incidental take regulations under section

101(a)(5)(A) of the MMPA, it must make a finding that the total taking will have a ''negligible impact'' on the affected ''species or stocks'' of marine mammals. NMFS' and U.S. Fish and Wildlife Service's implementing regulations for section 101(a)(5) both define ''negligible impact'' as ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival'' (50 CFR 216.103 and 50 CFR 18.27(c)). Recruitment (*i.e.,* reproduction) and survival rates are used to determine population growth rates [1] and, therefore are considered in evaluating population level impacts.

As we stated in the preamble to the final rule for the incidental take implementing regulations, not every population-level impact violates the negligible impact requirement. The negligible impact standard does not require a finding that the anticipated take will have ''no effect'' on population numbers or growth rates: ''The statutory standard does not require that the same recovery rate be maintained, rather that no significant effect on annual rates of recruitment or survival occurs. [T]he key factor is the significance of the level of impact on rates of recruitment or survival.'' (54 FR 40338, 40341–42; September 29, 1989).

While some level of impact on population numbers or growth rates of a species or stock may occur and still satisfy the negligible impact requirement—even without consideration of mitigation—the least practicable adverse impact provision separately requires NMFS to prescribe means of ''effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance,'' 50 CFR 216.102(b), which are typically identified as mitigation measures.[2]

The negligible impact and least practicable adverse impact standards in the MMPA both call for evaluation at the level of the ''species or stock.'' The MMPA does not define the term ''species.'' However, Merriam-Webster Dictionary defines ''species'' to include ''related organisms or *populations* potentially capable of interbreeding.'' See *www.merriam-webster.com/dictionary/species* (emphasis added). The MMPA defines ''stock'' as ''a group of marine mammals of the same species or smaller taxa in a common spatial arrangement that interbreed when mature.'' 16 U.S.C. 1362(11). The definition of ''population'' is ''a group of interbreeding organisms that represents the level of organization at which speciation begins.'' *www.merriam-webster.com/dictionary/population.* The definition of ''population'' is strikingly similar to the MMPA's definition of ''stock,'' with both involving groups of individuals that belong to the same species and located in a manner that allows for interbreeding. In fact, the term ''stock'' in the MMPA is interchangeable with the statutory term ''population stock.'' 16 U.S.C. 1362(11). Both the negligible impact standard and the least practicable adverse impact standard call for evaluation at the level of the species or stock, and the terms ''species'' and ''stock'' both relate to populations; therefore, it is appropriate to view both the negligible impact standard and the least practicable adverse impact standard as having a population-level focus.

This interpretation is consistent with Congress's statutory findings for enacting the MMPA, nearly all of which are most applicable at the species or stock (*i.e.,* population) level. *See* 16 U.S.C. 1361 (finding that it is species and population stocks that are or may be in danger of extinction or depletion; that it is species and population stocks that should not diminish beyond being significant functioning elements of their ecosystems; and that it is species and population stocks that should not be permitted to diminish below their optimum sustainable population level). Annual rates of recruitment (*i.e.,* reproduction) and survival are the key biological metrics used in the evaluation of population-level impacts, and accordingly these same metrics are also used in the evaluation of population level impacts for the least practicable adverse impact standard.

Recognizing this common focus of the least practicable adverse impact and negligible impact provisions on the ''species or stock'' does not mean we conflate the two standards; despite some common statutory language, we recognize the two provisions are different and have different functions. First, a negligible impact finding is required before NMFS can issue an incidental take authorization. Although it is acceptable to use the mitigation measures to reach a negligible impact finding (see 50 CFR 216.104(c)), no amount of mitigation can enable NMFS to issue an incidental take authorization for an activity that still would not meet the negligible impact standard. Moreover, even where NMFS can reach a negligible impact finding—which we emphasize does allow for the possibility of some ''negligible'' population-level impact—the agency must still prescribe measures that will affect the least practicable amount of adverse impact upon the affected species or stock.

Section 101(a)(5)(A)(i)(II) requires NMFS to issue, in conjunction with its authorization, binding—and enforceable—restrictions (in the form of regulations) setting forth how the activity must be conducted, thus ensuring the activity has the ''least practicable adverse impact'' on the affected species or stocks. In situations where mitigation is specifically needed to reach a negligible impact determination, section 101(a)(5)(A)(i)(II) also provides a mechanism for ensuring compliance with the ''negligible impact'' requirement. Finally, we reiterate that the least practicable adverse impact standard also requires consideration of measures for marine mammal habitat, with particular attention to rookeries, mating grounds, and other areas of similar significance, and for subsistence impacts, whereas the negligible impact standard is concerned solely with conclusions about the impact of an activity on annual rates of recruitment and survival.[3]

In *NRDC* v. *Pritzker,* the Court stated, ''[t]he statute is properly read to mean that even if population levels are not threatened *significantly,* still the agency must adopt mitigation measures aimed at protecting *marine mammals* to the greatest extent practicable in light of military readiness needs.'' *Id.* at 1134 (emphases added). This statement is consistent with our understanding stated above that even when the effects of an action satisfy the negligible impact standard (*i.e.,* in the Court's words, ''population levels are not threatened significantly''), still the agency must prescribe mitigation under the least practicable adverse impact standard. However, as the statute indicates, the focus of both standards is ultimately the impact on the affected ''species or stock,'' and not solely focused on or directed at the impact on individual marine mammals.

We have carefully reviewed and considered the Ninth Circuit's opinion in *NRDC* v. *Pritzker* in its entirety. While the Court's reference to ''marine mammals'' rather than ''marine mammal species or stocks'' in the italicized

[1] A growth rate can be positive, negative, or flat.

[2] For purposes of this discussion, we omit reference to the language in the standard for least practicable adverse impact that says we also must mitigate for subsistence impacts because they are not at issue in this regulation.

[3] Outside of the military readiness context, mitigation may also be appropriate to ensure compliance with the ''small numbers'' language in MMPA sections 101(a)(5)(A) and (D).

language above might be construed as a holding that the least practicable adverse impact standard applies at the individual ''marine mammal'' level, *i.e.,* that NMFS must require mitigation to minimize impacts to each individual marine mammal unless impracticable, we believe such an interpretation reflects an incomplete appreciation of the Court's holding. In our view, the opinion as a whole turned on the Court's determination that NMFS had not given separate and independent meaning to the least practicable adverse impact standard apart from the negligible impact standard, and further, that the Court's use of the term ''marine mammals'' was not addressing the question of whether the standard applies to individual animals as opposed to the species or stock as a whole. We recognize that while consideration of mitigation can play a role in a negligible impact determination, consideration of mitigation measures extends beyond that analysis. In evaluating what mitigation measures are appropriate, NMFS considers the potential impacts of the Specified Activities, the availability of measures to minimize those potential impacts, and the practicability of implementing those measures, as we describe below.

Implementation of Least Practicable Adverse Impact Standard

Given the *NRDC* v. *Pritzker* decision, we discuss here how we determine whether a measure or set of measures meets the ''least practicable adverse impact'' standard. Our separate analysis of whether the take anticipated to result from Navy's activities meets the ''negligible impact'' standard appears in the *Analysis and Negligible Impact Determination* section below.

Our evaluation of potential mitigation measures includes consideration of two primary factors:

(1) The manner in which, and the degree to which, implementation of the potential measure(s) is expected to reduce adverse impacts to marine mammal species or stocks, their habitat, and their availability for subsistence uses (where relevant). This analysis considers such things as the nature of the potential adverse impact (such as likelihood, scope, and range), the likelihood that the measure will be effective if implemented, and the likelihood of successful implementation; and

(2) The practicability of the measures for applicant implementation. Practicability of implementation may consider such things as cost, impact on activities, and, in the case of a military readiness activity, specifically considers personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity. 16 U.S.C. 1371(a)(5)(A)(iii).

While the language of the least practicable adverse impact standard calls for minimizing impacts to affected species or stocks, we recognize that the reduction of impacts to those species or stocks accrues through the application of mitigation measures that limit impacts to individual animals. Accordingly, NMFS' analysis focuses on measures that are designed to avoid or minimize impacts on individual marine mammals that are likely to increase the probability or severity of population-level effects.

While direct evidence of impacts to species or stocks from a specified activity is rarely available, and additional study is still needed to understand how specific disturbance events affect the fitness of individuals of certain species, there have been improvements in understanding the process by which disturbance effects are translated to the population. With recent scientific advancements (both marine mammal energetic research and the development of energetic frameworks), the relative likelihood or degree of impacts on species or stocks may often be inferred given a detailed understanding of the activity, the environment, and the affected species or stocks. This same information is used in the development of mitigation measures and helps us understand how mitigation measures contribute to lessening effects (or the risk thereof) to species or stocks. We also acknowledge that there is always the potential that new information, or a new recommendation that we had not previously considered, becomes available and necessitates reevaluation of mitigation measures (which may be addressed through adaptive management) to see if further reductions of population impacts are possible and practicable.

In the evaluation of specific measures, the details of the specified activity will necessarily inform each of the two primary factors discussed above (expected reduction of impacts and practicability), and are carefully considered to determine the types of mitigation that are appropriate under the least practicable adverse impact standard. Analysis of how a potential mitigation measure may reduce adverse impacts on a marine mammal stock or species, consideration of personnel safety, practicality of implementation, and consideration of the impact on effectiveness of military readiness activities are not issues that can be meaningfully evaluated through a yes/no lens. The manner in which, and the degree to which, implementation of a measure is expected to reduce impacts, as well as its practicability in terms of these considerations, can vary widely. For example, a time/area restriction could be of very high value for decreasing population-level impacts (*e.g.,* avoiding disturbance of feeding females in an area of established biological importance) or it could be of lower value (*e.g.,* decreased disturbance in an area of high productivity but of less firmly established biological importance). Regarding practicability, a measure might involve restrictions in an area or time that impede the Navy's ability to certify a strike group (higher impact on mission effectiveness), or it could mean delaying a small in-port training event by 30 minutes to avoid exposure of a marine mammal to injurious levels of sound (lower impact). A responsible evaluation of ''least practicable adverse impact'' will consider the factors along these realistic scales. Accordingly, the greater the likelihood that a measure will contribute to reducing the probability or severity of adverse impacts to the species or stock or their habitat, the greater the weight that measure is given when considered in combination with practicability to determine the appropriateness of the mitigation measure, and vice versa. In the evaluation of specific measures, the details of the specified activity will necessarily inform each of the two primary factors discussed above (expected reduction of impacts and practicability), and will be carefully considered to determine the types of mitigation that are appropriate under the least practicable adverse impact standard. We discuss consideration of these factors in greater detail below.

1. *Reduction of adverse impacts to marine mammal species or stocks and their habitat.*[4] The emphasis given to a measure's ability to reduce the impacts on a species or stock considers the degree, likelihood, and context of the anticipated reduction of impacts to individuals (and how many individuals)

[4] We recognize the least practicable adverse impact standard requires consideration of measures that will address minimizing impacts on the availability of the species or stocks for subsistence uses where relevant. Because subsistence uses are not implicated for this action, we do not discuss them. However, a similar framework would apply for evaluating those measures, taking into account the MMPA's directive that we make a finding of no unmitigable adverse impact on the availability of the species or stocks for taking for subsistence, and the relevant implementing regulations.

as well as the status of the species or stock.

The ultimate impact on any individual from a disturbance event (which informs the likelihood of adverse species- or stock-level effects) is dependent on the circumstances and associated contextual factors, such as duration of exposure to stressors. Though any proposed mitigation needs to be evaluated in the context of the specific activity and the species or stocks affected, measures with the following types of effects have greater value in reducing the likelihood or severity of adverse species- or stock-level impacts: Avoiding or minimizing injury or mortality; limiting interruption of known feeding, breeding, mother/young, or resting behaviors; minimizing the abandonment of important habitat (temporally and spatially); minimizing the number of individuals subjected to these types of disruptions; and limiting degradation of habitat. Mitigating these types of effects is intended to reduce the likelihood that the activity will result in energetic or other types of impacts that are more likely to result in reduced reproductive success or survivorship. It is also important to consider the degree of impacts that are expected in the absence of mitigation in order to assess the added value of any potential measures. Finally, because the least practicable adverse impact standard gives NMFS discretion to weigh a variety of factors when determining appropriate mitigation measures and because the focus of the standard is on reducing impacts at the species or stock level, the least practicable adverse impact standard does not compel mitigation for every kind of take, or every individual taken, if that mitigation is unlikely to meaningfully contribute to the reduction of adverse impacts on the species or stock and its habitat, even when practicable for implementation by the applicant.

The status of the species or stock is also relevant in evaluating the appropriateness of potential mitigation measures in the context of least practicable adverse impact. The following are examples of factors that may (either alone, or in combination) result in greater emphasis on the importance of a mitigation measure in reducing impacts on a species or stock: The stock is known to be decreasing or status is unknown, but believed to be declining; the known annual mortality (from any source) is approaching or exceeding the PBR level (as defined in 16 U.S.C. 1362(20)); the affected species or stock is a small, resident population; or the stock is involved in a UME or has other known vulnerabilities, such as recovering from an oil spill.

Habitat mitigation, particularly as it relates to rookeries, mating grounds, and areas of similar significance, is also relevant to achieving the standard and can include measures such as reducing impacts of the activity on known prey utilized in the activity area or reducing impacts on physical habitat. As with species- or stock-related mitigation, the emphasis given to a measure's ability to reduce impacts on a species or stock's habitat considers the degree, likelihood, and context of the anticipated reduction of impacts to habitat. Because habitat value is informed by marine mammal presence and use, in some cases there may be overlap in measures for the species or stock and for use of habitat.

We consider available information indicating the likelihood of any measure to accomplish its objective. If evidence shows that a measure has not typically been effective nor successful, then either that measure should be modified or the potential value of the measure to reduce effects should be lowered.

2. *Practicability.* Factors considered may include cost, impact on activities, and, in the case of a military readiness activity, personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity (16 U.S.C. 1371(a)(5)(A)(iii)).

NMFS reviewed the Specified Activities and the mitigation measures as described in the Navy's rulemaking/LOA application and the AFTT FEIS/OEIS to determine if they would result in the least practicable adverse effect on marine mammals. NMFS worked with the Navy in the development of the Navy's initially proposed measures, which are informed by years of implementation and monitoring. A complete discussion of the evaluation process used to develop, assess, and select mitigation measures, which was informed by input from NMFS, can be found in Chapter 5 (Mitigation) of the AFTT FEIS/OEIS and is summarized below in this section. The process described in Chapter 5 (Mitigation) of the AFTT FEIS/OEIS robustly supports NMFS' independent evaluation of whether the mitigation measures required by this rule meet the least practicable adverse impact standard. The Navy is required to implement the mitigation measures identified in this rule to avoid or reduce potential impacts from acoustic, explosive, and physical disturbance and ship strike stressors.

In summary (and described in more detail below in this section), the Navy has agreed to procedural mitigation measures that will reduce the probability and/or severity of impacts expected to result from acute exposure to acoustic sources or explosives, ship strike, and impacts to marine mammal habitat. Specifically, the Navy will use a combination of delayed starts, powerdowns, and shutdowns to minimize or avoid serious injury or mortality, minimize the likelihood or severity of PTS or other injury, and reduce instances of TTS or more severe behavioral disruption caused by acoustic sources or explosives. The Navy also will implement multiple time/area restrictions (several of which have been added since the previous AFTT MMPA incidental take rule) that would reduce take of marine mammals in areas or at times where they are known to engage in important behaviors, such as feeding or calving, where the disruption of those behaviors would have a higher probability of resulting in impacts on reproduction or survival of individuals that could lead to population-level impacts.

Since the proposed rule, NMFS and the Navy have agreed to additional mitigation measures that are expected to reduce the likelihood and/or severity of adverse impacts on marine mammal species/stocks and their habitat and are practicable for implementation. Below we summarize the added measures and describe the manner in which they are expected to reduce the likelihood or severity of adverse impacts on marine mammal species or stocks and their habitat. A full description of each measure is included in the mitigation tables below.

1. Pre-event in-water explosive event observations—The Navy will implement pre-event observation as part of all in-water explosive event mitigations. Additionally, if there are other platforms participating in these events (beyond the vessel or aircraft in which required Lookout(s) are located) and in the vicinity of the detonation area, they will also visually observe this area as part of the mitigation team. This added monitoring for a subset of activities for which it was not previously required (explosive bombs, missiles and rockets, projectiles, torpedoes, grenades, and line charge testing) in advance of explosive events increases the likelihood that marine mammals will be detected if they are in the mitigation area and that, if any animals are detected, explosions will be delayed by timely mitigation implementation, thereby further reducing the already low likelihood that animals will be injured or killed by the blast.

2. Post-event in-water explosive event observations—The Navy will implement post-event observation as part of all in-

water explosive event mitigations. Additionally, if there are other platforms participating in these events (beyond the vessel or aircraft in which required Lookout(s) are located) and in the vicinity of the detonation area, they will also visually observe this area as part of the mitigation team. This added monitoring for a subset of activities for which it was not previously required (explosive bombs, missiles and rockets, projectiles, torpedoes, grenades, and line charge testing) increases the likelihood that any injured marine mammals would be detected following an explosive event, which would increase our understanding of impacts and could potentially inform mitigation changes via the adaptive management provisions.

3. NE NARW Mitigation Area—The Navy will expand the NE NARW Mitigation Area to match the updated NE NARW ESA-designated critical habitat. All of the mitigation required in the NE NARW Mitigation Area and discussed in the proposed rule (see Table 63 in the proposed rule) will apply to the expanded NE NARW Mitigation Area. The reduction of activities in, and increase of protective measures in (discussed elsewhere), areas with higher concentrations of NARWs engaged in important feeding activities (such as they are in this area), is expected to reduce the probability and/or severity of impacts on NARWs that would be more likely to adversely affect the fitness of any individual, which in turn reduces the likelihood that any impacts would translate to adverse impacts on the stock.

4. NARW Dynamic Management Area notification—The Navy has agreed to broadcast awareness notification messages with NARW Dynamic Management Area information (*e.g.,* location and dates) to applicable Navy vessels operating in the vicinity of NARW Dynamic Management Areas. The information will alert vessels to the possible presence of a NARW to maintain safety of navigation and further reduce the potential for a vessel strike. Any expanded mechanisms for detecting NARW, either directly around a vessel or in the wider area to increase vigilance for vessels, further reduce the probability that a whale will be struck.

5. Gulf of Maine Planning Awareness Mitigation Area—The Navy will not conduct MTEs in this area. If the Navy identifies a National Security requirement to conduct an MTE, Navy will confer with NMFS to determine/verify that potential effects are addressed under the NEPA/MMPA/ESA analyses. The Navy will implement a 200 hr/year hull-mounted MFAS cap and include all sonar and explosives usage in the Gulf of Maine Planning Awareness Mitigation Area in the annual training and testing activity reports. Any limitation of activities in, and/or increase of protective measures in, areas with higher concentrations of NARW, fin whales, sei whales, humpback whales and minke whales engaged in important feeding activities (such as this area), is expected to reduce the probability and/or severity of impacts on NARW and other mysticetes that would be more likely to adversely affect the fitness of any individual, which in turn reduces the likelihood that any impacts would translate to adverse impacts on the stock. Reduction of MTEs in this area will also reduce the severity of impacts to the small resident population of harbor porpoises (Gulf of Maine stock).

6. Bryde's Whale Mitigation Area—The Navy (1) has agreed to the addition of a year-round, Bryde's Whale Mitigation Area, which will cover the BIA as described in NMFS' 2016 Status Review and include the area between 100 to 400 m isobaths between 87.5 degrees W to 27.5 degrees N; (2) has agreed to move the northern GOMEX ship shock trial box west, out of the Bryde's whale BIA/Bryde's Whale Mitigation Area, including a five nmi buffer; (3) will also implement a 200 hr/year hull-mounted MFAS cap and restrict all explosives except for mine warfare activities events in the Bryde's Whale Mitigation Area; and (4) will report the total hours and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS. Any limitation of activities in the Bryde's whale mitigation area is expected to reduce the probability and/or severity of impacts on Bryde's whales that would be more likely to adversely affect the fitness of any individual, which in turn reduces the likelihood that any impacts would translate to adverse impacts on the stock.

7. GOMEX Planning Awareness Mitigation Area—This area has been expanded to cover the BIA as described in NMFS' 2016 Status Review and include the area between 100 to 400 m isobaths between 87.5° W to 27.5° N. The Navy will not conduct MTEs in this area. If the Navy identifies a National Security requirement to conduct an MTE, Navy will confer with NMFS to determine/verify potential effects are addressed under the NEPA/MMPA/ESA analyses. Any limitation of activities in the area in which Bryde's whales are limited to is expected to reduce the probability and/or severity of impacts on NARWs that would be more likely to adversely affect the fitness of any individual, which in turn reduces the likelihood that any impacts would translate to adverse impacts on the stock.

8. Testing Event Removal—The Navy has removed one of their testing activities in the Northeast Range Complex (four events—USWT), which decreased the number of Level B harassment takes annually for NARW by 115 takes. This change also decreased annual Level B harassment takes by approximately 200 takes for ESA-listed fin whale and 20 takes for sei whales, as well as approximately 10,000 takes annually for harbor porpoise.

9. Jacksonville Operating Area Mitigation Area (November 15 through April 15)—The Navy will implement additional coordination and obtain Early Warning System NARW sightings data to aid in the implementation of procedural mitigation to minimize potential interactions with NARW in the Jacksonville Operating Area. This additional coordination will increase the likelihood that a NARW is detected and action taken to avoid vessel strike, thus further reducing the probability of a NARW strike.

10. SE NARW Critical Habitat Special Reporting Area (November 15 through April 15)—The Navy will report the total hours and counts of active sonar and in-water explosives used in a SE NARW Critical Habitat Special Reporting Area in its annual training and testing activity reports submitted to NMFS.

11. Navy Cherry Point Range Complex Nearshore Mitigation Area (March through September)—The Navy will minimize use of explosives in the Navy Cherry Point Range Complex Nearshore Mitigation Area to the extent practicable. This area overlaps with the NARW migratory BIA and is expected to reduce impacts to NARW that may be present in March and April.

12. Mid-Atlantic Planning Awareness Areas—The Navy has assessed and agreed to move the ship shock trial box east of the including a 5 nmi buffer. The reduction of activities in, and increase of protective measures in areas with higher concentrations of NARW (such as they are in this area) is expected to reduce the probability and/or severity of impacts on NARW that would be more likely to adversely affect the fitness of any individual, which in turn reduces the likelihood that any impacts would translate to adverse impacts on the stock.

The Navy assessed the measures it has agreed to in the context of personnel safety, practicality of implementation,

and their impacts on the Navy's ability to meet their Title 10 requirements and found that the measures were supportable. As described above, NMFS has independently evaluated all of the measures the Navy has committed to (including those above added since the proposed rule was published) in the manner described earlier in this section (*i.e.,* in consideration of their ability to reduce adverse impacts on marine mammal species and stocks and their habitat and their practicability for implementation). We have determined that the additional measures will further reduce impacts on the affected marine mammal species and stocks and their habitat beyond the initial measures proposed and, further, be practicable for Navy implementation.

The Navy also evaluated numerous measures in its AFTT FEIS/OEIS that were not included in the Navy's rulemaking/LOA application for the Specified Activities, and NMFS independently reviewed and concurs with Navy's analysis that their inclusion was not appropriate under the least practicable adverse impact standard based on our assessment. The Navy considered these additional potential mitigation measures in two groups. First, Chapter 5 (Mitigation) of the AFTT FEIS/OEIS, in the *Measures Considered but Eliminated* section, includes an analysis of an array of different types of mitigation that have been recommended over the years by non-governmental organizations (NGOs) or the public, through scoping or public comment on environmental compliance documents. As described in Chapter 5 of the AFTT FEIS/OEIS, commenters sometimes recommend that the Navy reduce their overall amount of training, reduce explosive use, modify their sound sources, completely replace live training with computer simulation, or include time of day restrictions. All of these mitigation measures could potentially reduce the number of marine mammals taken, via direct reduction of the activities or amount of sound energy put in the water. However, as the Navy has described in Chapter 5 *Mitigation* of the AFTT FEIS/OEIS, the Navy needs to train and test in the conditions in which it fights—and these types of modifications fundamentally change the activity in a manner that would not support the purpose and need for the training and testing (*i.e.,* are entirely impracticable) and therefore are not considered further. NMFS finds the Navy's explanation for why adoption of these recommendations would unacceptably undermine the purpose of the testing and training persuasive. After independent review, NMFS finds the Navy's judgment on the impacts of potential mitigation measures to personnel safety, practicality of implementation and the undermining of the effectiveness of training and testing persuasive, and for these reasons, NMFS finds that these measures do not meet the least practicable adverse impact standard because they are not practicable.

Second, in Chapter 5 *Mitigation* of the AFTT FEIS/OEIS, the Navy evaluated additional potential procedural mitigation measures, including increased mitigation zones, additional passive acoustic and visual monitoring, and decreased vessel speeds. Some of these measures have the potential to incrementally reduce take to some degree in certain circumstances, though the degree to which this would occur is typically low or uncertain. However, as described in the Navy's analysis, the measures would have significant direct negative effects on mission effectiveness and are considered impracticable (see Chapter 5 *Mitigation* of AFTT FEIS/OEIS). NMFS independently reviewed and concurred with the Navy's evaluation and concurred with this assessment, which supports NMFS' findings that the impracticability of this additional mitigation would greatly outweigh any potential minor reduction in marine mammal impacts that might result; therefore, these additional mitigation measures are not required under the least practicable adverse impact standard.

NMFS has independently reviewed the Navy's mitigation analysis (Chapter 5 *Mitigation* of the AFTT FEIS/OEIS as referenced above), which considers the same factors that NMFS would consider to satisfy the least practical adverse impact standard, and concurs with the conclusions. Therefore, NMFS is not proposing to include any additional measures in these regulations, other than the new measures that were agreed upon after the proposed rule. Below are the mitigation measures that NMFS determined will ensure the least practicable adverse impact on all affected species and stocks and their habitat, including the specific considerations for military readiness activities. The following sections summarize the mitigation measures that will be implemented in association with the training and testing activities analyzed in this document. The Navy's mitigation measures are organized into two categories: procedural mitigation and mitigation areas.

Procedural Mitigation

Procedural mitigation is mitigation that the Navy will implement whenever and wherever an applicable training or testing activity takes place within the AFTT Study Area. The Navy customizes procedural mitigation for each applicable activity category or stressor. Procedural mitigation generally involves: (1) The use of one or more trained Lookouts to diligently observe for specific biological resources (including marine mammals) within a mitigation zone, (2) requirements for Lookouts to immediately communicate sightings of specific biological resources to the appropriate watch station for information dissemination, and (3) requirements for the watch station to implement mitigation (*e.g.,* halt an activity) until certain recommencement conditions have been met. The first procedural mitigation (Table 43) is designed to aid Lookouts and other applicable personnel with their observation, environmental compliance, and reporting responsibilities. The remainder of the procedural mitigation measures (Tables 44 through Tables 63) are organized by stressor type and activity category and includes acoustic stressors (*i.e.,* active sonar, air guns, pile driving, weapons firing noise), explosive stressors (*i.e.,* sonobuoys, torpedoes, medium-caliber and large-caliber projectiles, missiles and rockets, bombs, sinking exercises, mines, anti-swimmer grenades, line charge testing and ship shock trials), and physical disturbance and strike stressors (*i.e.,* vessel movement, towed in-water devices, small-, medium-, and large-caliber non-explosive practice munitions, non-explosive missiles and rockets, non-explosive bombs and mine shapes).

TABLE 43—PROCEDURAL MITIGATION FOR ENVIRONMENTAL AWARENESS AND EDUCATION

Procedural Mitigation Description
Stressor or Activity:
• All training and testing activities, as applicable.
Mitigation Requirements:

TABLE 43—PROCEDURAL MITIGATION FOR ENVIRONMENTAL AWARENESS AND EDUCATION—Continued

Procedural Mitigation Description
• Appropriate personnel (including civilian personnel) involved in mitigation and training or testing activity reporting under the Proposed Action must complete one or more modules of the U.S. Navy Afloat Environmental Compliance Training Series, as identified in their career path training plan. Modules include: —Introduction to the U.S. Navy Afloat Environmental Compliance Training Series. The introductory module provides information on environmental laws (*e.g.*, ESA, MMPA) and the corresponding responsibilities that are relevant to Navy training and testing activities. The material explains why environmental compliance is important in supporting the Navy's commitment to environmental stewardship. —Marine Species Awareness Training. All bridge watch personnel, Commanding Officers, Executive Officers, maritime patrol aircraft aircrews, anti-submarine warfare and mine warfare rotary-wing aircrews, Lookouts, and equivalent civilian personnel must successfully complete the Marine Species Awareness Training prior to standing watch or serving as a Lookout. The Marine Species Awareness Training provides information on sighting cues, visual observation tools and techniques, and sighting notification procedures. Navy biologists developed Marine Species Awareness Training to improve the effectiveness of visual observations for biological resources, focusing on marine mammals and sea turtles, and including floating vegetation, jellyfish aggregations, and flocks of seabirds. —U.S. Navy Protective Measures Assessment Protocol. This module provides the necessary instruction for accessing mitigation requirements during the event planning phase using the Protective Measures Assessment Protocol software tool. —U.S. Navy Sonar Positional Reporting System and Marine Mammal Incident Reporting. This module provides instruction on the procedures and activity reporting requirements for the Sonar Positional Reporting System and marine mammal incident reporting.

Procedural Mitigation for Acoustic Stressors

Mitigation measures for acoustic stressors are provided in Tables 44 through 47.

Procedural Mitigation for Active Sonar

Procedural mitigation for active sonar is described in Table 44 below.

TABLE 44—PROCEDURAL MITIGATION FOR ACTIVE SONAR

Procedural Mitigation Description
Stressor or Activity: • Low-frequency active sonar, mid-frequency active sonar, high-frequency active sonar: —For vessel-based activities, mitigation applies only to sources that are positively controlled and deployed from manned surface vessels (*e.g.*, sonar sources towed from manned surface platforms). —For aircraft-based activities, mitigation applies only to sources that are positively controlled and deployed from manned aircraft that do not operate at high altitudes (*e.g.*, rotary-wing aircraft). Mitigation does not apply to active sonar sources deployed from unmanned aircraft or aircraft operating at high altitudes (*e.g.*, maritime patrol aircraft). Number of Lookouts and Observation Platform: • Hull-mounted sources: —1 Lookout: Platforms with space or manning restrictions while underway (at the forward part of a small boat or ship) and platforms using active sonar while moored or at anchor (including pierside). —2 Lookouts: Platforms without space or manning restrictions while underway (at the forward part of the ship). —4 Lookouts: Pierside sonar testing activities at Port Canaveral, Florida and Kings Bay, Georgia. • Sources that are not hull-mounted: —1 Lookout on the ship or aircraft conducting the activity. Mitigation Requirements: • Mitigation zones: —During the activity, at 1,000 yd power down 6 dB, at 500 yd power down an additional 4 dB (for a total of 10 dB), and at 200 yd shut down for low-frequency active sonar ≥200 decibels (dB) and hull-mounted mid-frequency active sonar. —200 yd. shut down for low-frequency active sonar <200 dB, mid-frequency active sonar sources that are not hull-mounted, and high-frequency active sonar. • Prior to the initial start of the activity (*e.g.*, when maneuvering on station): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, relocate or delay the start of active sonar transmission. • During the activity: —Low-frequency active sonar ≥200 decibels (dB) and hull-mounted mid-frequency active sonar: Observe the mitigation zone for marine mammals; power down active sonar transmission by 6 dB if observed within 1,000 yd. of the sonar source; power down an additional 4 dB (10 dB total) within 500 yd.; cease transmission within 200 yd. —Low-frequency active sonar <200 dB, mid-frequency active sonar sources that are not hull-mounted, and high-frequency active sonar: Observe the mitigation zone for marine mammals; cease active sonar transmission if observed within 200 yd. of the sonar source. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing or powering up active sonar transmission) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the sonar source; (3) the mitigation zone has been clear from any additional sightings for 10 min for aircraft-deployed sonar sources or 30 min for vessel-deployed sonar sources; (4) for mobile activities, the active sonar source has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting; or (5) for activities using hull-mounted sonar, the ship concludes that dolphins are deliberately closing in on the ship to ride the ship's bow wave, and are therefore out of the main transmission axis of the sonar (and there are no other marine mammal sightings within the mitigation zone).

Procedural Mitigation for Air Guns

Procedural mitigation for air guns is described in Table 45 below.

TABLE 45—PROCEDURAL MITIGATION FOR AIR GUNS

Procedural Mitigation Description
Stressor or Activity: • Air guns. Number of Lookouts and Observation Platform: • 1 Lookout positioned on a ship or pierside. Mitigation Requirements: • Mitigation zone: —150 yd around the air gun. • Prior to the initial start of the activity (*e.g.*, when maneuvering on station): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, relocate or delay the start of air gun use. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease air gun use. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing air gun use) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the air gun; (3) the mitigation zone has been clear from any additional sightings for 30 min; or (4) for mobile activities, the air gun has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

Procedural Mitigation for Pile Driving

Procedural mitigation for pile driving is described in Table 46 below.

TABLE 46—PROCEDURAL MITIGATION FOR PILE DRIVING

Procedural Mitigation Description
Stressor or Activity: • Pile driving and pile extraction sound during Elevated Causeway System training. Number of Lookouts and Observation Platform: • 1 Lookout positioned on the shore, the elevated causeway, or a small boat. Mitigation Requirements: • Mitigation zone: —100 yd. around the pile. • Prior to the initial start of the activity (for 30 min): —Observe the mitigation zone for floating vegetation; if observed, delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, delay the start of pile driving or vibratory pile extraction. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease impact pile driving or vibratory pile extraction. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing pile driving or pile extraction) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the pile driving location; or (3) the mitigation zone has been clear from any additional sightings for 30 min.

Procedural Mitigation for Weapons Firing Noise

Procedural mitigation for weapons firing noise is described in Table 47 below.

TABLE 47— PROCEDURAL MITIGATION FOR WEAPONS FIRING NOISE

Procedural Mitigation Description
Stressor or Activity: • Weapons firing noise associated with large-caliber gunnery activities. Number of Lookouts and Observation Platform: • 1 Lookout positioned on the ship conducting the firing. • Depending on the activity, the Lookout could be the same one described for Explosive Medium-Caliber and Large-Caliber Projectiles or Small-, Medium-, and Large-Caliber Non-Explosive Practice Munitions. Mitigation Requirements:

TABLE 47— PROCEDURAL MITIGATION FOR WEAPONS FIRING NOISE—Continued

Procedural Mitigation Description
• Mitigation zone: —30° on either side of the firing line out to 70 yd from the muzzle of the weapon being fired. • Prior to the initial start of the activity: —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, relocate or delay the start of weapons firing. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease weapons firing. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing weapons firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the firing ship; (3) the mitigation zone has been clear from any additional sightings for 30 min; or (4) for mobile activities, the firing ship has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

Procedural Mitigation for Explosive Stressors

Mitigation measures for explosive stressors are provided in Tables 48 through 58.

Procedural Mitigation for Explosive Sonobuoys

Procedural mitigation for explosive sonobuoys is described in Table 48 below.

TABLE 48—PROCEDURAL MITIGATION FOR EXPLOSIVE SONOBUOYS

Procedural Mitigation Description
Stressor or Activity: • Explosive sonobuoys. Number of Lookouts and Observation Platform: • 1 Lookout positioned in an aircraft or on small boat. • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties. Mitigation Requirements: • Mitigation zone: —600 yd. around an explosive sonobuoy. • Prior to the initial start of the activity (*e.g.,* during deployment of a sonobuoy field, which typically lasts 20–30 min): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Conduct passive acoustic monitoring for marine mammals; use information from detections to assist visual observations. —Visually observe the mitigation zone for marine mammals; if observed, relocate or delay the start of sonobuoy or source/receiver pair detonations. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease sonobuoy or source/receiver pair detonations. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the sonobuoy; or (3) the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained. • After completion of the activity (*e.g.,* prior to maneuvering off station): —When practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), these assets must assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Explosive Torpedoes

Procedural mitigation for explosive torpedoes is described in Table 49 below.

TABLE 49—PROCEDURAL MITIGATION FOR EXPLOSIVE TORPEDOES

Procedural Mitigation Description
Stressor or Activity: • Explosive torpedoes. Number of Lookouts and Observation Platform:

TABLE 49—PROCEDURAL MITIGATION FOR EXPLOSIVE TORPEDOES—Continued

Procedural Mitigation Description
• 1 Lookout positioned in an aircraft. • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties. Mitigation Requirements: • Mitigation zone: —2,100 yd around the intended impact location. • Prior to the initial start of the activity (*e.g.,* during deployment of the target): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Conduct passive acoustic monitoring for marine mammals; use information from detections to assist visual observations. —Visually observe the mitigation zone for marine mammals and jellyfish aggregations; if observed, relocate or delay the start of firing. • During the activity: —Observe the mitigation zone for marine mammals and jellyfish aggregations; if observed, cease firing. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or (3) the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained. • After completion of the activity (*e.g.,* prior to maneuvering off station): —When practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), these assets must assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Medium- and Large-Caliber Projectiles

Procedural mitigation for medium- and large-caliber projectiles is described in Table 50 below.

TABLE 50—PROCEDURAL MITIGATION FOR EXPLOSIVE MEDIUM-CALIBER AND LARGE-CALIBER PROJECTILES

Procedural Mitigation Description
Stressor or Activity: • Gunnery activities using explosive medium-caliber and large-caliber projectiles: —Mitigation applies to activities using a surface target. Number of Lookouts and Observation Platform: • 1 Lookout on the vessel or aircraft conducting the activity. • For activities using explosive large-caliber projectiles, depending on the activity, the Lookout could be the same as the one described for Weapons Firing Noise. • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties. Mitigation Requirements: • Mitigation zones: —200 yd around the intended impact location for air-to-surface activities using explosive medium-caliber projectiles. —600 yd around the intended impact location for surface-to-surface activities using explosive medium-caliber projectiles. —1,000 yd around the intended impact location for surface-to-surface activities using explosive large-caliber projectiles. • Prior to the initial start of the activity (*e.g.,* when maneuvering on station): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, relocate or delay the start of firing. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease firing. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; (3) the mitigation zone has been clear from any additional sightings for 10 min for aircraft-based firing or 30 min for vessel-based firing; or (4) for activities using mobile targets, the intended impact location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting. • After completion of the activity (*e.g.,* prior to maneuvering off station): —When practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), these assets must assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Explosive Missiles and Rockets

Procedural mitigation for explosive missiles and rockets is described in Table 51 below.

TABLE 51—PROCEDURAL MITIGATION FOR EXPLOSIVE MISSILES AND ROCKETS

Procedural Mitigation Description
Stressor or Activity: • Aircraft-deployed explosive missiles and rockets: —Mitigation applies to activities using a surface target. Number of Lookouts and Observation Platform: • 1 Lookout positioned in an aircraft. • If additional platforms are participating in the activity, personnel positioned in those assets (e.g., safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties. Mitigation Requirements: • Mitigation zones: —900 yd around the intended impact location for missiles or rockets with 0.6–20 lb net explosive weight. —2,000 yd around the intended impact location for missiles with 21–500 lb net explosive weight. • Prior to the initial start of the activity (*e.g.,* during a fly-over of the mitigation zone): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, relocate or delay the start of firing. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease firing. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or (3) the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained. • After completion of the activity (*e.g.,* prior to maneuvering off station): —When practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), these assets must assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Explosive Bombs

Procedural mitigation for explosive bombs is described in Table 52 below.

TABLE 52—PROCEDURAL MITIGATION FOR EXPLOSIVE BOMBS

Procedural Mitigation Description
Stressor or Activity: • Explosive bombs. Number of Lookouts and Observation Platform: • 1 Lookout positioned in the aircraft conducting the activity. • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties. Mitigation Requirements: • Mitigation zone: —2,500 yd around the intended target. • Prior to the initial start of the activity (*e.g.,* when arriving on station): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, relocate or delay the start of bomb deployment. • During the activity (*e.g.,* during target approach): —Observe the mitigation zone for marine mammals; if observed, cease bomb deployment. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing bomb deployment) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended target; (3) the mitigation zone has been clear from any additional sightings for 10 min; or (4) for activities using mobile targets, the intended target has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting. • After completion of the activity (*e.g.,* prior to maneuvering off station): —When practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), these assets must assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Sinking Exercises

Procedural mitigation for sinking exercises is described in Table 53 below.

TABLE 53—PROCEDURAL MITIGATION FOR SINKING EXERCISES

Procedural Mitigation Description
Stressor or Activity: • Sinking exercises. Number of Lookouts and Observation Platform: • 2 Lookouts (one positioned in an aircraft and one on a vessel). • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties. Mitigation Requirements: • Mitigation zone: —2.5 nmi around the target ship hulk. • Prior to the initial start of the activity (90 min prior to the first firing): —Conduct aerial observations of the mitigation zone for floating vegetation; delay the start until the mitigation zone is clear. —Conduct aerial observations of the mitigation zone for marine mammals and jellyfish aggregations; if observed, delay the start of firing. • During the activity: —Conduct passive acoustic monitoring for marine mammals; use information from detections to assist visual observations. —Visually observe the mitigation zone for marine mammals from the vessel; if observed, cease firing. —Immediately after any planned or unplanned breaks in weapons firing of longer than 2 hrs, observe the mitigation zone for marine mammals from the aircraft and vessel; if observed, delay recommencement of firing. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the target ship hulk; or (3) the mitigation zone has been clear from any additional sightings for 30 min. • After completion of the activity (for 2 hrs after sinking the vessel or until sunset, whichever comes first): —Observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), these assets must assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Explosive Mine Countermeasure and Neutralization Activities

Procedural mitigation for explosive mine countermeasure and neutralization activities is described in Table 54 below.

TABLE 54—PROCEDURAL MITIGATION FOR EXPLOSIVE MINE COUNTERMEASURE AND NEUTRALIZATION ACTIVITIES

Procedural Mitigation Description
Stressor or Activity: • Explosive mine countermeasure and neutralization activities. Number of Lookouts and Observation Platform: • 1 Lookout positioned on a vessel or in an aircraft when implementing the smaller mitigation zone. • 2 Lookouts (one positioned in an aircraft and one on a small boat) when implementing the larger mitigation zone. • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties. Mitigation Requirements: • Mitigation zones: —600 yd around the detonation site for activities using 0.1–5-lb net explosive weight. —2,100 yd around the detonation site for activities using 6–650 lb net explosive weight (including high explosive target mines). • Prior to the initial start of the activity (*e.g.,* when maneuvering on station; typically, 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, relocate or delay the start of detonations. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease detonations. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to detonation site; or (3) the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained. • After completion of the activity (typically 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained): —Observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), these assets must assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Explosive Mine Neutralization Activities Involving Navy Divers

Procedural mitigation for explosive mine neutralization activities involving Navy divers is described in Table 55 below.

TABLE 55—PROCEDURAL MITIGATION FOR EXPLOSIVE MINE NEUTRALIZATION ACTIVITIES INVOLVING NAVY DIVERS

Procedural Mitigation Description
Stressor or Activity: • Explosive mine neutralization activities involving Navy divers. Number of Lookouts and Observation Platform: • 2 Lookouts (two small boats with one Lookout each, or one Lookout on a small boat and one in a rotary-wing aircraft) when implementing the smaller mitigation zone. • 4 Lookouts (two small boats with two Lookouts each), and a pilot or member of an aircrew must serve as an additional Lookout if aircraft are used during the activity, when implementing the larger mitigation zone. • All divers placing the charges on mines must support the Lookouts while performing their regular duties and must report applicable sightings to their supporting small boat or Range Safety Officer. • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties. Mitigation Requirements:

TABLE 55—PROCEDURAL MITIGATION FOR EXPLOSIVE MINE NEUTRALIZATION ACTIVITIES INVOLVING NAVY DIVERS—Continued

Procedural Mitigation Description
• Mitigation zones: —500 yd around the detonation site during activities under positive control using 0.1–20 lb net explosive weight. —1,000 yd around the detonation site during activities using time-delay fuses (0.1–20 lb net explosive weight) and during activities under positive control using 21–60 lb net explosive weight charges. • Prior to the initial start of the activity (*e.g.,* when maneuvering on station for activities under positive control; 30 min for activities using time-delay firing devices): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, relocate or delay the start of detonations or fuse initiation. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease detonations or fuse initiation. —To the maximum extent practicable depending on mission requirements, safety, and environmental conditions, boats must position themselves near the mid-point of the mitigation zone radius (but outside of the detonation plume and human safety zone), must position themselves on opposite sides of the detonation location (when two boats are used), and must travel in a circular pattern around the detonation location with one Lookout observing inward toward the detonation site and the other observing outward toward the perimeter of the mitigation zone. —If used, aircraft must travel in a circular pattern around the detonation location to the maximum extent practicable. —The Navy must not set time-delay firing devices (0.1–20 lb net explosive weight) to exceed 10 min. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the detonation site; or (3) the mitigation zone has been clear from any additional sightings for 10 min during activities under positive control with aircraft that have fuel constraints, or 30 min during activities under positive control with aircraft that are not typically fuel constrained and during activities using time-delay firing devices. • After completion of an activity (for 30 min): —Observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), these assets must assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Maritime Security Operations—Anti-Swimmer Grenades

Procedural mitigation for maritime security operations—anti-swimmer grenades is described in Table 56 below.

TABLE 56—PROCEDURAL MITIGATION FOR MARITIME SECURITY OPERATIONS—ANTI-SWIMMER GRENADES

Procedural Mitigation Description
Stressor or Activity: • Maritime Security Operations—Anti-Swimmer Grenades. Number of Lookouts and Observation Platform: • 1 Lookout positioned on the small boat conducting the activity. • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties. Mitigation Requirements: • Mitigation zone: —200 yd around the intended detonation location. • Prior to the initial start of the activity (*e.g.,* when maneuvering on station): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, relocate or delay the start of detonations. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease detonations. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended detonation location; (3) the mitigation zone has been clear from any additional sightings for 30 min; or (4) the intended detonation location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting. • After completion of the activity (*e.g.,* prior to maneuvering off station): —When practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), these assets must assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Line Charge Testing

Procedural mitigation for line charge testing is described in Table 57 below.

TABLE 57—PROCEDURAL MITIGATION FOR LINE CHARGE TESTING

Procedural Mitigation Description
Stressor or Activity: • Line charge testing. Number of Lookouts and Observation Platform: • 1 Lookout positioned on a vessel. • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties. Mitigation Requirements: • Mitigation zone: —900 yd around the intended detonation location. • Prior to the initial start of the activity (*e.g.,* when maneuvering on station): —Observe the mitigation zone for floating vegetation; if observed, delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, delay the start of detonations. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease detonations. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended detonation location; or (3) the mitigation zone has been clear from any additional sightings for 30 min. • After completion of the activity (*e.g.,* prior to maneuvering off station): —When practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.,* providing range clearance), these assets must assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Ship Shock Trials

Procedural mitigation for ship shock trials is described in Table 58 below.

TABLE 58—PROCEDURAL MITIGATION FOR SHIP SHOCK TRIALS

Procedural Mitigation Description
Stressor or Activity: • Ship shock trials. Number of Lookouts and Observation Platform: • At least 10 Lookouts or trained marine species observers (or a combination thereof) positioned either in an aircraft or on multiple vessels (*i.e.,* a Marine Animal Response Team boat and the test ship): —If aircraft are used, Lookouts or trained marine species observers must be in an aircraft and on multiple vessels. —If aircraft are not used, a sufficient number of additional Lookouts or trained marine species observers must be used to provide vessel-based visual observation comparable to that achieved by aerial surveys. • If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties. Mitigation Requirements: • Mitigation zone: —3.5 nmi around the ship hull. • During event planning: —The Navy must not conduct ship shock trials in the Jacksonville Operating Area during North Atlantic right whale calving season from November 15 through April 15. —The Navy develops detailed ship shock trial monitoring and mitigation plans approximately 1-year prior to an event and must continue to provide these to NMFS for review and approval. —Pre-activity planning must include selection of one primary and two secondary areas where marine mammal populations are expected to be the lowest during the event, with the primary and secondary locations located more than 2 nmi from the western boundary of the Gulf Stream for events in the Virginia Capes Range Complex or Jacksonville Range Complex. —If it is determined during pre-activity surveys that the primary area is environmentally unsuitable (*e.g.,* observations of marine mammals or presence of concentrations of floating vegetation), the shock trial could be moved to a secondary site in accordance with the detailed mitigation and monitoring plan provided to NMFS. • Prior to the initial start of the activity at the primary shock trial location (in intervals of 5 hrs, 3 hrs, 40 min, and immediately before the detonation): —Observe the mitigation zone for floating vegetation; if observed, delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, delay triggering the detonation. • During the activity: —Observe the mitigation zone for marine mammals, large schools of fish, jellyfish aggregations, and flocks of seabirds; if observed, cease triggering the detonation. —After completion of each detonation, observe the mitigation zone for marine mammals; if any injured or dead marine mammals are observed, follow established incident reporting procedures and halt any remaining detonations until the Navy can consult with NMFS and review or adapt the mitigation, if necessary. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the ship hull; or (3) the mitigation zone has been clear from any additional sightings for 30 min. • After completion of the activity (during the following 2 days at a minimum, and up to 7 days at a maximum): —Observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, follow established incident reporting procedures. —If additional platforms are supporting this activity (*e.g.*, providing range clearance), these assets must assist in the visual observation of the area where detonations occurred.

Procedural Mitigation for Physical Disturbance and Strike Stressors

Mitigation measures for physical disturbance and strike stressors are provided in Table 59 through Table 63.

Procedural Mitigation for Vessel Movement

Procedural mitigation for vessel movement used during the Planned Activities is described in Table 59 below.

TABLE 59—PROCEDURAL MITIGATION FOR VESSEL MOVEMENT

Procedural Mitigation Description
Stressor or Activity: • Vessel movement: —The mitigation must not be applied if: (1) The vessel's safety is threatened, (2) the vessel is restricted in its ability to maneuver (*e.g.,* during launching and recovery of aircraft or landing craft, during towing activities, when mooring, etc.), or (3) the vessel is operated autonomously. Number of Lookouts and Observation Platform: • 1 Lookout on the vessel that is underway. Mitigation Requirements: • Mitigation zones: —500 yd around whales. —200 yd around other marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels). • During the activity: —When underway, observe the mitigation zone for marine mammals; if observed, maneuver to maintain distance. • Additional requirements: —The Navy must broadcast awareness notification messages with North Atlantic right whale Dynamic Management Area information (e.g., location and dates) to applicable Navy assets operating in the vicinity of the Dynamic Management Area. The information must alert assets to the possible presence of a North Atlantic right whale to maintain safety of navigation and further reduce the potential for a vessel strike. Platforms must use the information to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation, including but not limited to mitigation for vessel movement. —If a marine mammal vessel strike occurs, the Navy must follow the established incident reporting procedures.

Procedural Mitigation for Towed In-Water Devices

Procedural mitigation for towed in-water devices is described in Table 60 below.

TABLE 60—PROCEDURAL MITIGATION FOR TOWED IN-WATER DEVICES

Procedural Mitigation Description
Stressor or Activity: • Towed in-water devices: —Mitigation applies to devices that are towed from a manned surface platform or manned aircraft. —The mitigation must not be applied if the safety of the towing platform or in-water device is threatened. Number of Lookouts and Observation Platform: • 1 Lookout positioned on the manned towing platform. Mitigation Requirements: • Mitigation zones: —250 yd around marine mammals. • During the activity (*i.e.,* when towing an in-water device): —Observe the mitigation zone for marine mammals; if observed, maneuver to maintain distance.

Procedural Mitigation for Small-, Medium-, and Large-Caliber Non-Explosive Practice Munitions

Procedural mitigation for small-, medium-, and large-caliber non-explosive practice munitions is described in Table 61 below.

TABLE 61—PROCEDURAL MITIGATION FOR SMALL-, MEDIUM-, AND LARGE-CALIBER NON-EXPLOSIVE PRACTICE MUNITIONS

Procedural Mitigation Description
Stressor or Activity: • Gunnery activities using small-, medium-, and large-caliber non-explosive practice munitions: —Mitigation applies to activities using a surface target. Number of Lookouts and Observation Platform: • 1 Lookout positioned on the platform conducting the activity. • Depending on the activity, the Lookout could be the same as the one described for Weapons Firing Noise. Mitigation Requirements:

TABLE 61—PROCEDURAL MITIGATION FOR SMALL-, MEDIUM-, AND LARGE-CALIBER NON-EXPLOSIVE PRACTICE MUNITIONS—Continued

Procedural Mitigation Description
• Mitigation zone: —200 yd around the intended impact location. • Prior to the initial start of the activity (*e.g.,* when maneuvering on station): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, relocate or delay the start of firing. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease firing. • Commencement/recommencement conditions after a marine mammal sighting before or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; (3) the mitigation zone has been clear from any additional sightings for 10 min for aircraft-based firing or 30 min for vessel-based firing; or (4) for activities using a mobile target, the intended impact location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

Procedural Mitigation for Non-Explosive Missiles and Rockets

Procedural mitigation for non-explosive missiles and rockets is described in Table 62 below.

TABLE 62—PROCEDURAL MITIGATION FOR NON-EXPLOSIVE MISSILES AND ROCKETS

Procedural Mitigation Description
Stressor or Activity: • Aircraft-deployed non-explosive missiles and rockets: —Mitigation applies to activities using a surface target. Number of Lookouts and Observation Platform: • 1 Lookout positioned in an aircraft. Mitigation Requirements: • Mitigation zone: —900 yd around the intended impact location. • Prior to the initial start of the activity (*e.g.,* during a fly-over of the mitigation zone): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, relocate or delay the start of firing. • During the activity: —Observe the mitigation zone for marine mammals; if observed, cease firing. • Commencement/recommencement conditions after a marine mammal sighting prior to or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or (3) the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

Procedural Mitigation for Non-Explosive Bombs and Mine Shapes

Procedural mitigation for non-explosive bombs and mine shapes is described in Table 63 below.

TABLE 63—PROCEDURAL MITIGATION FOR NON-EXPLOSIVE BOMBS AND MINE SHAPES

Procedural Mitigation Description
Stressor or Activity: • Non-explosive bombs. • Non-explosive mine shapes during mine laying activities. Number of Lookouts and Observation Platform: • 1 Lookout positioned in an aircraft. Mitigation Requirements:

TABLE 63—PROCEDURAL MITIGATION FOR NON-EXPLOSIVE BOMBS AND MINE SHAPES—Continued

Procedural Mitigation Description
• Mitigation zone: —1,000 yd around the intended target. • Prior to the start of the activity (*e.g.,* when arriving on station): —Observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. —Observe the mitigation zone for marine mammals; if observed, relocate or delay the start of bomb deployment or mine laying. • During the activity (*e.g.,* during approach of the target or intended minefield location): —Observe the mitigation zone for marine mammals; if observed, cease bomb deployment or mine laying. • Commencement/recommencement conditions after a marine mammal sighting prior to or during the activity: —The Navy must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing bomb deployment or mine laying) until one of the following conditions has been met: (1) The animal is observed exiting the mitigation zone; (2) the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended target or minefield location; (3) the mitigation zone has been clear from any additional sightings for 10 min; or (4) for activities using mobile targets, the intended target has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

Mitigation Areas

In addition to procedural mitigation, the Navy will implement mitigation measures within mitigation areas and/or at times to avoid or minimize potential impacts on marine mammals (see the revised maps and tables, with expanded areas as described above, provided in Chapter 5 (Mitigation), Section 5.4 of the AFTT FEIS/OEIS). The Navy has taken into account public comments received on the AFTT DEIS/OEIS, best available science, and the practicability of implementing additional mitigation measures and has expanded and improved their mitigation areas and mitigation measures to further reduce impacts to marine mammals. As such, the Navy revised their mitigation areas since their application and the proposed rule (see above). The Navy re-analyzed existing mitigation areas and considered new habitat areas suggested by the public, NMFS, and other non-Navy organizations, including NARW ESA-designated critical habitat, important habitat for sperm whales and Bryde's whales, BIAs, and National Marine Sanctuaries. The Navy worked collaboratively with NMFS to develop mitigation areas using inputs from the Navy's operational community, the best available science discussed in Chapter 3 of the AFTT FEIS/OEIS (*Affected Environment and Environmental Consequences*), published literature, predicted activity impact footprints, marine species monitoring and density data, and the practicability of implementing additional mitigation measures. Following are the mitigation areas that the Navy has committed to implement and that are included in the final regulations (including a description of expanded areas and/or protections).

Mitigation Areas Off the Northeastern United States

Mitigation areas for the Northeastern United States are described in Table 64. The Navy has expanded the NE NARW Area and added the Gulf of Maine Planning Awareness Mitigation Area since the proposed rule and the location and boundaries of each mitigation area are included in the Navy's AFTT FEIS/OEIS.

TABLE 64—MITIGATION AREAS OFF THE NORTHEASTERN UNITED STATES

Mitigation Area Description
Stressor or Activity: • Sonar. • Explosives. • Physical disturbance and strikes. Mitigation Area Requirements (year-round):

TABLE 64—MITIGATION AREAS OFF THE NORTHEASTERN UNITED STATES—Continued

Mitigation Area Description
• Northeast North Atlantic Right Whale Mitigation Area: —The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area (i.e., the northeast North Atlantic right whale critical habitat) in its annual training and testing activity reports submitted to NMFS. —The Navy must minimize the use of low-frequency active sonar, mid-frequency active sonar, and high-frequency active sonar to the maximum extent practicable within the mitigation area. —The Navy must not use Improved Extended Echo Ranging sonobuoys (in or within 3 nmi of the mitigation area) or use, explosive and non-explosive bombs, in-water detonations, and explosive torpedoes within the mitigation area. —For activities using non-explosive torpedoes within the mitigation area, the Navy must conduct activities during daylight hrs in Beaufort sea state 3 or less. The Navy must use three Lookouts (one positioned on a vessel and two in an aircraft during dedicated aerial surveys) to observe the vicinity of the activity. An additional Lookout must be positioned on the submarine, when surfaced. Immediately prior to the start of the activity, Navy personnel must observe for floating vegetation and marine mammals; if observed, the activity must not commence until the vicinity is clear or the activity is relocated to an area where the vicinity is clear. During the activity, Navy personnel must observe for marine mammals; if observed, the activity must cease. To allow a sighted marine mammal to leave the area, the Navy must not recommence the activity until one of the following conditions has been met: (1) The animal is observed exiting the vicinity of the activity; (2) the animal is thought to have exited the vicinity of the activity based on a determination of its course, speed, and movement relative to the activity location; or (3) the area has been clear from any additional sightings for 30 min. During transits and normal firing, ships must maintain a speed of no more than 10 knots. During submarine target firing, ships must maintain speeds of no more than 18 knots. During vessel target firing, vessel speeds may exceed 18 knots for brief periods of time (*e.g.,* 10–15 min). —Before vessel transits within the mitigation area, the Navy must conduct a web query or email inquiry to the National Oceanographic and Atmospheric Administration Northeast Fisheries Science Center's North Atlantic Right Whale Sighting Advisory System to obtain the latest North Atlantic right whale sightings information. Vessels must use the sightings information to reduce potential interactions with North Atlantic right whales during transits. Vessels must implement speed reductions within the mitigation area after observing a North Atlantic right whale, if transiting within 5 nmi of a sighting reported to the North Atlantic Right Whale Sighting Advisory System within the past week, and if transiting at night or during periods of reduced visibility. • Gulf of Maine Planning Awareness Mitigation Area: —The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS. —The Navy must not conduct >200 hrs of hull-mounted mid-frequency active sonar per year within the mitigation area. —The Navy must not conduct major training exercises (Composite Training Unit Exercises or Fleet Exercises/Sustainment Exercises) within the mitigation area. If the Navy needs to conduct a major training exercise within the mitigation area in support of training requirements driven by national security concerns, it must confer with NMFS to verify that potential impacts are adequately addressed in the Navy's Final EIS/OEIS and associated consultation documents. • Northeast Planning Awareness Mitigation Areas: —The Navy will avoid conducting major training exercises (Composite Training Unit Exercises or Fleet Exercises/Sustainment Exercises) within the mitigation area to the maximum extent practicable. —The Navy must not conduct more than four major training exercises per year within the mitigation area (all or a portion of the exercise). If the Navy needs to conduct additional major training exercises in the mitigation area in support of training requirements driven by national security concerns, it must provide NMFS with advance notification and include the information in its annual training and testing activity reports submitted to NMFS.

Mitigation Areas Off the Mid-Atlantic and Southeastern United States

Mitigation areas off the Mid-Atlantic and Southeastern United States are described in Table 65 below. The location and boundaries of each mitigation area are included in the Navy's AFTT FEIS/OEIS.

TABLE 65—MITIGATION AREAS OFF THE MID-ATLANTIC AND SOUTHEASTERN UNITED STATES

Mitigation Area Description
Stressor or Activity: • Sonar. • Explosives. • Physical disturbance and strikes. Mitigation Area Requirements:

TABLE 65—MITIGATION AREAS OFF THE MID-ATLANTIC AND SOUTHEASTERN UNITED STATES—Continued

Mitigation Area Description
• Southeast North Atlantic Right Whale Mitigation Area (November 15 through April 15): —The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS. —The Navy must not conduct: (1) Low-frequency active sonar (except as noted below), (2) mid-frequency active sonar (except as noted below), (3) high-frequency active sonar, (4) missile and rocket activities (explosive and non-explosive), (5) small-, medium-, and large-caliber gunnery activities, (6) Improved Extended Echo Ranging sonobuoy activities, (7) explosive and non-explosive bombing activities, (8) in-water detonations, and (9) explosive torpedo activities within the mitigation area. —To the maximum extent practicable, the Navy must minimize the use of: (1) Helicopter dipping sonar, (2) low-frequency active sonar and hull-mounted mid-frequency active sonar used for navigation training, and (3) low-frequency active sonar and hull-mounted mid-frequency active sonar used for object detection exercises within the mitigation area. —Before transiting or conducting training or testing activities within the mitigation area, the Navy must initiate communication with the Fleet Area Control and Surveillance Facility, Jacksonville to obtain Early Warning System North Atlantic right whale sightings data. The Fleet Area Control and Surveillance Facility, Jacksonville must advise vessels of all reported whale sightings in the vicinity to help vessels and aircraft reduce potential interactions with North Atlantic right whales. Commander Submarine Force U.S. Atlantic Fleet must coordinate any submarine activities that may require approval from the Fleet Area Control and Surveillance Facility, Jacksonville. Vessels must use the sightings information to reduce potential interactions with North Atlantic right whales during transits. —Vessels must implement speed reductions if they are within 5 nmi of a sighting reported within the past 12 hrs, or when operating at night or during periods of poor visibility. —To the maximum extent practicable, vessels must minimize north-south transits in the mitigation area.
• Jacksonville Operating Area (November 15 through April 15): —Navy units conducting training or testing activities in the Jacksonville Operating Area must initiate communication with the Fleet Area Control and Surveillance Facility, Jacksonville to obtain Early Warning System North Atlantic right whale sightings data. The Fleet Area Control and Surveillance Facility, Jacksonville must advise vessels of all reported whale sightings in the vicinity to help vessels and aircraft reduce potential interactions with North Atlantic right whales. Commander Submarine Force U.S. Atlantic Fleet must coordinate any submarine activities that may require approval from the Fleet Area Control and Surveillance Facility, Jacksonville. The Navy must use the reported sightings information as it plans specific details of events (*e.g.,* timing, location, duration) to minimize potential interactions with North Atlantic right whales to the maximum extent practicable. The Navy must use the reported sightings information to assist visual observations of applicable mitigation zones and to aid in the implementation of procedural mitigation.
• Southeast North Atlantic Right Whale Critical Habitat Special Reporting Area (November 15 through April 15): —The Navy must report the total hrs and counts of active sonar and in-water explosives used in the Special Reporting Area (i.e., the southeast North Atlantic right whale critical habitat) in its annual training and testing activity reports submitted to NMFS.
• Mid-Atlantic Planning Awareness Mitigation Areas (year-round): —The Navy will avoid conducting major training exercises within the mitigation area (Composite Training Unit Exercises or Fleet Exercises/Sustainment Exercises) to the maximum extent practicable. —The Navy must not conduct the Ship Shock trial in the Mid-Atlantic Planning Awareness Areas including a 5-nmi buffer. —The Navy must not conduct more than four major training exercises per year (all or a portion of the exercise) within the mitigation area. If the Navy needs to conduct additional major training exercises in the mitigation area in support of training requirements driven by national security concerns, it must provide NMFS with advance notification and include the information in its annual training and testing activity reports submitted to NMFS.
• Navy Cherry Point Range Complex Nearshore Mitigation Area (March through September): —The Navy must not conduct explosive mine neutralization activities involving Navy divers in the mitigation area. —To the maximum extent practicable, the Navy must not use explosive sonobuoys, explosive torpedoes, explosive medium-caliber and large-caliber projectiles, explosive missiles and rockets, explosive bombs, explosive mines during mine countermeasure and neutralization activities, and anti-swimmer grenades in the mitigation area.

Mitigation Areas in the GOMEX

Mitigation areas in the GOMEX are described in Table 66 below. The Navy has expanded the GOMEX Planning Awareness Mitigation area and added the Bryde's Whale Mitigation area since the proposed rule and the location and boundaries of each mitigation area are included in the AFTT FEIS/OEIS.

TABLE 66—MITIGATION AREAS IN THE GOMEX

Mitigation Area Description
Stressor or Activity: • Sonar. • Explosives. Mitigation Area Requirements (Year-Round): • Bryde's Whale Mitigation Area: —The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS. —The Navy must not conduct >200 hrs of hull-mounted mid-frequency active sonar per year within the mitigation area. —The Navy must not use explosives (except during mine warfare activities) within the mitigation area. • Gulf of Mexico Planning Awareness Mitigation Areas: —The Navy must not conduct any major training exercises within the mitigation areas (all or a portion of the exercise). If the Navy needs to conduct a major training exercise within the mitigation areas in support of training requirements driven by national security concerns, it must confer with NMFS to verify that potential impacts are adequately addressed in the Navy's Final EIS/OEIS and associated consultation documents.

The Navy's analysis indicates that the measures in these mitigation areas are both practicable and will reduce the likelihood or severity of adverse impacts to marine mammal species and stocks or their habitat in the manner described in the Navy's analysis. After extensive coordination and independent consideration of the measures considered and eliminated by the Navy and the Navy's determinations as to how the measures would affect personnel safety, practicality to implement, and effectiveness to the Navy mission, NMFS finds the information persuasive to inform NMFS' LPAI finding and NMFS' independent analysis of these mitigation areas.

Summary of Mitigation Areas

Table 67 below includes a description of the mitigation implemented in each of the areas and immediately below we include a summary of the manner in

which the mitigation areas are expected to reduce impacts to marine mammals and the likelihood or severity of impacts to species or stock:

Northeast North Atlantic Right Whale Mitigation Areas (year-round)

The Navy has enlarged the mitigation area to cover the full extent of the northeast NARW ESA-designated critical habitat. The expanded area also encompasses all of the important feeding areas for humpback whales and fin whales, significant portions of the feeding areas for sei and minke whales (73 percent and 44 percent, respectively), as well as 82 percent of the portion in the U.S. EEZ of a small and resident population of harbor porpoises. Mitigation to limit the use of active sonar to the maximum extent practicable and not use certain explosive and non-explosive munitions will help the Navy further avoid or reduce potential impacts on NARWs year-round in their most important feeding areas, a mating area, and the northern portion of their migration habitat. These mitigations will also reduce the severity and scale of impacts on the other mysticetes and harbor porpoises. Conducting non-explosive torpedo activities during daylight hours in Beaufort sea state 3 or less will help increase Lookout effectiveness during these activities. Mitigation to obtain the latest sighting information from the NARW Sighting Advisory System will help vessels avoid NARWs during training and testing activities. The NARW Sighting Advisory System is a National Oceanographic and Atmospheric Administration program that collects sightings information off the northeastern United States from aerial surveys, shipboard surveys, whale watching vessels, and opportunistic sources, such as the U.S. Coast Guard, commercial ships, fishing vessels, and the public. The Navy will also implement new special reporting procedures to report the total hours and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS. The special reporting requirements will aid the Navy and NMFS in continuing to analyze potential impacts of training and testing in this area. The reduction of activities in, and increase of protective measures in, areas with higher concentrations of NARWs or other mysticetes engaged in important feeding activities (such as they are in this area), or NARWs engaged in mating activities, is expected to reduce the probability and/or severity of impacts to these species and stocks that would be more likely to adversely affect the fitness of any individual, which in turn reduces the likelihood that any impacts would translate to adverse impacts on the stock. Similarly, reduction in the scale or level of impacts in the vicinity of this small resident population of harbor porpoises is expected to reduce the probability that impacts would adversely impact the fitness of any individual and thereby translate to adverse impacts on the stock.

Gulf of Maine Planning Awareness Mitigation Area (year-round)

Newly developed for Phase III and since the proposed rule was published, the Gulf of Maine Planning Awareness Mitigation Area extends throughout the Gulf of Maine and southward over Georges Bank. The area covers the full extent of the northeast NARW ESA-designated critical habitat, including both a mating area and important feeding area. The expanded area also fully encompasses important feeding areas for humpback whales, minke whales, sei whales, and fin whales as well as all of the portion in the U.S. EEZ of a small and resident population of harbor porpoises. The Navy will not conduct MTEs in this area, which will further help the Navy avoid or reduce potential impacts on marine mammals from active sonar during major training exercises (which are associated with more severe effects because of the use of multiple platforms and higher-level sound sources, as well as longer-duration activities). The reduction of activities in, and increase of protective measures in, areas with higher concentrations of NARWs or other mysticetes engaged in important feeding activities (such as they are in this area), or NARWs engaged in mating activities, is expected to reduce the probability and/or severity of impacts to these species and stocks that would be more likely to adversely affect the fitness of any individual, which in turn reduces the likelihood that any impacts would translate to adverse impacts on the stock. Similarly, and reduction in the scale or level of impacts in the vicinity of this small resident population of harbor porpoises is expected to reduce the probability that impacts would adversely impact the fitness of any individual and thereby translate to adverse impacts on the stock. The Navy will also implement special reporting procedures to report the total hours and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS. The special reporting requirements will aid the Navy and NMFS in continuing to analyze potential impacts of training and testing in this area.

Northeast Planning Awareness Mitigation Areas (year-round)

The Northeast Planning Awareness Mitigation Areas extend across the shelf break and contain underwater canyons that have been associated with marine mammal feeding and abundance, including within a portion of the Northeast Canyons and Seamounts National Marine Monument. They are situated among highly productive environments, such as persistent oceanographic features associated with upwellings and steep bathymetric contours. The mitigation included within the Northeast Planning Awareness Mitigation Areas (Table 64) will help the Navy further avoid or reduce potential impacts from active sonar during major training exercises on marine mammals that inhabit, feed in, mate in, or migrate through the northeast region. For example, the mitigation areas overlap a portion of the NARW northern migration habitat. Fin whales are known to follow prey off the continental shelf in this region (Azzellino *et al.,* 2008; Panigada *et al.,* 2008). Sei whales have high abundance in two of the mitigation areas along the shelf break of Georges Bank and near Hydrographer Canyon (Waring *et al.,* 2014). The reduction of activities in, and increase of protective measures in, areas with higher concentrations of NARWs or other mysticetes is expected to reduce the probability of impacts to these species and stocks that would be more likely to adversely affect the fitness of any individual, which in turn reduces the likelihood that any impacts would translate to adverse impacts on the stock.

Mid-Atlantic Planning Awareness Mitigation Areas (year-round)

The Mid-Atlantic Planning Awareness Mitigation Areas extend across large swaths of shelf break and contain underwater canyons associated with high marine mammal diversity (*e.g.,* Norfolk Canyon). The mitigation areas are situated among highly productive environments, such as persistent oceanographic features associated with upwellings and steep bathymetric contours. Numerous species of marine mammals occur in the area, including beaked, fin, humpback, minke, and sperm whales; and pilot whales, bottlenose, short-beaked common, Atlantic spotted, striped, Clymene, and Risso's dolphins. The area is thought to be important for short-finned pilot whale feeding (as well as other odontocetes) and is associated with high

species abundance (Thorne *et al.,* 2017). The area is also used seasonally during migrations by numerous species and overlaps the NARW migration habitat identified by LaBrecque *et al.* (2015b). The Navy will avoid planning major training exercises to the maximum extent practicable and will not conduct more than four per year. The Navy has also agreed to move the ship shock trial box east of the Mid-Atlantic Planning Awareness Mitigation Areas including a 5-nmi buffer. Because of the diversity of marine mammals and other fauna, as well as the general increased use of the area for odontocete feeding, any reduction of the more impactful MTEs (more platforms, higher-level sources, and longer duration) would be expected to have a reduction in the probability of impacts to these species and stocks that would be more likely to adversely affect the fitness of any individual, which in turn reduces the likelihood that any impacts would translate to adverse impacts on the stock. Because of the high diversity of marine fauna, reduced training in this area would also be considered a direct reduction of impacts on marine mammal habitat.

Southeast North Atlantic Right Whale Mitigation Area (November 15 Through April 15)

The Navy has expanded the existing SE NARW Mitigation Area northward approximately 50 nmi along the coast of northern Georgia from the shoreline out to 10–12 nmi. The Navy expanded the mitigation area to correlate with the occurrence of NARWs to the maximum extent practicable based on readiness requirements. The mitigation area encompasses a portion of the NARW migration and calving areas identified by LaBrecque *et al.* (2015b) and a portion of the southeast NARW ESA-designated critical habitat. Mitigation to not conduct, or to limit the use of, active sonar to the maximum extent practicable (depending on the source) and to not conduct in-water detonations and certain activities using explosives and non-explosive practice munitions, will help the Navy further avoid or reduce potential impacts on NARWs in these key habitat areas seasonally. The Navy will implement special reporting procedures to report the total hours and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS. The special reporting requirements will aid the Navy and NMFS in continuing to analyze potential impacts of training and testing in the mitigation area. Mitigation for vessel movements includes minimizing north-south transits; implementing speed reductions after vessels observe a NARW, if they are within 5 nmi of a sighting reported within the past 12 hrs, or when operating in the mitigation area at night or during periods of poor visibility; and continuing to participate in and sponsor the Early Warning System. The Early Warning System is a comprehensive information exchange network dedicated to reducing the risk of vessel strikes to NARW off the southeast United States from all mariners (*i.e.,* Navy and non-Navy vessels). Navy participants include the Fleet Area Control and Surveillance Facility, Jacksonville; Commander, Naval Submarine Forces, Norfolk, Virginia; and Naval Submarine Support Command. The Navy, U.S. Coast Guard, U.S. Army Corps of Engineers, and NMFS collaboratively sponsor daily aerial surveys from December 1 through March 31 (weather permitting) to observe for NARWs from the shoreline out to approximately 30–35 nmi offshore. Aerial surveyors relay sightings information to all mariners transiting within the NARW calving habitat (*e.g.,* commercial vessels, recreational boaters, Navy ships). The reduction of activities in, and increase of protective measures in, areas with higher concentrations of NARWs engaged in calving activities and migration (such as they are in this area), is expected to reduce the probability and/or severity of impacts on NARWs that would be more likely to adversely affect the fitness of any individual, which in turn reduces the likelihood that any impacts would translate to adverse impacts on the stock. Additionally, these measures are expected to significantly increase the likelihood of detection of NARWs, which in turn significantly decreases the likelihood of a ship strike. Last, this area coincides with the ranges of two small resident stocks of bottlenose dolphins (Southern Georgia Estuarine and Jacksonville Estuarine) and is generally expect to reduce the scale and severity of impacts on these stocks, reducing the likelihood of population-level impacts.

Southeast North Atlantic Right Whale Critical Habitat Special Reporting Area

Newly developed for Phase III, the SE NARW Critical Habitat Special Reporting Area covers the entire southeast NARW ESA-designated critical habitat, as well as the ranges of three small resident populations of bottlenose dolphins (Southern Georgia Estuarine, Jacksonville Estuarine, and Charleston Estuarine). The Navy will implement special reporting procedures to report the total hours and counts of active sonar and in-water explosives used in the mitigation area (*i.e.,* the southeast NARW ESA-designated critical habitat) in its annual training and testing activity reports submitted to NMFS. The special reporting requirements will aid the Navy and NMFS in continuing to analyze potential impacts of training and testing in this area.

Jacksonville Operating Area

The Navy has developed new mitigation measures for units conducting training or testing activities in the Jacksonville Operating Area, which overlaps the majority of the southeast NARW ESA-designated critical habitat and extends far out to the edge of the continental shelf. The mitigation measures to obtain and use Early Warning System NARW sightings data will help vessels and aircraft reduce potential interactions (*i.e.,* reducing the likelihood of a strike) with NARWs in portions of the southeast NARW ESA-designated critical habitat and NARW migration and calving areas identified by LaBrecque *et al.* (2015b).

Navy Cherry Point Range Complex Nearshore Mitigation Area

The Navy is continuing an existing mitigation measure to not conduct explosive mine neutralization activities involving Navy divers from March through September within the mitigation area, which is defined as within 3.2 nmi of an estuarine inlet and within 1.6 nmi of the shoreline in the Navy Cherry Point Range Complex. For Phase III, the Navy is expanding the mitigation requirements in this mitigation area to include additional in-water explosives to the maximum extent practicable. Although the measure was primarily designed to reduce potential impacts on sea turtles near nesting beaches during the nesting season and on sandbar sharks in Habitat Areas of Particular Concern, the mitigation area also overlaps a portion of the NARW migration area identified by LaBrecque *et al.* (2015b). Any reduction of impacts where NARW may be concentrated contributes to a reduction in the probability that impacts will accrue to fitness impacts on individuals or, further, to impacts on the stock.

Bryde's Whale Mitigation Area (Year-Round)

Newly developed for Phase III, the Bryde's Whale Mitigation Area covers the extent of the Bryde's whale small and resident population area identified by LaBrecque *et al.* (2015a), including the extended area identified by NMFS

in its 2016 Bryde's whale status review (Rosel *et al.,* 2016). Mitigation to limit annual hours of mid-frequency active sonar use and to not use in-water explosives (except during mine warfare activities) will help the Navy avoid or reduce potential impacts on the small and resident population of Bryde's whales. To accomplish the mitigation for explosives, the Navy has adjusted the boundaries of the northern GOMEX ship shock trial area. The ship shock trial area is being relocated 5 nm from the western boundary of the Bryde's Whale Mitigation Area. This will help the Navy avoid the potential for Bryde's whales to be exposed to explosives during ship shock trials within the mitigation area. The Navy will implement special reporting procedures to report the total hours and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS. The special reporting requirements will aid the Navy and NMFS in continuing to analyze potential impacts of training and testing in this area. This overall reduction in activity and increase in protective measures across the majority of the Bryde's whale range minimizes the probability and/or severity of impacts on Bryde's whales that are likely to adversely affect the fitness of any individual, which in turn reduces the likelihood that any impacts would translate to adverse impacts on the stock.

GOMEX Planning Awareness Mitigation Areas (Year-Round)

The Navy is enlarging the more eastern GOMEX Planning Awareness Mitigation Area to fully encompass the Bryde's whale small and resident population area identified by LaBrecque *et al.* (2015a) and the extended area identified by NMFS in its 2016 Bryde's whale status review (Rosel *et al.,* 2016). The GOMEX Planning Awareness Mitigation Areas also overlap most of the Mississippi Canyon sperm whale habitat area and a portion of sperm whale habitat area west of the Dry Tortugas. They extend across large swaths of shelf break and contain underwater canyons associated with marine mammal abundance (*e.g.,* Mississippi Canyon, DeSoto Canyon). The mitigation areas are situated among highly productive environments, such as persistent oceanographic features associated with upwellings and steep bathymetric contours. The Navy will not conduct MTEs in these areas. Mitigation within the GOMEX Planning Awareness Mitigation Areas will help the Navy further avoid or reduce potential impacts from active sonar during MTEs (which have more platforms, higher source levels, and longer durations more likely to have more severe impacts) on marine mammals that inhabit, feed in, reproduce in, or migrate through these areas. Specifically, these mitigation areas would be expected to result in a reduction in the probability of impacts to the GOMEX stocks of Bryde's whales and sperm whale that would be more likely to adversely affect the fitness of any individual, which in turn reduces the likelihood that any impacts would translate to adverse impacts on the stock.

A summary of mitigation areas for marine mammals is described in Table 67 below.

TABLE 67—SUMMARY OF MITIGATION AREAS FOR MARINE MAMMALS

Summary of mitigation area requirements
Northeast North Atlantic Right Whale Mitigation Area
• The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports. • The Navy must minimize use of active sonar to the maximum extent practicable and must not use explosives that detonate in the water. • The Navy must conduct non-explosive torpedo testing during daylight hrs in Beaufort sea state 3 or less using three Lookouts (one on a vessel, two in an aircraft during aerial surveys) and an additional Lookout on the submarine when surfaced; during transits, ships must maintain a speed of no more than 10 knots; during firing, ships must maintain a speed of no more than 18 knots except brief periods of time during vessel target firing. • Vessels must obtain the latest North Atlantic right whale sightings data and implement speed reductions after they observe a North Atlantic right whale, if within 5 nmi of a sighting reported within the past week, and when operating at night or during periods of reduced visibility.
Gulf of Maine Planning Awareness Mitigation Area
• The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports. • The Navy must not conduct major training exercises and must not conduct >200 hrs of hull-mounted mid-frequency active sonar per year.
Northeast Planning Awareness Mitigation Areas and Mid-Atlantic Planning Awareness Mitigation Areas
• The Navy must avoid conducting major training exercises to the maximum extent practicable. • The Navy must not conduct more than four major training exercises per year.
Southeast North Atlantic Right Whale Mitigation Area (November 15–April 15)
• The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports. • The Navy must not use active sonar except as necessary for navigation training, object detection training, and dipping sonar. • The Navy must not expend explosive or non-explosive ordnance. • Vessels must obtain the latest North Atlantic right whale sightings data; must implement speed reductions after they observe a North Atlantic right whale, if within 5 nmi of a sighting reported within the past 12 hrs, and when operating at night or during periods of reduced visibility; and must minimize north-south transits to the maximum extent practicable.

TABLE 67—SUMMARY OF MITIGATION AREAS FOR MARINE MAMMALS—Continued

Summary of mitigation area requirements
Jacksonville Operating Area (November 15–April 15)
• Navy units conducting training or testing activities in the Jacksonville Operating Area must obtain and use Early Warning System North Atlantic right whale sightings data as they plan specific details of events to minimize potential interactions with North Atlantic right whales to the maximum extent practicable. The Navy must use the reported sightings information to assist visual observations of applicable mitigation zones and to aid in the implementation of procedural mitigation.
Southeast North Atlantic Right Whale Critical Habitat Special Reporting Area (November 15–April 15)
• The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports.
Navy Cherry Point Range Complex Nearshore Mitigation Area (March–September)
• The Navy must not conduct explosive mine neutralization activities involving Navy divers in the mitigation area. • To the maximum extent practicable, the Navy must not use explosive sonobuoys, explosive torpedoes, explosive medium-caliber and large-caliber projectiles, explosive missiles and rockets, explosive bombs, explosive mines during mine countermeasure and neutralization activities, and anti-swimmer grenades in the mitigation area.
Bryde's Whale Mitigation Area
• The Navy must report the total hrs and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports. • The Navy must not conduct >200 hrs of hull-mounted mid-frequency active sonar per year and must not use explosives (except during explosive mine warfare activities).
Gulf of Mexico Planning Awareness Mitigation Areas
• The Navy must not conduct any major training exercises under the Proposed Action.

Notes: Min.: minutes; nmi: nautical miles.

Summary of Procedural Mitigation

A summary of procedural mitigation is described in Table 68 below.

TABLE 68—SUMMARY OF PROCEDURAL MITIGATION

Stressor or activity	Mitigation zones sizes and other requirements
Environmental Awareness and Education	• Afloat Environmental Compliance Training program for applicable personnel.
Active Sonar	Depending on sonar source: • 1,000 yd power down, 500 yd power down, and 200 yd shut. down • 200 yd shut down.
Air Guns	• 150 yd.
Pile Driving	• 100 yd.
Weapons Firing Noise	• 30 degrees on either side of the firing line out to 70 yd.
Explosive Sonobuoys	• 600 yd.
Explosive Torpedoes	• 2,100 yd.
Explosive Medium-Caliber and Large-Caliber Projectiles.	• 1,000 yd (large-caliber projectiles). • 600 yd (medium-caliber projectiles during surface-to-surface activities). • 200 yd (medium-caliber projectiles during air-to-surface activities).
Explosive Missiles and Rockets	• 2,000 yd (21–500 lb net explosive weight). • 900 yd. (0.6–20 lb net explosive weight).
Explosive Bombs	• 2,500 yd.
Sinking Exercises	• 2.5 nmi.
Explosive Mine Countermeasure and Neutralization Activities.	• 2,100 yd (6–650 lb net explosive weight). • 600 yd (0.1–5 lb net explosive weight).
Explosive Mine Neutralization Activities Involving Navy Divers.	• 1,000 yd (21–60 lb net explosive weight for positive control charges and charges using time-delay fuses). • 500 yd (0.1–20 lb net explosive weight for positive control charges).
Maritime Security Operations—Anti-Swimmer Grenades.	• 200 yd.
Line Charge Testing	• 900 yd.
Ship Shock Trials	• 3.5 nmi.
Vessel Movement	• 500 yd (whales). • 200 yd (other marine mammals). • North Atlantic right whale Dynamic Management Area notification messages.
Towed In-Water Devices	• 250 yd.
Small-, Medium-, and Large-Caliber Non-Explosive Practice Munitions.	• 200 yd.

TABLE 68—SUMMARY OF PROCEDURAL MITIGATION—Continued

Stressor or activity	Mitigation zones sizes and other requirements
Non-Explosive Missiles and Rockets	• 900 yd.
Non-Explosive Bombs and Mine Shapes	• 1,000 yd.

Notes: lb: pounds; nmi: nautical miles; yd: yards.

Mitigation Conclusions

NMFS has carefully evaluated the Navy's mitigation measures—many of which were developed with NMFS' input during the previous phases of Navy training and testing authorizations—and considered a broad range of other measures (*i.e.,* the measures considered but eliminated in the AFTT FEIS/OEIS, which reflect many of the comments that have arisen via NMFS or public input in past years) in the context of ensuring that NMFS prescribes the means of effecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Our evaluation of mitigation measures included consideration of the following factors in relation to one another: The manner in which, and the degree to which, the successful implementation of the mitigation measures is expected to reduce the likelihood and/or magnitude of adverse impacts to marine mammal species and stocks and their habitat; the proven or likely efficacy of the measures; and the practicability of the measures for applicant implementation, including consideration of personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity.

Based on our evaluation of the Navy's planned measures, as well as other measures considered by the Navy and NMFS, NMFS has determined that the mitigation measures included in this rule are appropriate means of effecting the least practicable adverse impacts on marine mammals species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, considering specifically personnel safety, practicality of implementation, and impact on the effectiveness of the military readiness activity. Additionally, as described in more detail below, the final rule includes an adaptive management provision, which ensures that mitigation is regularly assessed and provides a mechanism to improve the mitigation, based on the factors above, through modification as appropriate.

Monitoring

Section 101(a)(5)(A) of the MMPA states that in order to authorize incidental take for an activity, 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 incidental take 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.

Integrated Comprehensive Monitoring Program (ICMP)

The Navy's ICMP is intended to coordinate marine species monitoring efforts across all regions and to allocate the most appropriate level and type of effort for each range complex based on a set of standardized objectives, and in acknowledgement of regional expertise and resource availability. The ICMP is designed to be flexible, scalable, and adaptable through the adaptive management and strategic planning processes to periodically assess progress and reevaluate objectives. This process includes conducting an annual adaptive management review meeting, at which the Navy and NMFS jointly consider the prior-year goals, monitoring results, and related scientific advances to determine if monitoring plan modifications are warranted to more effectively address program goals. Although the ICMP does not specify actual monitoring field work or individual projects, it does establish a matrix of goals and objectives that have been developed in coordination with NMFS. As the ICMP is implemented through the Strategic Planning Process, detailed and specific studies will be developed which support the Navy's top-level monitoring goals. In essence, the ICMP directs that monitoring activities relating to the effects of Navy training and testing activities on marine species should be designed to contribute towards one or more of the following top-level goals:

- An increase in our understanding of the likely occurrence of marine mammals and/or ESA-listed marine species in the vicinity of the action (*i.e.,* presence, abundance, distribution, and/or density of species);
- An increase in our understanding of the nature, scope, or context of the likely exposure of marine mammals and/or ESA-listed species to any of the potential stressor(s) associated with the action (*e.g.,* sound, explosive detonation, or military expended materials), through better understanding of one or more of the following: (1) The action and the environment in which it occurs (*e.g.,* sound source characterization, propagation, and ambient noise levels); (2) the affected species (*e.g.,* life history or dive patterns); (3) the likely co-occurrence of marine mammals and/or ESA-listed marine species with the action (in whole or part), and/or; (4) the likely biological or behavioral context of exposure to the stressor for the marine mammal and/or ESA-listed marine species (*e.g.,* age class of exposed animals or known pupping, calving or feeding areas);
- An increase in our understanding of how individual marine mammals or ESA-listed marine species respond (behaviorally or physiologically) to the specific stressors associated with the action (in specific contexts, where possible, *e.g.,* at what distance or received level);
- An increase in our understanding of how anticipated individual responses, to individual stressors or anticipated combinations of stressors, may impact either: (1) The long-term fitness and survival of an individual; or (2) the population, species, or stock (*e.g.,* through effects on annual rates of recruitment or survival);
- An increase in our understanding of the effectiveness of mitigation and monitoring measures;
- A better understanding and record of the manner in which the authorized entity complies with the incidental take regulations and LOAs and the ESA Incidental Take Statement;
- An increase in the probability of detecting marine mammals (through improved technology or methods), both specifically within the mitigation zone (thus allowing for more effective implementation of the mitigation) and in general, to better achieve the above goals; and

▪ Ensuring that adverse impact of activities remains at the least practicable level.

Strategic Planning Process for Marine Species Monitoring

The Navy also developed the Strategic Planning Process for Marine Species Monitoring, which establishes the guidelines and processes necessary to develop, evaluate, and fund individual projects based on objective scientific study questions. The process uses an underlying framework designed around intermediate scientific objectives and a conceptual framework incorporating a progression of knowledge, spanning occurrence, exposure, response, and consequence. The Strategic Planning Process for Marine Species Monitoring is used to set overarching intermediate scientific objectives, develop individual monitoring project concepts, identify potential species of interest at a regional scale, evaluate, prioritize and select specific monitoring projects to fund or continue supporting for a given fiscal year, execute and manage selected monitoring projects, and report and evaluate progress and results. This process addresses relative investments to different range complexes based on goals across all range complexes, and monitoring would leverage multiple techniques for data acquisition and analysis whenever possible. The Strategic Planning Process for Marine Species Monitoring is also available online (*http://www.navymarinespeciesmonitoring.us/*).

Past and Current Monitoring in the AFTT Study Area

NMFS has received multiple years' worth of annual exercise and monitoring reports addressing active sonar use and explosive detonations within the AFTT Study Area and other Navy range complexes. The data and information contained in these reports have been considered in developing mitigation and monitoring measures for the training and testing activities within the AFTT Study Area. The Navy's annual exercise and monitoring reports may be viewed at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities* and *http://www.navymarinespeciesmonitoring.us.*

The Navy's marine species monitoring program typically supports 10–15 projects in the Atlantic at any given time with an annual budget of approximately $3.5M. Current projects cover a range of species and topics from collecting baseline data on occurrence and distribution, to tracking whales and sea turtles, to conducting behavioral response studies on beaked whales and pilot whales. The Navy's marine species monitoring web portal provides details on past and current monitoring projects, including technical reports, publications, presentations, and access to available data and can be found at: *https://www.navymarinespeciesmonitoring.us/regions/atlantic/current-projects/*.

Following is a summary of the work currently planned for 2019, some of which is wrapping up and some of which will continue for multiple years, based on the planning and review process outlined above, which includes input from NMFS and the Marine Mammal Commission. Additional details are available on the Navy's website (*https://www.navymarinespeciesmonitoring.us/regions/atlantic/current-projects/*):

▪ Atlantic Behavioral Response Study (Hatteras study area)—Assessing behavioral response of beaked whales and pilot whales to tactical military sonar and simulated scaled sonar with controlled exposure experiments.

▪ Pinniped Tagging and Tracking in Southeast Virginia (lower Chesapeake Bay)—Documenting habitat use, movements, and haul-out patterns of seals in the Hampton Roads region of the Chesapeake Bay and coastal Atlantic.

▪ Pinniped Haul-out Counts and Photo-Identification (lower Chesapeake Bay and Virginia eastern shore)—Documenting occurrence and seasonal site fidelity of seals at select haul-out locations in the lower Chesapeake Bay.

▪ Mid-Atlantic Humpback Whale Monitoring (coastal SE Virginia)—Photo identification and deployment of satellite-linked tracking tags to document occurrence, baseline behavior, and habitat use of humpback whales in the coastal mid-Atlantic waters of Virginia.

▪ Behavioral Reactions of Juvenile Humpback Whales to Approaching Ships (Chesapeake Bay shipping channels)—Assessing response of humpback whales to vessel approaches using DTags and visual focal follow methods.

▪ NARW Monitoring—Assess the behavior and distribution of NARWs using multiple methods including deployment of DTags in coastal waters of the Southeast calving grounds, and passive acoustic monitoring using autonomous underwater gliders in the mid-Atlantic region.

▪ Occurrence, Ecology, and Behavior of Deep-diving Odontocetes (Hatteras study area)—Deployment of satellite-linked tags to document and assess habitat use and diving behavior of beaked whales and pilot whales.

▪ Vessel baseline surveys and tagging of cetaceans (USWTR study area of Jacksonville OPAREA)—continuation of vessel-based visual surveys for cetaceans in the USWTR region, as well as satellite-linked tagging of priority species to document habitat use and movement patterns.

▪ Passive Acoustic baseline monitoring—Continue deployment of High-frequency Acoustic Recording packages (or similar) at multiple locations along the mid-Atlantic and SE coast to document seasonal patterns of species occurrence.

▪ Occurrence and Ecology of North Atlantic Shelf Break Species and Effects of Anthropogenic Noise Impacts—Assessment of acoustic niche and spatial/seasonal occurrence of beaked whales and Kogia, occurrence and acoustic behavior of baleen whales, and anthropogenic drivers of cetacean distribution using passive acoustics.

▪ Bryde's whale monitoring in GOMEX—collaboration with SEFSC to assess occurrence and distribution of Bryde's whales in GOMEX.

▪ Mid-Atlantic Continental Shelf Break Cetacean Study (VACAPES OPAREA)—Assess occurrence, habitat use, movement patterns, and baseline behavior of cetaceans (primarily medium to large whales) in continental shelf break region of the VACAPES OPAREA with visual surveys, photo ID, biopsy sampling, and satellite-linked tagging.

▪ Mid-Atlantic & Southeast Humpback Catalog—Establish a centralized collaborative humpback whale photo-id catalog for the mid-Atlantic and southeast regions to support management and environmental planning.

Adaptive Management

The final regulations governing the take of marine mammals incidental to Navy training and testing activities in the AFTT Study Area contain an adaptive management component. Our understanding of the effects of Navy training and testing activities (*e.g.* acoustic and explosive stressors) on marine mammals continues to evolve, which makes the inclusion of an adaptive management component both valuable and necessary within the context of five-year regulations.

The reporting requirements associated with this rule are designed to provide NMFS with monitoring data from the previous year to allow NMFS to consider whether any changes to existing mitigation and monitoring

requirements are appropriate. NMFS and the Navy would meet to discuss the monitoring reports, Navy research and development studies, and current science and whether mitigation or monitoring modifications are appropriate. The use of adaptive management allows NMFS to consider new information from different sources to determine (with input from the Navy regarding practicability) on an annual or biennial basis if mitigation or monitoring measures should be modified (including additions or deletions). Mitigation measures could be modified if new data suggests that such modifications would have a reasonable likelihood of reducing adverse effects to marine mammals and if the measures are practicable.

The following are some of the possible sources of applicable data to be considered through the adaptive management process: (1) Results from monitoring and exercises reports, as required by MMPA authorizations; (2) compiled results of Navy funded R&D studies; (3) results from specific stranding investigations; (4) results from general marine mammal and sound research; and (5) any information which reveals that marine mammals may have been taken in a manner, extent, or number not authorized by these regulations or subsequent LOAs. The results from monitoring reports and other studies may be viewed at *https://www.navymarinespeciesmonitoring.us/*.

Reporting

In order to issue incidental take authorization for an activity, section 101(a)(5)(A) of the MMPA states that NMFS must set forth ''requirements pertaining to the monitoring and reporting of such taking.'' Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring. Reports from individual monitoring events, results of analyses, publications, and periodic progress reports for specific monitoring projects will be posted to the Navy's Marine Species Monitoring web portal: *http://www.navymarinespeciesmonitoring.us.* Currently, there are several different reporting requirements pursuant to these regulations:

Notification of Injured, Live Stranded or Dead Marine Mammals

The Navy will consult the Notification and Reporting Plan, which sets out notification, reporting, and other requirements when injured, live stranded, or dead marine mammals are detected. The Notification and Reporting Plan is available for review at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

Annual AFTT Monitoring Report

The Navy will submit an annual report to NMFS of the AFTT monitoring describing the implementation and results from the previous calendar year. Data collection methods will be standardized across range complexes and AFTT Study Area to allow for comparison in different geographic locations. The report will be submitted either 90 days after the calendar year, or 90 days after the conclusion of the monitoring year to be determined by the Adaptive Management process. Such a report would describe progress of knowledge made with respect to intermediate scientific objectives within the AFTT Study Area associated with the Integrated Comprehensive Monitoring Program. Similar study questions shall be treated together so that summaries can be provided for each topic area. The report need not include analyses and content that does not provide direct assessment of cumulative progress on the monitoring plan study questions.

Annual AFTT Exercise Report

Each year, the Navy will submit a preliminary report to NMFS detailing the status of authorized sound sources within 21 days after the anniversary of the date of issuance of the LOAs. Each year, the Navy shall submit a detailed report to NMFS within 3 months after the anniversary of the date of issuance of the LOA. The annual report shall contain information on Major Training Exercises (MTEs) and Shock Trials, Sinking Exercise (SINKEX) events, and a summary of all sound sources used, including within specified mitigation areas (total hours or quantity (per the LOA) of each bin of sonar or other non-impulsive source and total annual expended/detonated ordnance (missiles, bombs, sonobuoys, etc.) for each explosive bin). The report will also include the details regarding specific requirements associated with specific mitigation areas. The analysis in the detailed report will be based on the accumulation of data from the current year's report and data presented in the previous report. Information included in the classified annual reports may be used to inform future adaptive management of activities within the AFTT Study Area.

Major Training Exercises Notification

The Navy shall submit an electronic report to NMFS within fifteen calendar days after the completion of any major training exercise indicating: Location of the exercise; beginning and end dates of the exercise; and type of exercise.

Five-Year Close-Out Exercise Report

This report will be included as part of the 2023 annual exercise report. This report will provide the annual totals for each sound source bin with a comparison to the annual allowance and the five-year total for each sound source bin with a comparison to the five-year allowance. The draft report will be submitted to NMFS three months after the expiration of the rule. NMFS will provide comments, if any, to the Navy on the draft close-out report within three months of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or three months after the submittal of the draft report if NMFS does not provide comments.

Analysis and Negligible Impact Determination

Negligible Impact Analysis

Introduction

NMFS has defined negligible impact as ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.,* population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be ''taken'' through mortality, serious injury, and Level A or Level B harassment (as presented in Tables 39 and 41), 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' 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, other ongoing sources of human-caused mortality, ambient noise levels, and specific consideration of take by Level A harassment or serious injury or mortality (hereafter referred to as M/SI) previously authorized for other NMFS activities).

In the *Estimated Take of Marine Mammals* section, we identified the subset of potential effects that would be expected to rise to the level of takes, and then identified the number of each of those mortality takes that we believe could occur or harassment takes that are likely to occur based on the methods described. The impact that any given take will have is dependent on many case-specific factors that need to be considered in the negligible impact analysis (*e.g.,* the context of behavioral exposures such as duration or intensity of a disturbance, the health of impacted animals, the status of a species that incurs fitness-level impacts to individuals, etc.). Here we evaluate the likely impacts of the enumerated harassment takes that are proposed for authorization and anticipated to occur under this rule, in the context of the specific circumstances surrounding these predicted takes. We also include a specific assessment of serious injury or mortality takes that could occur, as well as consideration of the traits and statuses of the affected species and stocks. Last, we collectively evaluate this information, as well as other more taxa-specific information and mitigation measure effectiveness, in group-specific discussions that support our negligible impact conclusions for each stock.

Harassment

The Navy's Specified Activities reflects representative levels/ranges of training and testing activities, accounting for the natural fluctuation in training, testing, and deployment schedules. This approach is representative of how Navy's activities are conducted over any given year over any given five-year period. Specifically, the Navy provided a range of levels for each activity/source type for a year—they used the maximum annual level to calculate annual takes, and they used the sum of three nominal years (average level) and two maximum years to calculate five-year takes for each source type. The *Description of the Specified Activity* section contains a more realistic annual representation of activities, but includes years of a higher maximum amount of training and testing to account for these fluctuations. There may be some flexibility in the exact number of hours, items, or detonations that may vary from year to year, but take totals would not exceed the five-year totals indicated in Tables 39 through 41. We base our analysis and negligible impact determination (NID) on the maximum number of takes that would be reasonably expected to occur and are being authorized, although, as stated before, the number of takes are only a part of the analysis, which includes extensive qualitative consideration of other contextual factors that influence the degree of impact of the takes on the affected individuals. To avoid repetition, we provide some general analysis immediately below that applies to all the species listed in Tables 39 through 41, given that some of the anticipated effects of the Navy's training and testing activities on marine mammals are expected to be relatively similar in nature. However, below that, we break our analysis into species (and/or stock), or groups of species (and the associated stocks) where relevant similarities exist, to provide more specific information related to the anticipated effects on individuals of a specific stock or where there is information about the status or structure of any species that would lead to a differing assessment of the effects on the species or stock. Organizing our analysis by grouping species or stocks that share common traits or that will respond similarly to effects of the Navy's activities and then providing species- or stock-specific information allows us to avoid duplication while assuring that we have analyzed the effects of the specified activities on each affected species or stock.

The Navy's harassment take request is based on its model and quantitative assessment of mitigation, which NMFS believes appropriately, although likely somewhat conservatively, predicts the maximum amount of Level B harassment that is reasonably expected to occur. In the discussions below, the ''acoustic analysis'' refers to the Navy's modeling results and quantitative assessment of mitigation. The model calculates sound energy propagation from sonar, other active acoustic sources, and explosives during naval activities; the sound or impulse received by animat dosimeters representing marine mammals distributed in the area around the modeled activity; and whether the sound or impulse energy received by a marine mammal exceeds the thresholds for effects. Assumptions in the Navy model intentionally err on the side of overestimation when there are unknowns. Naval activities are modeled as though they would occur regardless of proximity to marine mammals, meaning that no mitigation is considered (*e.g.,* no power down or shut down) and without any avoidance of the activity by the animal. The final step of the quantitative analysis of acoustic effects, which occurs after the modeling, is to consider the implementation of mitigation and the possibility that marine mammals would avoid continued or repeated sound exposures. NMFS provided input to, independently reviewed, and concurred with, the Navy on this process and the Navy's analysis, which is described in detail in Chapter 6 of the Navy's rulemaking/LOA application (*https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities*), was used to quantify harassment takes for this rule.

Generally speaking, the Navy and NMFS anticipate more severe effects from takes resulting from exposure to higher received levels (though this is in no way a strictly linear relationship for behavioral effects throughout species, individuals, or circumstances) and less severe effects from takes resulting from exposure to lower received levels. However, there is also growing evidence of the importance of distance in predicting marine mammal behavioral response to sound—*i.e.,* sounds of a similar level emanating from a more distant source have been shown to be less likely to evoke a response of equal magnitude (DeRuiter 2012). The estimated number of Level A and Level B harassment takes does not equate to the number of individual animals the Navy expects to harass (which is lower), but rather to the instances of take (*i.e.,* exposures above the Level A and Level B harassment threshold) that are anticipated to occur over the five-year period. These instances may represent either brief exposures (seconds or minutes) or, in some cases, longer durations of exposure within a day. Some individuals may experience multiple instances of take (meaning over multiple days) over the course of the year, while some members of a species or stock may not experience take at all which means that the number of individuals taken is smaller than the total estimated takes. In other words, where the instances of take exceed the number of individuals in the population, repeated takes (on more than one day) of some individuals are predicted. Generally speaking, the higher the number of takes as compared to the population abundance, the more repeated takes of individuals are likely, and the higher the actual percentage of individuals in the population that are likely taken at least once in a year. We

look at this comparative metric to give us a relative sense of where larger portions of the stocks are being taken by Navy activities and where there is a higher likelihood that the same individuals are being taken across multiple days and where that number of days might be higher. In the ocean, the use of sonar and other active acoustic sources is often transient and is unlikely to repeatedly expose the same individual animals within a short period, for example within one specific exercise, however, some repeated exposures across different activities could occur over the year, especially where events occur in generally the same area with more resident species. In short, we expect that the total anticipated takes represent exposures of a smaller number of individuals of which some were exposed multiple times, but based on the nature of the Navy activities and the movement patterns of marine mammals, it is unlikely that individuals from most species or stocks would be taken over more than a few sequential days. This means repeated takes of individuals are likely to occur, they are more likely to result from non-sequential exposures from different activities and marine mammals are not predicted to be taken for more than a few days in a row, at most. As described elsewhere, the nature of the majority of the exposures would be expected to be of a less severe nature and based on the numbers it is likely that any individual exposed multiple times is still only taken on a small percentage of the days of the year. The greater likelihood is that not every individual is taken, or perhaps a smaller subset is taken with a slightly higher average and larger variability of highs and lows, but still with no reason to think that any individuals would be taken a significant portion of the days of the year, much less that many of the days of disturbance would be sequential.

Some of the lower level physiological stress responses (*e.g.,* orientation or startle response, change in respiration, change in heart rate) discussed earlier would likely co-occur with the predicted harassments, although these responses are more difficult to detect and fewer data exist relating these responses to specific received levels of sound. Level B harassment takes, then, may have a stress-related physiological component as well; however, we would not expect the Navy's generally short-term, intermittent, and (typically in the case of sonar) transitory activities to create conditions of long-term, continuous noise leading to long-term physiological stress responses in marine mammals.

The estimates calculated using the behavioral response function do not differentiate between the different types of behavioral responses that rise to the level of Level B harassments. As described in the Navy's application, the Navy identified (with NMFS' input) the types of behaviors that would be considered a take (moderate behavioral responses as characterized in Southall *et al.,* 2007 (*e.g.,* altered migration paths or dive profiles, interrupted nursing, breeding or feeding, or avoidance) that also would be expected to continue for the duration of an exposure). The Navy then compiled the available data indicating at what received levels and distances those responses have occurred, and used the indicated literature to build biphasic behavioral response curves that are used to predict how many instances of Level B behavioral harassment occur in a day. Take estimates alone do not provide information regarding the potential fitness or other biological consequences of the reactions on the affected individuals. We therefore consider the available activity-specific, environmental, and species-specific information to determine the likely nature of the modeled behavioral responses and the potential fitness consequences for affected individuals.

Use of sonar and other transducers would typically be transient and temporary. The majority of acoustic effects to mysticetes from sonar and other active sound sources during testing and training activities would be primarily from ASW events. It is important to note although ASW is one of the warfare areas of focus during MTEs, there are significant periods when active ASW sonars are not in use. Nevertheless, behavioral reactions are assumed more likely to be significant during MTEs than during other ASW activities due to the duration (*i.e.,* multiple days), scale (*i.e.,* multiple sonar platforms), and use of high-power hull-mounted sonar in the MTEs. In other words, in the range of potential behavioral effects that might expect to be part of a response that qualifies as an instance Level B behavioral harassment (which by nature of the way it is modeled/counted, occurs within one day), the less severe end might include exposure to comparatively lower levels of a sound, at a detectably greater distance from the animal, for a few or several minutes, and that could result in a behavioral response such as avoiding an area that an animal would otherwise have chosen to move through or feed in for some amount of time or breaking off one or a few feeding bouts. More severe effects could occur when the animal gets close enough to the source to receive a comparatively higher level, is exposed continuously to one source for a longer time, or is exposed intermittently to different sources throughout a day. Such effects might result in an animal having a more severe flight response and leaving a larger area for a day or more or potentially losing feeding opportunities for a day. However, such severe behavioral effects are expected to occur infrequently.

To help assess this, for sonar (LFAS/MFAS/HFAS) used in the AFTT Study Area, the Navy provided information estimating the percentage of animals that may be taken by Level B harassment under each behavioral response function that would occur within 6-dB increments (percentages discussed below in the *Group and Species-Specific Analyses* section). As mentioned above, all else being equal, an animal's exposure to a higher received level is more likely to result in a behavioral response that is more likely to lead to adverse effects, which could more likely accumulate to impacts on reproductive success or survivorship of the animal, but other contextual factors (such as distance) are important also. The majority of Level B harassment takes are expected to be in the form of milder responses (*i.e.,* lower-level exposures that still rise to the level of take, but would likely be less severe in the range of responses that qualify as take) of a generally shorter duration. We anticipate more severe effects from takes when animals are exposed to higher received levels or at closer proximity to the source. Because stocks belonging to the same species and species belonging to taxa that share common characteristics are likely to respond and be affected in similar ways, these discussions are presented within each species group below in the *Group and Species-Specific Analyses* section. Specifically, given a range of behavioral responses that may be classified as Level B harassment, to the degree that higher received levels are expected to result in more severe behavioral responses, only a smaller percentage of the anticipated Level B harassment from Navy activities might necessarily be expected to potentially result in more severe responses (see the *Group and Species-Specific Analyses* section below for more detailed information). To fully understand the likely impacts of the predicted/authorized take on an individual (*i.e.,* what is the likelihood or degree of fitness impacts), one must look closely at the available contextual

information, such as the duration of likely exposures and the likely severity of the exposures (*e.g.,* whether they will occur for a longer duration over sequential days or the comparative sound level that will be received). Moore and Barlow (2013) emphasizes the importance of context (*e.g.,* behavioral state of the animals, distance from the sound source, etc.) in evaluating behavioral responses of marine mammals to acoustic sources.

Diel Cycle

As noted previously, many animals perform vital functions, such as feeding, resting, traveling, and socializing on a diel cycle (24-hour cycle). Behavioral reactions to noise exposure, when taking place in a biologically important context, such as disruption of critical life functions, displacement, or avoidance of important habitat, are more likely to be significant if they last more than one diel cycle or recur on subsequent days (Southall *et al.,* 2007). Henderson *et al.,* 2016 found that ongoing smaller scale events had little to no impact on foraging dives for Blainville's beaked whale, while multi-day training events may decrease foraging behavior for Blainville's beaked whale (Manzano-Roth *et al.,* 2016). Consequently, a behavioral response lasting less than one day and not recurring on subsequent days is not considered severe unless it could directly affect reproduction or survival (Southall *et al.,* 2007). Note that there is a difference between multiple-day substantive behavioral reactions and multiple-day anthropogenic activities. For example, just because an at-sea exercise lasts for multiple days does not necessarily mean that individual animals are either exposed to those exercises for multiple days or, further, exposed in a manner resulting in a sustained multiple day substantive behavioral response. Large multi-day Navy exercises such as ASW activities, typically include vessels that are continuously moving at speeds typically 10–15 kn, or higher, and likely cover large areas that are relatively far from shore (typically more than 3 nmi from shore) and in waters greater than 600 ft deep. Additionally marine mammals are moving as well, which would make it unlikely that the same animal could remain in the immediate vicinity of the ship for the entire duration of the exercise. Further, the Navy does not necessarily operate active sonar the entire time during an exercise. While it is certainly possible that these sorts of exercises could overlap with individual marine mammals multiple days in a row at levels above those anticipated to result in a take, because of the factors mentioned above, it is considered unlikely for the majority of takes. However, it is also worth noting that the Navy conducts many different types of noise-producing activities over the course of the year and it is likely that some marine mammals will be exposed to more than one and taken on multiple days, even if they are not sequential.

Durations of Navy activities utilizing tactical sonar sources and explosives vary and are fully described in Appendix A of the AFTT FEIS/OEIS. Sonar used during ASW would impart the greatest amount of acoustic energy of any category of sonar and other transducers analyzed in the Navy's rulemaking/LOA application and include hull-mounted, towed, sonobuoy, helicopter dipping, and torpedo sonars. Most ASW sonars are MFAS (1–10 kHz); however, some sources may use higher or lower frequencies. ASW training activities using hull mounted sonar proposed for the AFTT Study Area generally last for only a few hours. Some ASW training and testing can generally last for 2–10 days, or as much as 21 days for an MTE-Large Integrated ASW (see Table 4). For these multi-day exercises there will typically be extended intervals of non-activity in between active sonar periods. Because of the need to train in a large variety of situations, the Navy does not typically conduct successive ASW exercises in the same locations. Given the average length of ASW exercises (times of sonar use) and typical vessel speed, combined with the fact that the majority of the cetaceans would not likely remain in proximity to the sound source, it is unlikely that an animal would be exposed to LFAS/MFAS/HFAS at levels or durations likely to result in a substantive response that would then be carried on for more than one day or on successive days.

Most planned explosive events are scheduled to occur over a short duration (1–8 hours); however, the explosive component of the activity only lasts for minutes (see Tables 4 through 7). Although explosive exercises may sometimes be conducted in the same general areas repeatedly, because of their short duration and the fact that they are in the open ocean and animals can easily move away, it is similarly unlikely that animals would be exposed for long, continuous amounts of time, or demonstrate sustained behavioral responses. Although SINKEXs may last for up to 48 hrs (4–8 hrs, possibly 1–2 days), they are almost always completed in a single day and only one event is planned annually for the AFTT training activities. They are stationary and conducted in deep, open water where fewer marine mammals would typically be expected to be encountered. They also have shutdown procedures and rigorous monitoring, *i.e.,* during the activity, the Navy conducts passive acoustic monitoring and visually observes for marine mammals 90 min prior to the first firing, during the event, and 2 hrs after sinking the vessel. All of these factors make it unlikely that individuals would be exposed to the exercise for extended periods or on consecutive days.

Last, as described previously, Navy modeling uses the best available science to predict the instances of exposure above certain acoustic thresholds, which are equated, as appropriate, to harassment takes (and further corrected to account for mitigation and avoidance). As further noted, for active acoustics it is more challenging to parse out the number of individuals taken by Level B harassment from this larger number of instances. One method that NMFS can use to help better understand the overall scope of the impacts is to compare these total instances of take against the abundance of that stock. For example, if there are 100 takes in a population of 100, one can assume either that every individual was exposed above acoustic thresholds in no more than one day, or that some smaller number were exposed in one day but a few of those individuals were exposed multiple days within a year. Where the instances of take exceed 100 percent of the population, multiple takes of some individuals are predicted and expected to occur within a year. Generally speaking, the higher the number of takes as compared to the population abundance, the more multiple takes of individuals are likely, and the higher the actual percentage of individuals in the population that are likely taken at least once in a year. We look at this comparative metric to give us a relative sense of where larger portions of the stocks are being taken by Navy activities and where there is a higher likelihood that the same individuals are being taken across multiple days and where that number of days might be higher. At a minimum, it provides a relative picture of the scale of impacts to each stock.

In short, we expect that the total anticipated takes represent exposures of a smaller number of individuals of which some would be exposed multiple times, but based on the nature of the Navy's activities and the movement patterns of marine mammals, it is unlikely that any particular subset would be taken over more than several sequential days (with a few possible

exceptions discussed in the stock-specific conclusions).

When calculating the proportion of a population affected by takes (*e.g.,* the number of takes divided by population abundance), it is important to choose an appropriate population estimate to make the comparison. In this case, we appropriately compared the predicted takes to abundance estimates generated from the same underlying density estimate used to calculate the predicted take (described earlier and below), versus abundance estimates from the SARs, which are not based on the same data (and are more limited) and would not be appropriate for this purpose. The SARs provide the official population estimate for a given species or stock in U.S. waters in a given year and are typically based solely on the most recent survey data, but they are not the only information used to estimate takes. Instead here modeled density layers are used, which incorporate the SAR surveys and other survey data. If takes are calculated from another dataset (for example a broader sample of survey data) and compared to the population estimate from the SARs, it would misrepresent the percent of the population affected because of different population baselines. Note that to further refine NMFS' comparison of take to the population (which may be found in the *Group and Species-Specific Analyses* section below), comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty and takes are notably greater) and across the whole AFTT Study Area, which offers a more comprehensive comparison for many stocks.

The Navy uses, and NMFS concurs with, the use of spatially and temporally explicit density models (based on the best available science) that vary in space and time to estimate their potential impacts to species. See the *U.S. Navy Marine Species Density Database Phase III for the Atlantic Fleet Training and Testing Area Technical Report* to learn more on how the Navy selects density information and the models selected for individual species. These models may better characterize how Navy impacts can vary in space and time but often predict different population abundances than the SARs.

Models may predict different population abundances for many reasons. The models may be based on different data sets or different temporal predictions may be made. The SARs are often based on single years of NMFS surveys whereas the models used by the Navy generally include multiple years of survey data from NMFS, the Navy, and other sources. To present a single, best estimate, the SARs often use a single season survey where they have the best spatial coverage (generally summer). Navy models often use predictions for multiple seasons, where appropriate for the species, even when survey coverage in non-summer seasons is limited, to characterize impacts over multiple seasons as Navy activities may occur in any season. Predictions may be made for different spatial extents. Many different, but equally valid, habitat and density modeling techniques exist and these can also be the cause of differences in population predictions. Differences in population estimates may be caused by a combination of these factors. Even similar estimates should be interpreted with caution and differences in models must be fully understood before drawing conclusions.

The AFTT Study Area covers a broad area in the western North Atlantic Ocean and the GOMEX. The Navy has tried to find density estimates for this entire area, where appropriate given species distributions. However, only a small number of Navy training and testing activities occur outside of the U.S. EEZ. As such, NMFS believes that the average population predicted by Navy models across seasons in the U.S. EEZ is the best baseline to use when analyzing takes as a proportion of population. This is a close approximation of the actual population used in Navy take analysis as occasionally sound can propagate outside of the U.S. EEZ and a small number of exercises do occur in international waters. This approximation will be less accurate for species with major changes in density close to the U.S. EEZ or far offshore. Models of individual species or stocks were not available for all species and takes had to be proportioned to the species or stock level from takes predicted on models at higher taxonomic levels. See the various Navy technical reports mentioned previously in this rule that detail take estimation and density model selection proposed by Navy and adopted by NMFS for details.

TTS

NMFS and the Navy have estimated that some individuals of some species of marine mammals may sustain some level of TTS from active sonar. As mentioned previously, in general, TTS can last from a few minutes to days, be of varying degree, and occur across various frequency bandwidths, all of which determine the severity of the impacts on the affected individual, which can range from minor to more severe. Tables 72–77 indicate the number of takes by TTS that may be incurred by different stocks from exposure to active sonar and explosives. No TTS is estimated from air guns or pile driving activities because it is unlikely to occur. The TTS sustained by an animal is primarily classified by three characteristics:

1. Frequency—Available data (of mid-frequency hearing specialists exposed to mid- or high-frequency sounds; Southall *et al.,* 2007) suggest that most TTS occurs in the frequency range of the source up to one octave higher than the source (with the maximum TTS at ½ octave above). The Navy's MF sources, which are the highest power and most numerous sources and the ones that cause the most take, utilize the 1–10 kHz frequency band, which suggests that if TTS were to be induced by any of these MF sources it would be in a frequency band somewhere between approximately 2 and 20 kHz, which is in the range of communication calls for many odontocetes. There are fewer hours of HF source use and the sounds would attenuate more quickly, plus they have lower source levels, but if an animal were to incur TTS from these sources, it would cover a higher frequency range (sources are between 10 and 100 kHz, which means that TTS could range up to 200 kHz), which could overlap with the range in which some odontocetes communicate or echolocate. However, HF systems are typically used less frequently and for shorter time periods than surface ship and aircraft MF systems, so TTS from these sources is unlikely. There are fewer LF sources and the majority are used in the more readily mitigated testing environment, and TTS from LF sources would most likely occur below 2 kHz, which is in the range where many mysticetes communicate and also where other non-communication auditory cues are located (waves, snapping shrimp, fish prey). TTS from explosives would be broadband. Also of note, the majority of sonar sources from which TTS may be incurred occupy a narrow frequency band, which means that the TTS incurred would also be across a narrower band (*i.e.,* not affecting the majority of an animal's hearing range). This frequency provides information about the cues to which a marine mammal may be temporarily less sensitive, but not the degree or duration of sensitivity loss.

2. Degree of the shift (*i.e.,* by how many dB the sensitivity of the hearing is reduced)—Generally, both the degree of TTS and the duration of TTS will be greater if the marine mammal is exposed to a higher level of energy (which would

occur when the peak dB level is higher or the duration is longer). The threshold for the onset of TTS was discussed previously in this rule. An animal would have to approach closer to the source or remain in the vicinity of the sound source appreciably longer to increase the received SEL, which would be difficult considering the Lookouts and the nominal speed of an active sonar vessel (10–15 kn) and the relative motion between the sonar vessel and the animal. In the TTS studies discussed in the proposed rule, some using exposures of almost an hour in duration or up to 217 SEL, most of the TTS induced was 15 dB or less, though Finneran *et al.* (2007) induced 43 dB of TTS with a 64-second exposure to a 20 kHz source. However, since any hull-mounted sonar such as the SQS–53 (MFAS), emits a ping typically every 50 seconds, incurring those levels of TTS is highly unlikely. In short, given the anticipated duration and levels of sound exposure, we would not expect marine mammals to incur more than relatively low levels of TTS (*i.e.,* single digits of sensitivity loss). To add context to this degree of TTS, individual marine mammals may regularly experience variations of 6dB differences in hearing sensitivity across time (Finneran *et al.,* 2000; Schlundt *et al.,* 2000; Finneran *et al.,* 2002).

3. Duration of TTS (recovery time)—In the TTS laboratory studies (as discussed in the proposed rule), some using exposures of almost an hour in duration or up to 217 SEL, almost all individuals recovered within 1 day (or less, often in minutes), although in one study (Finneran *et al.,* 2007), recovery took 4 days.

Based on the range of degree and duration of TTS reportedly induced by exposures to non-pulse sounds of energy higher than that to which free-swimming marine mammals in the field are likely to be exposed during LFAS/MFAS/HFAS training and testing exercises in the AFTT Study Area, it is unlikely that marine mammals would ever sustain a TTS from MFAS that alters their sensitivity by more than 20 dB for more than a few hours—and any incident of TTS would likely be far less severe due to the short duration of the majority of the events and the speed of a typical vessel, especially given the fact that the higher power sources resulting in TTS are predominantly intermittent, which have been shown to result in shorter durations of TTS. Also, for the same reasons discussed in the *Analysis and Negligible Impact Determination—Diel Cycle* section, and because of the short distance within which animals would need to approach the sound source, it is unlikely that animals would be exposed to the levels necessary to induce TTS in subsequent time periods such that their recovery is impeded. Additionally, though the frequency range of TTS that marine mammals might sustain would overlap with some of the frequency ranges of their vocalization types, the frequency range of TTS from MFAS (the source from which TTS would most likely be sustained because the higher source level and slower attenuation make it more likely that an animal would be exposed to a higher received level) would not usually span the entire frequency range of one vocalization type, much less span all types of vocalizations or other critical auditory cues.

Tables 72–77 indicate the number of incidental takes by TTS that are likely to result from the Navy's activities. As a general point, the majority of these TTS takes are the result of exposure to hull-mounted MFAS (MF narrower band sources), with fewer from explosives (broad-band lower frequency sources), and even fewer from LF or HF sonar sources (narrower band). As described above, we expect the majority of these takes to be in the form of mild (single-digit), short-term (minutes to hours), narrower band (only affecting a portion of the animals hearing range) TTS. This means that for one to several times per year, for several minutes to maybe a few hours (high end) each, a taken individual will have slightly diminished hearing sensitivity (slightly more than natural variation, but nowhere near total deafness) more often within a narrower mid- to higher frequency band that may overlap part (but not all) of a communication, echolocation, or predator range, but sometimes across a lower or broader bandwidth. The significance of TTS is also related to the auditory cues that are germane within the time period that the animal incurs the TTS—for example, if an odontocete has TTS at echolocation frequencies, but incurs it at night when it is resting and not feeding, for example, it is not impactful. In short, the expected results of any one of these small number of mild TTS occurrences could be that (1) it does not overlap signals that are pertinent to that animal in the given time period, (2) it overlaps parts of signals that are important to the animal, but not in a manner that impairs interpretation, or (3) it reduces detectability of an important signal to a small degree for a short amount of time—in which case the animal may be aware and be able to compensate (but there may be slight energetic cost), or the animal may have some *reduced* opportunities (*e.g.,* to detect prey) or *reduced* capabilities to react with maximum effectiveness (*e.g.,* to detect a predator or navigate optimally). However, given the small number of times that any individual might incur TTS, the low degree of TTS and the short anticipated duration, and the low likelihood that one of these instances would occur in a time period in which the specific TTS overlapped the entirety of a critical signal, it is unlikely that TTS of the nature expected to result from Navy activities would result in behavioral changes or other impacts that would impact any individual's (of any hearing sensitivity) reproduction or survival.

Acoustic Masking or Communication Impairment

The ultimate potential impacts of masking on an individual (if it were to occur) are similar to those discussed for TTS, but an important difference is that masking only occurs during the time of the signal (and potential secondary arrivals of indirect rays), versus TTS, which continues beyond the duration of the signal. Fundamentally, masking is referred to as a chronic effect because one of the key harmful components of masking is its duration—the fact that an animal would have reduced ability to hear or interpret critical cues becomes much more likely to cause a problem the longer it is occurring. Also inherent in the concept of masking is the fact that the potential for the effect is only present during the times that the animal and the source are in close enough proximity for the effect to occur (and further, this time period would need to coincide with a time that the animal was utilizing sounds at the masked frequency). As our analysis has indicated, because of the relative movement of vessels and the species involved in this rule, we do not expect the exposures with the potential for masking to be of a long duration. In addition, masking is fundamentally more of a concern at lower frequencies (because low frequency signals propagate significantly further than higher frequencies and because they are more likely to overlap both the narrower LF calls of mysticetes, as well as many non-communication cues such as fish and invertebrate prey, and geologic sounds that inform navigation) and from continuous sources where there is no quiet time between pulses within which auditory signals can be detected and interpreted. For these reasons, dense aggregations of, and long exposure to, continuous LF activity, such as shipping or seismic airgun operation (the latter

signal changes from intermittent to continuous at distance), are much more of a concern for masking, whereas comparatively short-term exposure to the predominantly intermittent pulses of MFAS or HFAS, or explosions are not expected to result in a meaningful amount of masking. While the Navy occasionally uses LF and more continuous sources, it is not in the contemporaneous aggregate amounts that would accrue to a masking concern. Specifically, the nature of the activities and sound sources used by the Navy do not support the likelihood of a level of masking accruing that would have the potential to affect reproductive success or survival. Additional detail is provided below.

Standard hull-mounted MFAS typically ping every 50 seconds for hull-mounted sources. Some hull-mounted anti-submarine sonars can also be used in an object detection mode known as ''Kingfisher'' mode (*e.g.,* used on vessels when transiting to and from port) where pulse length is shorter but pings are much closer together in both time and space since the vessel goes slower when operating in this mode. For the majority of sources, the pulse length is significantly shorter than hull-mounted active sonar, on the order of several microseconds to tens of milliseconds. Some of the vocalizations that many marine mammals make are less than one second long, so, for example with hull-mounted sonar, there would be a 1 in 50 chance (only if the source was in close enough proximity for the sound to exceed the signal that is being detected) that a single vocalization might be masked by a ping. However, when vocalizations (or series of vocalizations) are longer than one second, masking would not occur. Additionally, when the pulses are only several microseconds long, the majority of most animals' vocalizations would not be masked.

Most ASW sonars and countermeasures use MF frequencies and a few use LF and HF frequencies. Most of these sonar signals are limited in the temporal, frequency, and spatial domains. The duration of most individual sounds is short, lasting up to a few seconds each. A few systems operate with higher duty cycles or nearly continuously, but they typically use lower power, which means that an animal would have to be closer, or in the vicinity for a longer time, to be masked to the same degree as by a higher level source. Nevertheless, masking could occasionally occur at closer ranges to these high-duty cycle and continuous active sonar systems, but as described previously, it would be expected to be of a short duration when the source and animal are in close proximity. Most ASW activities are geographically dispersed and last for only a few hours, often with intermittent sonar use even within this period. Most ASW sonars also have a narrow frequency band (typically less than one-third octave). These factors reduce the likelihood of sources causing significant masking. HF signals (above 10 kHz) attenuate more rapidly in the water due to absorption than do lower frequency signals, thus producing only a very small zone of potential masking. If masking or communication impairment were to occur briefly, it would more likely be in the frequency range of MFAS (the more powerful source), which overlaps with some odontocete vocalizations; however, it would likely not mask the entirety of any particular vocalization, communication series, or other critical auditory cue, because the signal length, frequency, and duty cycle of the MFAS/HFAS signal does not perfectly resemble the characteristics of any marine mammal's vocalizations.

Masking could occur briefly in mysticetes due to the overlap between their low-frequency vocalizations and the dominant frequencies of airgun pulses. However, masking in odontocetes or pinnipeds is less likely unless the airgun activity is in close range when the pulses are more broadband. Masking is more likely to occur in the presence of broadband, relatively continuous noise sources such as during vibratory pile driving and from vessels, however, the duration of temporal and spatial overlap with any individual animal and the spatially separated sources that the Navy uses would not be expected to result in more than short-term, low impact masking that would not affect reproduction or survival.

The other sources used in Navy training and testing, many of either higher frequencies (meaning that the sounds generated attenuate even closer to the source) or lower amounts of operation, are similarly not expected to result in masking. For the reasons described here, any limited masking that could potentially occur would be minor and short-term and not expected to have adverse impacts on reproductive success or survivorship.

PTS from Sonar Acoustic Sources and Explosives and Tissue Damage From Explosives

Tables 72–77 indicate the number of individuals of each of species and stock for which Level A harassment in the form of PTS resulting from exposure to active sonar and/or explosives is estimated to occur. Tables 72–77 also indicate the number of individuals of each of species and stock for which Level A harassment in the form of tissue damage resulting from exposure to explosive detonations is estimated to occur. The number of individuals to potentially incur PTS annually (from sonar and explosives) for the predicted species ranges from 0 to 454 (454 for harbor porpoise), but is more typically a few up to 31 (with the exception of a few species). The number of individuals to potentially incur tissue damage from explosives for the predicted species ranges from 0 to 36 (36 for short-beaked common dolphin), but is typically zero in most cases.

NMFS believes that many marine mammals would deliberately avoid exposing themselves to the received levels of active sonar necessary to induce injury by moving away from or at least modifying their path to avoid a close approach. Additionally, in the unlikely event that an animal approaches the sonar-emitting vessel at a close distance, NMFS believes that the mitigation measures (*i.e.,* shutdown/powerdown zones for active sonar) would typically ensure that animals would not be exposed to injurious levels of sound. As discussed previously, the Navy utilizes both aerial (when available) and passive acoustic monitoring (during ASW exercises, passive acoustic detections are used as a cue for Lookouts' visual observations when passive acoustic assets are already participating in an activity) in addition to Lookouts on vessels to detect marine mammals for mitigation implementation. As discussed previously, the Navy utilized a post-modeling quantitative assessment to adjust the take estimates based on avoidance and the likely success of some portion of the mitigation measures. As is typical in predicting biological responses, it is challenging to predict exactly how avoidance and mitigation will affect the take of marine mammals, and therefore the Navy erred on the side of caution in choosing a method that would more likely still overestimate the take by PTS to some degree. Nonetheless, these modified Level A harassment take numbers are the most appropriate estimates of what is likely to occur, and we have analyzed them.

If a marine mammal is able to approach a surface vessel within the distance necessary to incur PTS in spite of the mitigation measures, the likely speed of the vessel (nominally 10–15 kn) and relative motion of the vessel would make it very difficult for the

animal to remain in range long enough to accumulate enough energy to result in more than a mild case of PTS. As mentioned previously and in relation to TTS, the likely consequences to the health of an individual that incurs PTS can range from mild to more serious dependent upon the degree of PTS and the frequency band it is in. The majority of any PTS incurred as a result of exposure to Navy sources would be expected to be in the 2–20 kHz region (resulting from the most powerful hull-mounted sonar) and could overlap a small portion of the communication frequency range of many odontocetes, whereas other marine mammal groups have communication calls at lower frequencies. Regardless of the frequency band though, the more important point in this case is that any PTS accrued as a result of exposure to Navy activities would be expected to be of a small amount (single digits). Permanent loss of some degree of hearing is a normal occurrence for older animals, and many animals are able to compensate for the shift, both in old age or at younger ages as the result of stressor exposure. While a small loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, at the expected scale it would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival.

We also assume that the acoustic exposures sufficient to trigger onset PTS (or TTS) would be accompanied by physiological stress responses, although the sound characteristics that correlate with specific stress responses in marine mammals are poorly understood. As discussed above for Level B behavioral harassment, we would not expect the Navy's generally short-term, intermittent, and (in the case of sonar) transitory activities to create conditions of long-term, continuous noise leading to long-term physiological stress responses in marine mammals that could affect reproduction or survival.

The Navy implements mitigation measures (described in the *Mitigation Measures* section) during explosive activities, including delaying detonations when a marine mammal is observed in the mitigation zone. Nearly all explosive events will occur during daylight hours to improve the sightability of marine mammals and thereby improve mitigation effectiveness. Observing for marine mammals during the explosive activities will include aerial and passive acoustic detection methods (when they are available and part of the activity) before the activity begins, in order to cover the mitigation zones that can range from 200 yds (183 m) to 2,500 yds (2,286 m) depending on the source (*e.g.,* explosive sonobuoy, explosive torpedo, explosive bombs), and 2.5 nmi for sinking exercise (see Tables 48—57).

Observing for marine mammals during ship shock (which includes Lookouts in aircraft or on multiple vessels) begins 5 hrs before the detonation and extends 3.5 nmi from the ship's hull (see Table 58). The required mitigation is expected to reduce the likelihood that all of the takes will occur. Some, though likely not all, of that reduction was quantified in the Navy's quantitative assessment of mitigation; however, we analyze the type and amount of take by Level A harassment in Tables 39 through 41. Generally speaking, tissue damage injuries from explosives could range from minor lung injuries (the most sensitive organ and first to be affected) that consist of some short-term reduction of health and fitness immediately following the injury that heals quickly and will not have any discernible long-term effects, up to more impactful permanent injuries across multiple organs that may cause health problems and negatively impact reproductive success (*i.e.,* increase the time between pregnancies or even render reproduction unlikely) but fall just short of a ''serious injury'' by virtue of the fact that the animal is not expected to die. Nonetheless, due to the Navy's mitigation and detection capabilities, we would not expect marine mammals to typically be exposed to a more severe blast located closer to the source—so the impacts likely would be on the less severe end. It is still difficult to evaluate how these injuries may or may not impact an animal's fitness, however, these effects are only seen in very small numbers (single digits with the exception of two stocks) and in species of fairly high to very high abundances. In short, it is unlikely that any, much less all, of the small number of injuries accrued to any one stock would result in reduced reproductive success of any individuals, but even if a few did, the status of the affected stocks are such that it would not be expected to adversely impact rates of reproduction.

Serious Injury and Mortality

NMFS is authorizing a very small number of serious injuries or mortalities that could occur in the event of a ship strike or as a result of marine mammal exposure to explosive detonations. We note here that the takes from potential ship strikes or explosive exposures enumerated below could result in non-serious injury, but their worst potential outcome (mortality) is analyzed for the purposes of the negligible impact determination.

In addition, we discuss here the connection, and differences, between the legal mechanisms for authorizing incidental take under section 101(a)(5) for activities such as the Navy's testing and training in the AFTT Study Area, and for authorizing incidental take from commercial fisheries. In 1988, Congress amended the MMPA's provisions for addressing incidental take of marine mammals in commercial fishing operations. Congress directed NMFS to develop and recommend a new long-term regime to govern such incidental taking (see MMC, 1994). The need to develop a system suited to the unique circumstances of commercial fishing operations led NMFS to suggest a new conceptual means and associated regulatory framework. That concept, PBR, and a system for developing plans containing regulatory and voluntary measures to reduce incidental take for fisheries that exceed PBR were incorporated as sections 117 and 118 in the 1994 amendments to the MMPA.

PBR is defined in section 3 of 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 OSP and, although not controlling, can be one measure considered among other factors when evaluating the effects of M/SI on a marine mammal species or stock during the section 101(a)(5)(A) process. OSP is defined in section 3 of the MMPA as ''the number of animals which will result in the maximum productivity of the population or the species, keeping in mind the carrying capacity of the habitat and the health of the ecosystem of which they form a constituent element.'' Through section 2, an overarching goal of the statute is to ensure that each species or stock of marine mammal is maintained at or returned to its OSP.

PBR values are calculated by NMFS as the level of annual removal from a stock that will allow that stock to equilibrate within OSP at least 95 percent of the time, and is the product of factors relating to the minimum population estimate of the stock (N_{min}), the productivity rate of the stock at a small population size, and a recovery factor. Determination of appropriate values for these three elements incorporates significant precaution, such that application of the parameter to the management of marine mammal stocks may be reasonably certain to achieve the

goals of the MMPA. For example, calculation of the minimum population estimate (N_{min}) incorporates the level of precision and degree of variability associated with abundance information, while also providing (typically the 20th percentile of a log-normal distribution of the population estimate) reasonable assurance that the stock size is equal to or greater than the estimate (Barlow *et al.,* 1995). In general, the three factors are developed on a stock-specific basis in consideration of one another in order to produce conservative PBR values that appropriately account for both imprecision that may be estimated, as well as potential bias stemming from lack of knowledge (Wade, 1998).

Congress called for PBR to be applied within the management framework for commercial fishing incidental take under section 118 of the MMPA. As a result, PBR cannot be applied appropriately outside of the section 118 regulatory framework without consideration of how it applies within the section 118 framework, as well as how the other statutory management frameworks in the MMPA differ from the framework in section 118. PBR was not designed and is not used as an absolute threshold limiting commercial fisheries. Rather, it serves as a means to evaluate the relative impacts of those activities on marine mammal stocks. Even where commercial fishing is causing M/SI at levels that exceed PBR, the fishery is not suspended. When M/SI exceeds PBR in the commercial fishing context under section 118, NMFS may develop a take reduction plan, usually with the assistance of a take reduction team. The take reduction plan will include measures to reduce and/or minimize the taking of marine mammals by commercial fisheries to a level below the stock's PBR. That is, where the total annual human-caused M/SI exceeds PBR, NMFS is not required to halt fishing activities contributing to total M/SI but rather utilizes the take reduction process to further mitigate the effects of fishery activities via additional bycatch reduction measures. In other words, under section 118 of the MMPA, PBR does not serve as a strict cap on the operation of commercial fisheries that may incidentally take marine mammals.

Similarly, to the extent PBR may be relevant when considering the impacts of incidental take from activities other than commercial fisheries, using it as the sole reason to deny (or issue) incidental take authorization for those activities would be inconsistent with Congress's intent under section 101(a)(5) and the use of PBR under section 118. The standard for authorizing incidental take under section 101(a)(5) continues to be, among other things, whether the total taking will have a negligible impact on the species or stock. When Congress amended the MMPA in 1994 to add section 118 for commercial fishing, it did not alter the standards for authorizing non-commercial fishing incidental take under section 101(a)(5), implicitly acknowledging that the negligible impact standard under section 101(a)(5) is separate from the PBR metric under section 118. In fact, in 1994 Congress also amended section 101(a)(5)(E) (a separate provision governing commercial fishing incidental take for species listed under the ESA) to add compliance with the new section 118 but retained the requirement for a negligible impact finding under section 101(a)(5)(A), showing that Congress understood that the determination of negligible impact and application of PBR may share certain features but are, in fact, different.

Since the introduction of PBR, NMFS has used the concept almost entirely within the context of implementing sections 117 and 118 and other commercial fisheries management-related provisions of the MMPA. Although there are a few examples where PBR has informed agency deliberations under other sections of the MMPA, where PBR has been raised it has been a consideration and not dispositive to the issue at hand. Further, the agency's thoughts regarding the potential role of PBR in relation to other programs of the MMPA have evolved since the agency's earlier applications to section 101(a)(5) decisions. The MMPA requires that PBR be estimated in SARs and that it be used in applications related to the management of take incidental to commercial fisheries (*i.e.,* the take reduction planning process described in section 118 of the MMPA and the determination of whether a stock is ''strategic'' as defined in section 3), but nothing in the statute requires the application of PBR outside the management of commercial fisheries interactions with marine mammals.

Nonetheless, NMFS recognizes that as a quantitative metric, PBR may be useful as a consideration when evaluating the impacts of other human-caused activities on marine mammal stocks. Outside the commercial fishing context, and in consideration of all known human-caused mortality, PBR can help inform the potential effects of M/SI requested to be authorized under 101(a)(5)(A). As noted by NMFS and the USFWS in our implementation regulations for the 1986 amendments to the MMPA (54 FR 40341, September 29, 1989), the Services consider many factors, when available, in making a negligible impact determination, including, but not limited to, the status of the species or stock relative to OSP (if known); whether the recruitment rate for the species or stock is increasing, decreasing, stable, or unknown; the size and distribution of the population; and existing impacts and environmental conditions. In this multi-factor analysis, PBR can be a useful indicator for when, and to what extent, the agency should take an especially close look at the circumstances associated with the potential mortality, along with any other factors that could influence annual rates of recruitment or survival.

When considering PBR during evaluation of effects of M/SI under section 101(a)(5)(A), we first calculate a metric for each species or stock that incorporates information regarding ongoing anthropogenic M/SI into the PBR value (*i.e.,* PBR minus the total annual anthropogenic mortality/serious injury estimate), which is called ''residual PBR.'' (Wood *et al.,* 2012). We focus our analysis on residual PBR because it incorporates anthropogenic mortality occurring from other sources. We then consider how the anticipated or potential incidental M/SI from the activities being evaluated compares to residual PBR using the following framework.

Where a specified activity could cause (and NMFS is contemplating authorizing) incidental M/SI that is less than 10 percent of residual PBR (the ''insignificance threshold, see below), we consider M/SI from the specified activities to represent an insignificant incremental increase in ongoing anthropogenic M/SI for the marine mammal stock in question that alone (*i.e.,* in the absence of any other take) will not adversely affect annual rates of recruitment and survival. As such, this amount of M/SI would not be expected to affect rates of recruitment or survival in a manner resulting in more than a negligible impact on the affected stock unless there are other factors that could affect reproduction or survival, such as Level A and/or Level B harassment, or considerations such as information that illustrates the uncertainty involved in the calculation of PBR for some stocks. In a prior incidental take rulemaking, this threshold was identified as the ''significance threshold,'' but it is more accurately labeled an insignificance threshold, and so we use that terminology here. Assuming that any additional incidental take by Level A or Level B harassment from the activities in question would not combine with the effects of the authorized M/SI to exceed

the negligible impact level, the anticipated M/SI caused by the activities being evaluated would have a negligible impact on the species or stock. However, M/SI above the 10 percent insignificance threshold does not indicate that the M/SI associated with the specified activities is approaching a level that would necessarily exceed negligible impact. Rather, the 10 percent insignificance threshold is meant only to identify instances where additional analysis of the anticipated M/SI is not required because the negligible impact standard clearly will not be exceeded on that basis alone.

Where the anticipated M/SI is near, at, or above residual PBR, consideration of other factors (positive or negative), including those outlined above, as well as mitigation is especially important to assessing whether the M/SI will have a negligible impact on the species or stock. PBR is a conservative metric and not sufficiently precise to serve as an absolute predictor of population effects upon which mortality caps would appropriately be based. For example, in some cases stock abundance (which is one of three key inputs into the PBR calculation) is underestimated because marine mammal survey data within the U.S. EEZ are used to calculate the abundance even when the stock range extends well beyond the U.S. EEZ. An underestimate of abundance could result in an underestimate of PBR. Alternatively, we sometimes may not have complete M/SI data beyond the U.S. EEZ to compare to PBR, which could result in an overestimate of residual PBR. M/SI that exceeds PBR may still potentially be found to be negligible in light of other factors that offset concern, especially when robust mitigation and adaptive management provisions are included.

In *Conservation Council for Hawaii* v. *National Marine Fisheries Service,* 97 F. Supp.3d 1210, 1225 (D. Haw. 2015), which concerned a challenge to NMFS' issuance of letters of authorization to the Navy for activities in an area of the Pacific Ocean known as the HSTT Study Area, the Court reached a different conclusion, stating, ''Because any mortality level that exceeds PBR will not allow the stock to reach or maintain its OSP, such a mortality level could not be said to have only a 'negligible impact' on the stock.'' As described above, the Court's statement fundamentally misunderstands the two terms and incorrectly indicates that these concepts (PBR and ''negligible impact'') are directly connected, when in fact nowhere in the MMPA is it indicated that these two terms are equivalent.

Specifically, PBR was designed as a tool for evaluating mortality and is defined as the number of animals that can be removed while ''allowing the stock to reach or maintain OSP,'' with the formula for PBR designed to ensure that growth towards OSP is not reduced by more than 10 percent (or equilibrate to OSP 95 percent of the time). Separately, and without reference to PBR, NMFS' long-standing MMPA implementing regulations state that take will have a negligible impact when it does not ''adversely affect the species or stock through effects on annual rates of recruitment or survival.'' OSP (to which PBR is linked) is defined in the statute as a population which falls within a range from the population level that is the largest supportable within the ecosystem to the population level that results in maximum net productivity. OSP is an aspirational goal of the overall statute and PBR is designed to ensure minimal deviation from this overarching goal. The ''negligible impact'' determination and finding protects against ''adverse impacts on the affected species and stocks'' when evaluating specific activities.

For all these reasons, even where M/SI exceeds residual PBR, it is still possible for the take to have a negligible impact on the species or stock. While ''allowing a stock to reach or maintain OSP'' would ensure that NMFS approached the negligible impact standard in a conservative and precautionary manner so that there were not ''adverse effects on affected species or stocks,'' it is equally clear that in some cases the time to reach this aspirational OSP could be slowed by more than 10 percent (*i.e.,* total human-caused mortality in excess of PBR could be allowed) without adversely affecting a species or stock. Another difference between the two standards is the temporal scales upon which the terms focus. That is, OSP contemplates the incremental, 10 percent reduction in the rate to approach a goal that is tens or hundreds of years away. The negligible impact analysis, on the other hand, necessitates an evaluation of annual rates of recruitment or survival to support the decision of whether to issue five-year regulations.

Accordingly, while PBR is useful for evaluating the effects of M/SI in section 101(a)(5)(A) determinations, it is just one consideration to be assessed in combination with other factors and should not be considered determinative. The accuracy and certainty around the data that feed any PBR calculation (*e.g.,* the abundance estimates) must be carefully considered. This approach of using PBR as a trigger for concern while also considering other relevant factors provides a reasonable and appropriate means of evaluating the effects of potential mortality on rates of recruitment and survival, while demonstrating that it is possible to exceed PBR by some small amount and still make a negligible impact determination under section 101(a)(5)(A).

Our evaluation of the M/SI for each of the species and stocks for which mortality could occur follows. No mortalities or serious injuries are anticipated from Navy's sonar activities. In addition, all mortality authorized for some of the same species or stocks over the next several years pursuant to our final rulemaking for the NMFS' NEFSC has been incorporated into the residual PBR.

We first consider maximum potential incidental M/SI from Navy's ship strike analysis for the affected mysticetes and sperm whales (see Table 69) and from the Navy's explosive detonations for the affected dolphin species (see Table 70) in consideration of NMFS' threshold for identifying insignificant M/SI take. By considering the maximum potential incidental M/SI in relation to PBR and ongoing sources of anthropogenic mortality, we begin our evaluation of whether the potential incremental addition of M/SI through Navy's ship strikes and explosive detonations may affect the species' or stocks' annual rates of recruitment or survival. We also consider the interaction of those mortalities with incidental taking of that species or stock by harassment pursuant to the specified activity.

Based on the methods discussed previously, NMFS believes that mortal takes of three large whales over the course of the five-year rule could occur, but that no more than one over the five years of any species of humpback whale, fin whale, sei whale, minke whale, or sperm whale (North Atlantic stock) would occur. This means an annual average of 0.2 whales from each species or stock as described in Table 69 (*i.e.,* 1 take over 5 years divided by 5 to get the annual number) is planned for authorization.

TABLE 69—SUMMARY INFORMATION RELATED TO AFTT SHIP STRIKE, 2018–2023

Species (stock)	Stock abundance (Nbest)*	Annual planned take by serious injury or mortality [1]	Total annual M/SI * [2]	Fisheries interactions (Y/N); Annual rate of M/SI from Fisheries Interactions *	Vessel collisions (Y/N); annual rate of M/SI from vessel collision *	PBR *	NEFSC authorized take (annual)	Residual PBR–PBR minus annual M/SI and NEFSC authorized take [3]	Stock trend * [4]	UME (Y/N); number and year
Fin whale (Western North Atlantic).	1,618	0.2	2.5	Y; 1.1	Y; 1.4	2.5	0	0	?	N
Sei whale (Nova Scotia).	357	0.2	0.6	N; 0	Y; 0.6	0.5	0	−0.1	?	N
Minke Whale (Canadian East Coast).	2,591	0.2	7.5	Y; 6.5	Y; 1.1	14	1	5.5	?	Y/43; total in 2018 (27 in 2017 and 60 in 2018).
Humpback whale (Gulf of Maine).	[5] 896	0.2	9.8	Y; 7.1	Y; 2.7	14.6	0	4.8	↑	Y/81; total in 2018 (26 in 2016, 33 in 2017 and 22 in 2018).
Sperm whale (North Atlantic).	2,288	0.2	0.8	Y; 0.6	Y; 0.2	3.6	0	2.8	?	?

* Presented in the draft 2018 SARS.
[1] This column represents the annual take by serious injury or mortality by vessel collision and was calculated by the number of mortalities planned for authorization divided by five years (the length of the rule and LOAs).
[2] This column represents the total number of incidents of M/SI that could potentially accrue to the specified species or stock. This number comes from the SAR, but deducts the takes accrued from either Navy strikes or NEFSC takes as noted in the SARs to ensure not double-counted against PBR. However, for these species, there were no takes from either Navy or NEFSC as noted in the SARs to deduct that would be considered double-counting.
[3] This value represents the calculated PBR less the average annual estimate of ongoing anthropogenic mortalities (*i.e.,* total annual human-caused M/SI, which is presented in the draft 2018 SARs) and authorized take for NEFSC.
[4] See relevant SARs for more information regarding stock status and trends.

The Navy has also requested a small number of takes by serious injury or mortality from explosives. To calculate the annual average of mortalities for explosives in Table 70 we used the same method as described for vessel strikes. The annual average is the number of takes divided by five years to get the annual number.

The following species takes by serious injury or mortality from explosions (ship shock trials) are being authorized by NMFS. A total of nine mortalities (one Atlantic white-sided dolphin, one pantropical spotted dolphin, one spinner dolphin, and six short-beaked common dolphins) are possible over the 5-year period and therefore the 0.2 mortalities annually for Atlantic white-sided dolphin, pantropical spotted dolphin, and spinner dolphin and 1.2 mortalities annually for short-beaked common dolphin are described in Table 70.

TABLE 70—SUMMARY INFORMATION RELATED TO AFTT SERIOUS INJURY OR MORTALITY FROM EXPLOSIVES (SHIP SHOCK TRIALS), 2018–2023

Species (stock)	Stock abundance (Nbest) *	Annual planned take by serious injury or mortality [1]	Total annual M/SI * [2]	Fisheries interactions (Y/N); annual rate of M/SI from fisheries interactions *	PBR *	NEFSC authorized take (annual)	Residual PBR–PBR minus annual M/SI and NEFSC authorized take [3]	Stock trend * [4]	UME (Y/N); number and year
Atlantic white-sided dolphin (Western N. Atlantic).	48,819	0.2	30	30	304	0.6	273.4	?	N
Pantropical spotted dolphin (Northern GOMEX).	50,880	0.2	4.4	4.4	407	0	402.6	?	Y/3; in 2010–2014.
Short-beaked common dolphin (Western N. Atlantic).	70,184	1.2	406	406	557	2	149	?	N
Spinner dolphin (Northern GOMEX).	11,411	0.2	0	0	62	0	62	?	Y/7; in 2010–2014.

* Presented in the draft 2018 SARS.
[1] This column represents the annual take by serious injury or mortality during ship shock trials and was calculated by the number of mortalities planned for authorization divided by five years (the length of the rule and LOAs).
[2] This column represents the total number of incidents of M/SI that could potentially accrue to the specified species or stock. This number comes from the SAR, but deducts the takes accrued from either Navy or NEFSC takes as noted in the SARs to ensure not double-counted against PBR. However, for these species, there were no takes from either Navy or NEFSC as noted in the SARs to deduct that would be considered double-counting.
[3] This value represents the calculated PBR less the average annual estimate of ongoing anthropogenic mortalities (*i.e.,* total annual human-caused M/SI, which is presented in the draft 2018 SARs) and authorized take for NEFSC.
[4] See relevant SARs for more information regarding stock status and trends.

Species or Stocks With M/SI Below the Insignificance Threshold

As noted above, for a species or stock with incidental M/SI less than 10 percent of residual PBR, we consider M/SI from the specified activities to represent an insignificant incremental increase in ongoing anthropogenic M/SI that alone (*i.e.,* in the absence of any other take and barring any other unusual circumstances) will not adversely affect annual rates of recruitment and survival. In this case, as shown in Tables 69 and 70, the following species or stocks have potential or estimated, and authorized, M/SI below their insignificance threshold: Humpback whales (Gulf of Maine), sperm whale (North Atlantic), Atlantic white-sided dolphins (Western Atlantic stock), Pantropical spotted dolphins (Northern GOMEX stock), short-beaked common dolphins (Western North Atlantic stock), spinner dolphins (Northern GOMEX stock), and minke whales (Canadian East Coast). While the authorized mortality of humpback whales and minke whales is below the insignificance threshold, because of the ongoing UMEs for these species, we address how other factors in the evaluation of how the authorized serious injury or mortality inform the negligible impact determination immediately below. For the other five stocks with authorized mortality below the insignificance threshold, there are no other known factors, information, or unusual circumstances that indicate anticipated M/SI below the insignificance threshold could have adverse effects on annual rates of recruitment or survival and they are not discussed further.

For the remaining stocks with anticipated potential M/SI above the insignificance threshold, how that M/SI compares to residual PBR and discussion of additional factors are discussed in the section that follows.

Humpback Whale

Authorized mortality of humpback whales is below the insignificance threshold. Additionally, when evaluating the mortality authorization in the context of the PBR designated for the Gulf of Maine stock, a primary consideration is that, although the Gulf of Maine stock is the only stock designated under the MMPA, it is but one of several North Atlantic feeding groups associated with the West Indies breeding population DPS (which is not considered at risk and thereby not ESA-listed) found within the AFTT Study Area. Humpbacks encountered along the East Coast within the AFTT Study Area may be from the Gulf of Maine stock, the Newfoundland feeding group, the Gulf of St. Lawrence feeding group, or one of the other three feeding groups associated with the West Indies DPS. The Gulf of Maine stock likely dominates the northern portion of the AFTT Study Area, where there is far less Navy activity and ship traffic, but the southeastern and mid-Atlantic tissue sampling and photo ID work (of relatively small sample size) suggests that Gulf of Maine stock individuals might comprise approximately of 30 percent of the individuals in the rest of the of the AFTT study area, *i.e.,* the mid- and south Atlantic portion (Hayes *et al.,* 2017). In other words, if there were a mortality, it would not necessarily come from the Gulf of Maine stock. It is more appropriate to consider the mortality in the context of the much larger West Indies DPS, which has an increasing growth trend of 3.1 percent (Bettridge *et al.,* 2015) and would have a much higher PBR if it were calculated for the whole DPS or any of the other feeding groups (none of which are designated as stocks). Similarly, the humpback UME is of concern, but the number of recorded deaths along the Atlantic Coast could come from a number of feeding groups (at least four of which definitely have individuals that move through the AFTT Study Area) and should be considered in that context. In other words, the addition of the single Navy authorized mortality means that the total human-caused mortality to all humpbacks recorded from the Atlantic (which actually occurs from multiple feeding groups, most of which are not considered stocks) is still less than the insignificance threshold of the Gulf of Maine stock alone, meaning that if the human-caused mortality in the Atlantic were compared against the abundance (and associated PBR) of the much larger (and increasing) DPS (or multiple feeding groups) to which the deaths actually accrue, the single Navy mortality would be even more clearly unlikely to have any effects on annual rates of recruitment or survival.

Of additional note, specifically, there are over 10,000 humpback whales in the West Indies DPS. If one were to calculate a PBR for that group, using a recovery factor of 0.5 (which is appropriate for stocks when the OSP is not known), an rmax of 0.4, and assuming very conservatively that nmin would be 5,000 or more (for U.S. stocks nmin is typically 80% or more of the abundance estimate in the SAR), PBR would be around 50. Eighty-four mortalities have been recorded during the UME (since 2016), averaging 28 per year. However, average mortalities from 2011–2015 averaged about 13, which means that there are about 15 more mortalities annually during the UME than typically recorded when there is no UME. If these UME mortalities were combined with other annual human-caused mortalities and were viewed through the PBR lens (for human-caused mortalities), total human-caused mortality (inclusive of additional UME deaths, which are not necessarily human-caused, as a portion have been attributed to vessel strike, while others are inconclusive) would be well under the residual PBR for the West Indies DPS.

Also of note, the Atlantic Large Whale Take Reduction Plan (ALWTRP) is a program to reduce the risk of serious injury and death of large whales caused by accidental entanglement in U.S. commercial trap/pot and gillnet fishing gear. Since its implementation in 1997, it aims to reduce the number of whales taken by gear entanglements focusing on fin whales, humpback whales, and NARW. In 2003, the Atlantic Large Whale Take Reduction Team (Team) agreed to manage entanglement risk by first reducing the risk associated with groundlines and then reducing the risk associated with vertical lines in commercial trap/pot and gillnet gear. In 2014, the Plan was amended (79 FR 36586, June 27, 2014) to address large whale entanglement risks associated with vertical line (or buoy lines) from commercial trap/pot fisheries. This amendment included gear modifications, gear setting requirements, an expanded seasonal trap/pot closure (Massachusetts Restricted Area), and gear marking for both trap/pot and gillnet fisheries. The original Massachusetts Restricted Area was a seasonal closure from January 1 through April 30 for all trap/pot fisheries. In a subsequent Plan amendment, the boundary for the Massachusetts Restricted Area was expanded by 900 mi^2 (2.59 km^2), and the start date changed to February 1 (79 FR 73848, December 12, 2014).

Currently the Atlantic Large Whale Take Reduction Plan has two seasonal trap/pot closures: The Massachusetts Restricted Area (50 CFR 229.32(c)(3)) and the Great South Channel Trap/Pot Closure (50 CFR 229.32(c)(4)). The Massachusetts Restricted Area prohibits fishing with, setting, or possessing trap/pot gear in this area unless stowed in accordance with § 229.2 from February 1 to April 30. The Great South Channel Trap/Pot Closure prohibits fishing with, setting, or possessing trap/pot gear in this area unless stowed in accordance with § 229.2 from April 1 through June

30. Effective September 1, 2015, the ALWTRP included new gear marking areas for gillnets and trap/pots for Jeffrey's Ledge and Jordan Basin (Gulf of Maine), two important high-use areas for humpback whales and NARWs. The only study available that examined the effectiveness of the ALWTRP reviewed the regulations up to 2009 (Pace *et al.,* 2014) and the results called for additional mitigation measures needed to reduce entanglements. Since that time, NMFS put two major regulatory actions in place—the 2007 sinking groundline rule that went into effect in 2009 (73 FR 51228) and the 2014 vertical line rule that went into effect in 2015 (79 FR 36586). The Office of Law Enforcement (OLE) reports that of gear checked by OLE under the ALWTRP, they found a compliance rate of 94.49 percent in FY–2015 and 84.42 percent in FY–2016. In addition, NMFS Fisheries Science Centers held a working group in May 2018 to make recommendations on the best analytical approach to measure how effective these regulations have been, however, the results of the meeting are not yet available. For more information on this program please refer to *https://www.greateratlantic.fisheries.noaa.gov/protected/whaletrp/.*

Minke Whale

Authorized mortality of minke whales is below the insignificance threshold. The abundance and PBR of minke whales is significantly greater than what is reflected in the current SAR because the most recent population estimate is based only on surveys in U.S. waters and slightly into Canada, and did not cover the habitat of the entire Canadian East Coast stock. The 2015 SAR abundance included data from the 2007 Canadian Trans-North Atlantic Sighting Surveys (TNASS), which appropriately included surveys of Nova Scotian and Newfoundland Canadian waters and estimated an abundance of 20,741 minkes with a PBR of 162, as opposed to the current estimates of 2,591 and 14, respectively. However, as recommended in the guidelines for preparing SARs (NMFS 2016), estimates older than eight years are deemed unreliable, so the 2018 SAR population estimate does not include data from the 2007 TNASS. While it is certainly possible that the numbers in Canadian waters have changed since the last TNASS survey, there is no reason to think that the majority of the individuals in the stock would not still occupy the Canadian portion of the range. Additionally, the current abundance estimate does not account for availability bias due to submerged animals (*i.e.,* estimates are not corrected to account for the fact that given X number of animals seen at the surface, we can appropriately assume that Y number were submerged and not counted). Without a correction for this bias, the abundance estimate is likely further biased low. Last, while the UME is a concern, we note that the deaths should be considered in the context of the whole stock, which most certainly has a significantly higher abundance and PBR than those reflected in the SAR.

Of additional note, specifically, the PBR was previously estimated at 162 when the full abundance was considered. Fifty-two mortalities have been recorded during the UME (since 2017), averaging 26 per year. However, average mortalities from 2011–2016 averaged about 13, which means that there are about 13 more mortalities annually during the UME than typically recorded when there is no UME. If these UME mortalities were combined with other annual human-caused mortalities and were viewed through the PBR lens (for human-caused mortalities), and we assumed that PBR was in the vicinity of the PBR previously reported (162), total human-caused mortality (inclusive of additional UME deaths) would still be well under residual PBR for the full stock of minke whales.

Species or Stocks With M/SI Above the Insignificance Threshold

Fin Whale

For fin whales (Western North Atlantic stock) PBR is currently set at 2.5 and the total annual M/SI is 2.5, yielding a residual PBR of 0. The M/SI value includes the records of 1.0 annual fishery interaction and 1.5 annual vessel collisions. For the reasons discussed above, those collisions are unlikely to be from Navy vessels. NMFS is authorizing one mortality over the five-year duration of the rule (indicated as 0.2 annually for the purposes of comparing to PBR), which means that residual PBR is exceeded by 0.2 (although of note, Navy take alone does not exceed PBR itself). However as explained earlier, this does not mean that the stock is not at or increasing toward OSP or that one lethal take by the Navy in the five years covered by this rule would adversely affect the stock through annual reproduction or survival rates. To the contrary, consideration of the information outlined below indicates that the Navy's authorized mortality is not expected to result in more than a negligible impact on this stock.

The abundance of fin whales is likely significantly greater than what is reflected in the current SAR because the most recent population estimate is based only on surveys in U.S. waters and slightly into Canada, and did not cover the habitat of the entire stock, which extends over a very large additional area into Nova Scotian and Newfoundland waters. Accordingly, if a PBR were calculated based on an appropriately enlarged abundance, it would be notably higher. Additionally, the current abundance estimate does not account for availability bias due to submerged animals (*i.e.,* estimates are not corrected to account for the fact that given X number of animals seen at the surface, we can appropriately assume that Y number were submerged and not counted). Without a correction for this bias, the abundance estimate is likely further biased low. Because of these limitations, the current calculated PBR is not a reliable indicator of how removal of animals will affect the stock's ability to reach or maintain OSP. We note that, generally speaking, while the abundance may be underestimated in this manner for some stocks due to the lack of surveys in areas outside of the U.S. EEZ, it is also possible that the human-caused mortality could be underestimated in the un-surveyed area. However, in the case of fin whales, most mortality is caused by entanglement in gear that is deployed relatively close to shore and, therefore, unrecorded mortality offshore would realistically be proportionally less as compared to the unsurveyed abundance and therefore the premise that PBR is likely underestimated still holds. Given the small amount by which residual PBR is exceeded and more significant degree (proportionally) to which abundance is likely underestimated, it is reasonable to think that if a more realistic PBR were used, the anticipated total human-caused mortality would be notably under it.

Additionally, the ALWTRP (as described above) is a program to reduce the risk of serious injury and death of large whales caused by accidental entanglement in U.S. commercial trap/pot and gillnet fishing gear. It aims to reduce the number of whales taken by gear entanglements focusing on fin whales, humpback whales, and NARW. ALWTRP measures have equal effectiveness in reducing entanglement of fin whales.

We also note that in this case, 0.2 M/SI means one mortality in one of the five years and zero mortalities in four of those five years. Therefore, residual PBR would not be exceeded in 80 percent of the years covered by this rule. In these particular situations where authorized M/SI is fractional, consideration must be given to the lessened impacts

anticipated due to the absence of mortality in four of the five years. Last, we reiterate the fact that PBR is a conservative metric and also is not sufficiently precise to serve as an absolute predictor of population effects upon which mortality caps would appropriately be based, which is especially important given the subtle difference between zero and one across the five-year period, which is the smallest possible distinction one can have if there is any consideration of mortality.

Nonetheless, the exceedance of residual PBR necessitates close attention to the remainder of the impacts on fin whales from this activity to ensure that the total authorized impacts are negligible. This information will be considered in combination with our assessment of the impacts of harassment takes later in the section.

Sei Whale

For sei whales (Nova Scotia stock) PBR is currently set at 0.5 and the total annual M/SI is 0.6, yielding a residual PBR of −0.1. The fact that residual PBR is negative means that the total anticipated human-caused mortality is expected to exceed PBR even in the absence of additional take by the Navy. The M/SI value includes no records of annual fishery interactions, but 0.6 annual vessel collisions. For the reasons discussed above, those collisions are unlikely to be from Navy vessels. NMFS is authorizing one mortality over the five-year duration of the rule (indicated as 0.2 annually for the purposes of comparing to PBR), which means that residual PBR is exceeded by 0.3. However as explained earlier, this does not necessarily mean that the stock is not at or increasing toward OSP or that one lethal take by the Navy in the five years would adversely affect reproduction or survival rates. In fact, consideration of the additional information below supports our determination that the Navy's authorized mortality is not expected to result in more than a negligible impact on this stock.

The abundance of sei whales is likely significantly greater than what is reflected in the current SAR because the population estimate is based only on surveys in U.S. waters and slightly into Canada, and did not cover the habitat of the entire stock, which extends over a large additional area around to the south of Newfoundland. Accordingly, if a PBR were calculated based on an appropriately enlarged abundance, it would be higher. Additionally, the current abundance estimate does not account for availability bias due to submerged animals (*i.e.,* estimates are not corrected to account for the fact that given X number of animals seen at the surface, we can appropriate assume that Y number were submerged and not counted). Without a correction for this bias, the abundance estimate is likely biased low. Because of these limitations, the current calculated PBR is not a reliable indicator of how removal of animals will affect the stock's ability to reach or maintain OSP. We note that, generally speaking, while the abundance may be underestimated in this manner for some stocks due to the lack of surveys in areas outside of the U.S. EEZ, it is also possible that the human-caused mortality could be underestimated in the un-surveyed area. However, in the case of sei whales, most mortality is caused by ship strike and the density of ship traffic is higher the closer you are to shore (making strikes more likely closer to shore) and, therefore, unrecorded mortality offshore would realistically be proportionally less as compared to the unsurveyed abundance and therefore the premise that PBR is likely underestimated still holds. Given the small amount by which residual PBR is exceeded, and more significant degree (proportionally) to which abundance is likely underestimated, it is reasonable to think that if a more realistic PBR were used, the anticipated total human mortality would be notably under it.

We also note that in this case, 0.2 M/SI means one mortality in one of five years and zero mortalities in four of those five years. Residual PBR is not being exceeded in 80 percent of the years. In these particular situations where authorized M/SI is fractional, consideration must be given to the lessened impacts anticipated due to the absence of mortality in four of the five years. Last, we reiterate the fact that PBR is a conservative metric and also is not sufficiently precise to serve as an absolute predictor of population effects upon which mortality caps would appropriately be based, which is especially important given the subtle difference between zero and one across the five-year period, which is the smallest possible distinction one can have if there is any consideration of mortality.

Nonetheless, the exceedance of residual PBR necessitates close attention to the remainder of the impacts on sei whales from this activity to ensure that the total authorized impacts are negligible. This information will be considered in combination with our assessment of the impacts of harassment takes later in the section.

Group and Species-Specific Analyses

Overview

The maximum amount and type of incidental take of marine mammals reasonably likely to occur and therefore authorized from exposures to sonar and other active acoustic sources and explosions during the five-year training and testing period are shown in Tables 39 and 40 as well as ship shock trials shown in Table 41. The vast majority of predicted exposures (greater than 99 percent) are expected to be Level B harassment (non-injurious TTS and behavioral reactions) from acoustic and explosive sources during training and testing activities at relatively low received levels.

As noted previously, the estimated Level B harassment takes represent instances of take, not the number of individuals taken (the much lower and less frequent Level A harassment takes are far more likely to be associated with separate individuals), and in many cases some individuals are expected to be taken more than one time, while in other cases a portion of individuals will not be taken at all. Below, we compare the take numbers for stocks to their associated abundance estimates to evaluate the magnitude of impacts across the stock and to individuals. Specifically, when an abundance percentage comparison is below 100, it means that that percentage or less of the individuals in the stock will be affected (*i.e.,* some individuals will not be taken at all), that the average for those taken is one day per year, and that we would not expect any individuals to be taken more than a few times in a year. When it is more than 100 percent, it means there will definitely be some number of repeated takes of individuals. For example, if the percentage is 300, the average would be each individual is taken on three days in a year if all were taken, but it is more likely that some number of individuals will be taken more than three times and some number of individuals fewer or not at all. While it is not possible to know the maximum number of days across which individuals of a stock might be taken, in acknowledgement of the fact that it is more than the average, for the purposes of this analysis, we assume a number approaching twice the average. For example, if the percentage of take compared to the abundance is 800, we estimate that some individuals might be taken 16 times. Those comparisons are included in the sections below. For some stocks these numbers have been adjusted slightly (single digits) since the proposed rule to more consistently apply this approach, but these minor

changes did not change the analysis or findings.

Use of sonar and other transducers would typically be transient and temporary. The majority of acoustic effects to mysticetes from sonar and other active sound sources during testing and training activities would be primarily from ASW events. It is important to note that although ASW is one of the warfare areas of focus during MTEs, there are significant periods when active ASW sonars are not in use. Nevertheless, behavioral reactions are assumed more likely to be significant during MTEs than during other ASW activities due to the duration (*i.e.,* multiple days) and scale (*i.e.,* multiple sonar platforms) of the MTEs. On the the less severe end, exposure to comparatively lower levels of a sound at a detectably greater distance from the animal, for a few or several minutes, could result in a behavioral response such as avoiding an area that an animal would otherwise have moved through or feed in or breaking off one or a few feeding bouts. More severe behavioral effects could occur when an animal gets close enough to the source to receive a comparatively higher level of sound, is exposed continuously to one source for a longer time, or is exposed intermittently to different sources throughout a day. Such effects might result in an animal having a more severe flight response and leaving a larger area for a day or more, or potentially losing feeding opportunities for a day. However, such severe behavioral effects are expected to occur infrequently.

Occasional, milder behavioral reactions are unlikely to cause long-term consequences for individual animals or populations, and even if some smaller subset of the takes are in the form of a longer (several hours or a day) and more severe responses, if they are not expected to be repeated over sequential days, impacts to individual fitness are not anticipated. Nearly all studies and experts agree that infrequent exposures of a single day or less are unlikely to impact an individual's overall energy budget (Farmer *et al.,* 2018; Harris *et al.,* 2017; King *et al.,* 2015; NAS 2017; New *et al.,* 2014; Southall *et al.,* 2007; Villegas-Amtmann *et al.,* 2015). When impacts to individuals increase in magnitude or severity such that either repeated and sequential higher severity impacts occur (the probability of this goes up for an individual the higher total number of takes it has) or the total number of moderate to more severe impacts increases substantially, especially if occurring across sequential days, then it becomes more likely that the aggregate effects could potentially interfere with feeding enough to reduce energy budgets in a manner that could impact reproductive success via longer cow-calf intervals, terminated pregnancies, or calf mortality. It is important to note that these impacts only accrue to females, which only comprise a portion of the population (typically approximately 50 percent). Based on energetic models, it takes energetic impacts of a significantly greater magnitude to cause the death of an adult marine mammal, and females will always terminate a pregnancy or stop lactating before allowing their health to deteriorate. Also, the death of an adult has significantly more impact on population growth rates than reductions in reproductive success, and death of males has very little effect on population growth rates. However, as explained earlier, such severe impacts from the Navy's activities would be very infrequent and not likely to occur at all for most species and stocks. Even for those species or stocks where it is possible for a small number of females to experience reproductive effects, we explain below why there still will be no effect on rates of recruitment or survival.

Deepwater Horizon (DWH) Oil Spill

As discussed in the proposed rule, tens of thousands of marine mammals were exposed to the DWH surface slick, where they inhaled, aspirated, ingested, and came into contact with oil components (Dias *et al.,* 2017). The oil's physical and toxic effects damaged tissues and organs, leading to a constellation of adverse health effects, including reproductive failure, adrenal disease, lung disease, and poor body condition, as observed in bottlenose dolphins (De Guise *et al.,* 2017; Kellar *et al.,* 2017). Coastal and estuarine bottlenose dolphin populations were some of the most severely injured (Hohn *et al.,* 2017; Rosel *et al.,* 2017; Thomas *et al.,* 2017), as described previously in relation to the UME, but oceanic species were also exposed and experienced increased mortality, increased reproductive failure, and a higher likelihood of other adverse health effects.

Due to the scope of the spill, the magnitude of potentially injured populations, and the difficulties and limitations of working with marine mammals, it is impossible to quantify injury without uncertainty. Wherever possible, the quantification results represent ranges of values that encapsulate the uncertainty inherent in the underlying datasets. The population model outputs shown in Table 71 best represent the temporal magnitude of the injury and the potential recovery time from the injury (DWH NRDA Trustees (Deepwater Horizon Natural Resource Damage Assessment Trustees), 2016). The values in the table inform the baseline levels of both individual health and susceptibility to additional stressors, as well as stock status, with which the effects of the Navy takes are considered in the negligible impact analysis.

Table 71. Summary of Modeled Effects of DWH Oil Spill.

Common name	% Population exposed to oil (95% CI)	% Population killed (95% CI)	% Females with reproductive failure (95% CI)	% Population with adverse health effects (95% CI)	% Maximum population reduction (95% CI)	Years to recovery (95% CI)[b]
Bryde's whale	48 (23–100)	17 (7–24)	22 (10–31)	18 (7–28)	~22	69
Sperm whale	16 (11–23)	6 (2–8)	7 (3–10)	6 (2–9)	~7	21
Kogia spp.	15 (8–29)	5 (2–7)	7 (3–10)	6 (2–9)	~6	11
Beaked whales	12 (7–22)	4 (2–6)	5 (3–8)	4 (2–7)	~6	10
Rough-toothed dolphin	41 (16–100)	14 (6–20)	19 (9–26)	15 (6–23)	~17	54
Bottlenose dolphin, oceanic	10 (5–10)	3 (1–5)	5 (2–6)	4 (1–6)	~4	n/a
Bottlenose dolphin, northern coastal	82 (55–100)	38 (26–58)	37 (17–53)	30 (11–47)	~50 (32–73)	39 (23–76)
Bottlenose dolphin, western coastal	23 (16–32)	1 (1–2)	10 (5–15)	8 (3–13)	~5 (3–9)	n/a
Shelf dolphins[a]	13 (9–19)	4 (2–6)	6 (3–8)	5 (2–7)	~3	n/a
Clymene dolphin	7 (3–15)	2 (1–4)	3 (2–5)	3 (1–4)	~3	n/a
Pantropical spotted dolphin	20 (15–26)	7 (3–10)	9 (4–13)	7 (3–11)	~9	39
Spinner dolphin	47 (24–91)	16 (7–23)	21 (10–30)	17 (6–27)	~23	105
Striped dolphin	13 (8–22)	5 (2–7)	6 (3–9)	5 (2–8)	~6	14
Risso's dolphin	8 (5–13)	3 (1–4)	3 (2–5)	3 (1–4)	~3	n/a
Melon-headed whale	15 (6–36)	5 (2–7)	7 (3–10)	6 (2–9)	~7	29
Pygmy killer whale	15 (7–33)	5 (2–8)	7 (3–10)	6 (2–9)	~7	29
False killer whale	18 (7–48)	6 (3–9)	8 (4–12)	7 (3–11)	~9	42
Short-finned pilot whale	6 (4–9)	2 (1–3)	3 (1–4)	2 (1–3)	~3	n/a

Modified from DWH NRDA Trustees (2016).
CI = confidence interval. No CI was calculated for population reduction or years to recovery for shelf or oceanic stocks.
[a] "Shelf dolphins" includes Atlantic spotted dolphins and the shelf stock of bottlenose dolphins (20–200 m water depth). These two species were combined because the abundance estimate used in population modeling was derived from aerial surveys and the species could not generally be distinguished from the air.
[b] It is not possible to calculate YTR for stocks with maximum population reductions of less than or equal to 5 percent.

Group and Species-Specific Analyses

The analysis below in some cases (*e.g.,* porpoises, pinnipeds) addresses species collectively if they occupy the same functional hearing group (*i.e.,* low, mid, and high-frequency cetaceans and pinnipeds in water), have similar hearing capabilities, and/or are known to behaviorally respond similarly to acoustic stressors. Because some of these species have similar hearing capabilities and respond similarly to received sound, it would be duplicative to repeat the same analysis for each species. In addition, animals belonging to each stock within a species have the same hearing capabilities and behaviorally respond in the same manner as animals in other stocks within the species. Thus, our analysis below considers the effects of Navy's activities on each affected stock even where discussion is organized by functional hearing group and/or information is evaluated at the species level. Where there are meaningful differences between stocks within a species that would further differentiate the analysis (*e.g.,* the status of the stock or mitigation related to biologically important areas for the stock), they are either described within the section or the discussion for those species or stocks is included as a separate subsection.

Mysticetes

This section builds on the broader discussion above and brings together the discussion of the different types and amounts of take that different stocks will incur, the applicable mitigation for each stock, and the status of the stocks to support the negligible impact determinations for each stock. We have already described above why we believe the incremental addition of the small number of low-level PTS takes will not have any meaningful effect towards inhibiting reproduction or survival. We have also described the unlikelihood of any masking or habitat impacts to any groups that would rise to the level of affecting individual fitness. For mysticetes, there is no predicted tissue damage from explosives for any stock. Much of the discussion below focuses on the behavioral effects and the mitigation measures that reduce the probability or severity of effects in biologically important areas. Because there are multiple stock-specific factors in relation to the status of the species (UMEs) as well as mortality take for multiple stocks, we break out stock-specific findings at the end of the section.

In Table 72 below, for mysticetes, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Since the proposed rule, the Navy has removed one of their testing events in the Northeast Range Complex (four events—USWT), which decreased the number of Level B harassment takes annually for NARW by 115 takes. This change also decreased annual Level B harassment takes by approximately 200 takes for ESA-listed fin whales and 20 takes for sei whales.

Table 72: Annual takes of Level B and Level A harassment, mortality for mysticetes in the AFTT Study Area and number indicating the instances of total take as a percentage of stock abundance.

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percentage of abundance	
		Level B Harassment		Level A Harassment								
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage	Mortality	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ
Suborder Mysticeti (baleen whales)												
Family Balaenidae (right whales)												
North Atlantic right whale*	Western North Atlantic	203	268	0	0	0	471	471	343	343	137	137
Family Balaenopteridae (roquals)												
Blue whale*	Western North Atlantic (Gulf of St. Lawrence)	12	35	0	0	0	44	47	9	104	489	45
Bryde's whale	Northern Gulf of Mexico	24	31	1	0	0	56	56	50	50	112	112
	NSD	77	260	0	0	0	313	337	50	563	626	60
Minke whale	Canadian East Coast	796	3,284	5	0	0.2	3913	4085	730	7686	536	53
Fin whale*	Western North Atlantic	1,716	3,671	33	0	0.2	5368	5420	1,660	14769	323	37
Humpback whale	Gulf of Maine	248	498	3	0	0.2	698	749	496	4580	141	16
Sei whale*	Nova Scotia	245	556	4	0	0.2	779	805	246	11737	317	7

Note: Above we compare predicted takes to abundance estimates generated from the same underlying density estimate (as described in the *Estimated Take of Marine Mammals* section), versus abundance estimates directly from NMFS' SARs, which are not based on the same data and would not be appropriate for this purpose. Note that comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty and takes are notably greater) and across the whole Study Area (which offers a more comprehensive comparison for many stocks).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing plus take from one large ship shock trial.

The annual mortality of 0.2 is because we expect no more than one mortality over the course of five years from vessel strikes as previously described above.

The majority of takes by harassment of mysticetes in the AFTT Study Area are caused by sources from the MF1 active sonar bin (which includes hull-mounted sonar) because they are high level sources in the 1–10 kHz range, which overlaps the most sensitive area of hearing for mysticetes, and of the sources expected to result in take, they also are used in a large portion of exercises (see Table 1.5–5 in the Navy's application). Most of the takes (64 percent) from the MF1 bin in the AFTT Study Area would result from received levels between 160 and 172 dB SPL, while another 32 percent would result from exposure between 172 and 178 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF3 = 96 percent between 142 and 154, MF4 = 98 percent between 136 and 145, MF5 = 97 percent between 118 and 142, and HF4 = 98 percent between 100 and 148 dB SPL. These values may be derived from the information in Tables 6.4–8 through 6.4–12 in the Navy's rulemaking/LOA application (though they were provided directly to NMFS upon request). For mysticetes, explosive training and testing activities do not result in any Level B behavioral harassment or PTS, and the TTS takes are in the single digits and comprise a fraction (approximately 1–10 percent) of those caused by exposure to active sonar. There are no takes of mysticetes by pile driving or airguns. Based on this information, the majority of the Level B behavioral harassment is expected to be of low to sometimes moderate severity and of a relatively shorter duration.

Research and observations show that if mysticetes are exposed to sonar or other active acoustic sources they may react in a number of ways depending on the characteristics of the sound source, their experience with the sound source, and whether they are migrating or on seasonal grounds (*i.e.,* breeding or feeding). Behavioral reactions may include alerting, breaking off feeding dives and surfacing, diving or swimming away, or no response at all (Richardson, 1995; Nowacek, 2007; Southall *et al.,* 2007; DOD, 2017). Overall, mysticetes have been observed to be more reactive to acoustic disturbance when a noise source is located directly on their migration route. Mysticetes disturbed while migrating could pause their migration or route around the disturbance. Although they may pause temporarily, they will resume migration shortly after. Animals disturbed while engaged in other activities such as feeding or reproductive behaviors may be more likely to ignore or tolerate the disturbance and continue their natural behavior patterns. As noted in the *Potential Effects of Specified Activities on Marine Mammals and Their Habitat* section, there are multiple examples from behavioral response studies of odontocetes ceasing their feeding dives when exposed to sonar pulses at certain levels, but alternately, blue whales were less likely to show a visible response to sonar exposures at certain levels when feeding than when traveling. However, Goldbogen *et al.* (2013) indicated some horizontal displacement of deep foraging blue whales in response to simulated MFA sonar. Most Level B behavioral harassment of mysticetes is likely to be short-term and low to moderate severity, with no anticipated effect on reproduction or survival from Level B harassment.

Richardson *et al.* (1995) noted that avoidance (temporary displacement of an individual from an area) reactions are the most obvious manifestations of disturbance in marine mammals. Avoidance is qualitatively different from the startle or flight response, but also differs in the magnitude of the response (*i.e.,* directed movement, rate of travel, etc.). Oftentimes avoidance is temporary, and animals return to the area once the noise has ceased. Some mysticetes may avoid larger activities such as a MTE as it moves through an area, although these activities generally do not use the same training locations

day-after-day during multi-day activities. Therefore, displaced animals could return quickly after the MTE finishes. Due to the limited number and broad geographic scope of MTEs, it is unlikely that most mysticetes would encounter a major training exercise more than once per year and no MTEs will occur in the GOMEX or the Gulf of Maine area where the BIA feeding areas for NARW, fin whales, humpback whales, minke whales, and sei whales are located. In the ocean, the use of sonar and other active acoustic sources is transient and is unlikely to expose the same population of animals repeatedly over a short period of time, especially given the broader-scale movements of mysticetes.

The implementation of mitigation and the sightability of mysticetes (due to their large size) further reduces the potential for a significant behavioral reaction or a threshold shift to occur (*i.e.,* shutdowns are expected to be successfully implemented, though we have analyzed the impacts that are anticipated to occur and that we are therefore authorizing. As noted previously, when an animal incurs a threshold shift, it occurs in the frequency from that of the source up to one octave above. This means that the vast majority of threshold shift caused by Navy sonar sources will typically occur in the range of 2–20 kHz (from the 1–10 kHz MF1 bin), and if resulting from hull-mounted sonar, will be in the range of 3.5–7 kHz. The majority of mysticete vocalizations, including for NARW, occurs in frequencies below 1 kHz, which means that TTS incurred by mysticetes will not interfere with conspecific communication Additionally, many of the other critical sounds that serve as cues for navigation and prey (*e.g.,* waves, fish, invertebrates) occur below a few kHz, which means that detection of these signals will not be inhibited by most threshold shift either. When we look in ocean areas where the Navy has been intensively training and testing with sonar and other active acoustic sources for decades, there is no data suggesting any long-term consequences to reproduction or survival rates of mysticetes from exposure to sonar and other active acoustic sources.

The Navy will implement mitigation areas that will avoid or reduce impacts from harassment to mysticetes and these areas contain some of the BIAs for large whales and ESA-designated critical habitat for NARW. The NARW is an at-risk species with an ongoing UME. In order to mitigate the number and potential severity of any NARW harassment takes, from November 15 through April 15, the Navy will not conduct LFAS/MFAS/HFAS, except for sources that will be minimized to the maximum extent practicable during helicopter dipping, navigation training, and object detection exercises within the SE NARW Mitigation Area. As discussed previously, the majority of takes result from exposure to the higher power hull-mounted sonar during major training exercises, which will not occur here. The activities that are allowed to occur such as those used for navigation training or object detection exercises use lower level sources that operate in a manner less likely to result in more concerning affects (*i.e.,* single sources for shorter overall amounts of time—*e.g.,* activity is less than 30 min). Animals in these protected areas are engaged in important behaviors, either feeding or interacting with calves, during which if they were disturbed the effects could be more impactful (*e.g.,* if whales were displaced from preferred feeding habitat for long periods, there could be energetic consequences more likely to lead to an adverse effect on fitness, or if exposure to activities caused a severe disturbance to a cow-calf pair that resulted in the pair becoming separated, it could increase the risk of predation for the calf). By limiting activities, the number of takes that would occur in these areas is decreased and the probability of a more severe impact is reduced. The SE NARW Mitigation Area encompasses a portion of the NARW migration and calving areas identified by LaBrecque *et al.* (2015a) and a portion of the southeastern NARW ESA-designated critical habitat. Outside of the SE NARW Mitigation Area, active sonar would be used for ASW activities and for pierside sonar testing at Kings Bay, Georgia. The best available density data for the AFTT Study Area shows that the areas of highest density are off the southeastern United States in areas that coincide with the SE NARW Mitigation Area. Therefore, the majority of active sonar use would occur outside of the areas of highest seasonal NARW density and important use areas off the southeastern United States. In addition, before transiting or conducting testing and training activities, the Navy will coordinate to obtain Early Warning System NARW sighting data to help vessels and aircraft reduce potential interactions with NARWs.

The Navy will also minimize the use of active sonar in the NE NARW Mitigation Area. Refer to the *Mitigation Measures* section of this rule for a description of the area. Torpedo (non-explosive) activities can occur throughout the year, however, based on typical testing schedules only a limited number would likely be conducted in August and September. Many NARW will have migrated south out of the area by that time. Torpedo training or testing activities would not occur in or within 2.7 nmi of the Stellwagen Bank National Marine Sanctuary, which is critical habitat for NARW foraging. Stellwagen Bank National Marine Sanctuary also provides feeding and nursery grounds for NARW, humpback, sei, and fin whales. Since the proposed rule, the Navy has agreed to expand the NE NARW Mitigation Area to cover the full extent of the northeast NARW ESA-designated critical habitat designated under the ESA and has agreed not to conduct MTEs in the Gulf of Maine Planning Awareness Mitigation Area. One hundred percent of the NARW feeding area on Jeffreys Ledge and the NARW mating area in the central Gulf of Maine are included in the expanded NE NARW Mitigation Area (as well as in the Gulf of Maine Planning Awareness Area). The expanded NE NARW Mitigation Area covers Cape Cod Bay, Jeffreys Ledge, the western edge of Georges Bank, and the northern portion of the Great South Channel; 100 percent of the NARW feeding area on Cape Cod Bay and Massachusetts Bay and 95.08 percent of the NARW feeding area in the Great South Channel and the northern edge of George's Bank is included in the expanded NE NARW Mitigation Area. The mitigation measures required in the previous NE NARW Mitigation Area will carry over to the expanded mitigation area and be implemented year-round. These same important feeding and mating areas for NARW in the northeast are 100 percent included in the Gulf of Maine Planning Awareness Mitigation Area.

The humpback whale (1 BIA), minke whale (2 BIAs), fin whale (2 BIAs), and sei whale (1 BIA) feeding BIAs (6 total) are also located within the NE NARW Mitigation Area or Gulf of Maine Planning Awareness Mitigation Area (or both). Ninety-seven percent of the humpback whale feeding area in the Gulf of Maine, Stellwagen Bank, and the Great South Channel are included in the NE NARW Mitigation Area (100 percent in the Gulf of Maine Planning Awareness Mitigation Area). One hundred percent of the minke whale feeding BIA (central Gulf of Maine—Parker Ridge and Cashes Ledge) is included in the NE NARW Mitigation Area and the Gulf of Maine Planning Awareness Mitigation Area. One hundred percent of the fin whale feeding area BIA in the southern and the

northern Gulf of Maine are included in the NE NARW Mitigation Area and the Gulf of Maine Planning Awareness Mitigation Area. Seventy-three percent of the sei whale feeding area in the Gulf of Maine is included in the NE NARW Mitigation Area (100 percent in the Gulf of Maine Planning Awareness Mitigation Area). Approximately half of the minke whale feeding area in the southwestern Gulf of Maine and Georges Bank is included in the NE NARW Mitigation Area (100 percent in the Gulf of Maine Planning Awareness Mitigation Area). The Navy will limit the use of active sonar to the maximum extent practicable and not use certain explosive and non-explosive munitions year-round within the NE NARW Mitigation Area to further reduce potential impacts on large whales feeding and NARW in their most important feeding areas, a mating area, and the northern portion of their migration habitat. Newly developed for this regulatory period, the Gulf of Maine Planning Awareness Mitigation Area extends throughout the Gulf of Maine and southward over Georges Bank. The mitigation will further reduce potential impacts on marine mammals from active sonar during MTEs within key areas of biological importance, including NARW critical habitat; a portion of the northern NARW migration area; NARW, humpback whale, minke whale, sei whale, and fin whale feeding areas; and a NARW mating area.

The Bryde's whale BIA is inclusive of the GOMEX Planning Awareness Mitigation Areas and the Navy will not conduct MTEs in the GOMEX. Since the proposed rule, the Navy agreed upon the addition of a mitigation area for Bryde's whale. The Bryde's Whale Mitigation Area covers the extent of the Bryde's whale small and resident population area identified by LaBrecque *et al.* (2015b), including the extended area identified by NMFS in its 2016 Bryde's whale status review (Rosel *et al.,* 2016). In this mitigation area, the Navy will limit annual hours of MFAS use and will not use in-water explosives (except during mine warfare activities) to avoid or reduce potential impacts on the small and resident population of Bryde's whales.

As described previously there are three ongoing UMEs for NARW, humpback whales, and minke whales. There is significant concern regarding the status of the NARW, both because of the ongoing UME and because of the overall status of the stock. However, the Navy's mitigation measures make NARW mortality unlikely— and we are not authorizing such take—and the newly expanded mitigation areas further reduce the extent of potential Level B harassment by behavioral disruption in areas that are important for NARW, hence reducing the significance of such disruption. NMFS also has concern regarding the UMEs for humpback and minke whales. NMFS, in coordination with our stranding network partners, continues to investigate the recent mortalities, environmental conditions, and population monitoring to better understand how the recent humpback and minke whale mortalities occurred. Also, these unexplained mortalities have been evaluated in the context of other human-caused mortality and the single authorized mortalities for these species in the sections above. Ship speed reduction rules are in effect for commercial and large vessels during times of high concentrations of NARW, and require vessels greater than or equal to 65 feet in length to reduce speeds to 10 kn or less while entering or departing ports. While this rule was put into place primarily for the NARW presence in New England and Mid-Atlantic waters, it does benefit other whale species, such as humpback whales that are in those areas from November through July. NOAA is reviewing ship-tracking data to ensure compliance with the ship speed reduction rule around Cape Cod, New York, and the Chesapeake Bay areas. The UME for minke whales was recently declared. Preliminary findings in several of the whales have shown evidence of human interactions or infectious disease. These findings are not consistent across all of the whales examined, so more research is needed. As part of the UME investigation process, NOAA is assembling an independent team of scientists to coordinate with the Working Group on Marine Mammal Unusual Mortality Events to review the data collected, sample stranded whales, and determine the next steps for the investigation.

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely impact rates of recruitment or survival for any of the affected mysticete stocks:

NARW (Western stock)—As described previously, the status of NARW is precarious and they are listed as endangered under the ESA. There is a UME associated with the recent unusually high number of deaths (some of which have been attributed to entanglement), the number of births in recent years has been unusually low, and recent studies have reported individuals showing poor health or high stress levels. Accordingly and as described above, the Navy is implementing a comprehensive suite of mitigation measures that not only avoid the likelihood of ship strikes, but also minimize the severity of behavioral disruption by minimizing impacts in areas that are important for feeding and calving, thus ensuring that the relatively small number of Level B harassment takes that do occur are not expected to affect reproductive success or survivorship via detrimental impacts to energy intake or cow/calf interactions. Specifically, no mortality or Level A harassment is anticipated or authorized. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance (137 percent) combined with the fact that the AFTT Study Area overlaps most if not all of the range, suggests that many to most of the individuals in the stock will likely be taken, but only on one or two days per year, with no reason to think the days would likely be sequential. Regarding the severity of those individual takes by Level B behavioral harassment, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short), the received sound levels are largely below 172 dB with some lesser portion up to 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response), and that because of the mitigation the exposures will not occur in areas or at times where impacts would be likely to affect feeding and energetics or important cow/calf interactions that could lead to reduced reproductive success or survival. Regarding the severity of TTS takes, we have explained that they are expected to be low-level and of short duration and the associated lost opportunities and capabilities are not at a level that would impact reproduction or survival.

Altogether, any individual NARW is likely to be disturbed at a low-moderate level on no more than a couple of likely non-sequential days per year (and not in biologically important areas). Even given the fact that some of the affected individuals may have compromised health, there is nothing to suggest that such a low magnitude and severity of effects would result in impacts on reproduction or survival of any individual, much less impacts on annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on NARW.

Blue Whale (Western North Atlantic stock)—This is a wide-ranging stock that is best considered as ''an occasional

visitor'' to the U.S. EEZ, which may represent the southern limit of its feeding range (2017 SARS), though no specific feeding areas have been identified. For this reason, the abundances calculated by the Navy based on survey data in the U.S. EEZ are very low (9 and 104, in the U.S. EEZ and throughout the range respectively) and while NMFS' 2018 SAR does not predict an abundance, it does report an Nmin (minimum abundance) of 440. There is no currently reported trend for the population and there are no specific issues with the status of the stock that cause particular concern (*e.g.,* UMEs), although the species is listed as endangered under the ESA. No mortality or Level A harassment is anticipated or authorized for blue whales. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), given the number of total takes (47), the large range and wide-ranging nature of blue whales, and the minimum abundance identified in the SAR, there is no reason to think that any single animal will be taken by Level B harassment more than one time (though perhaps a few could be) and less than 10 percent of the population is likely to be impacted. Regarding the severity of those individual Level B harassment behavioral takes, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels are largely below 172 dB with a portion up to 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, we have explained that they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival.

Altogether, no more than 10 percent of the stock is likely to be impacted and any individual blue whale is likely to be disturbed at a low-moderate level on no more than a day or two days per year and not in any known biologically important areas. This low magnitude and severity of effects is unlikely to result in impacts on the reproduction or survival of any individual, much less impacts on annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on blue whales.

Bryde's whale (Northern GOMEX stock)—The Bryde's whale is a small resident population. Although there is no current UME, the small size of the population and its constricted range, combined with the lingering effects of exposure to oil from the DWH oil spill (which include adverse health effects on individuals, as well as population effects) are cause for considerable caution. Accordingly, as described above, the Navy is implementing considerable time/area mitigation (including an expansion since the rule was proposed) to minimize impacts within their limited range, including not planning MTEs, which include the most powerful sound sources operating in a more concentrated area, limiting the hours of other sonar use, and not using explosives, with the exception of mine warfare activities, which has both reduced the amount of take and reduced the likely severity of impacts. No mortality or Level A harassment by tissue damage injury is anticipated or authorized, and only one Level A harassment by PTS take is estimated and authorized. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance (112 percent, Table 72) combined with the fact that the AFTT Study Area overlaps all of the small range, suggests that most to all of the individuals in the stock will likely be taken, but only on one or two days per year, with no reason to think the days would likely be sequential. Regarding the severity of those individual Level B harassment behavioral takes, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short); the received sound levels are largely below 172 dB with a portion up to 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response); and that because of the mitigation the exposures will be of a less impactful nature. Regarding the severity of TTS takes, we have explained that they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival. For similar reasons (described above) the one estimated Level A harassment take by PTS for this stock is unlikely to have any effects on the reproduction or survival of any individuals.

Altogether, any individual Bryde's whale is likely to be disturbed at a low-moderate level on no more than one or two days per year. Even given the fact that some of the affected individuals may have compromised health, there is nothing to suggest that such a low magnitude and severity of effects would result in impacts on the reproduction or survival of any individual, much less annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the GOMEX stock of Bryde's whales.

Bryde's whale (NSD)—These Bryde's whales span the mid- and southern Atlantic and have not been designated as a stock under the MMPA. There is no currently reported trend for the population and there are no specific issues with the status of the stock that cause particular concern (*e.g.,* UMEs). No mortality or Level A harassment is anticipated or authorized. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 626 percent and 60 percent (Table 72), though the percentages would be far lower if compared against the abundance of the entire range of this species in the Atlantic. This information suggests that only a portion of the stock is likely impacted (significantly less than 60 percent given the large range), but that there is likely some repeat exposure (5 to 12 days within a year) of some subset of individuals within the U.S. EEZ if some animals spend extended time within the U.S. EEZ. Regarding the severity of those individual Level B harassment behavioral takes, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels are largely below 172 dB with a portion up to 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Regarding the severity of TTS takes, we have explained that they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival.

Altogether, only a portion of the population is impacted and any individual Bryde's whale is likely to be disturbed at a low to moderate level, with likely many animals exposed only once or twice and a subset potentially disturbed across 5 to 12 likely non-sequential days not in any known biologically important areas. This low magnitude and severity of effects is not expected to result in impacts on annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will

have a negligible impact on Bryde's whales.

Minke whale (Canadian East Coast stock)—This stock of minke whales spans the East Coast and far into Northern Canada waters. Minke whales in the Atlantic are currently experiencing a UME wherein there have been unexpectedly elevated deaths along the Atlantic Coast, some of which have been preliminarily attributed to human interaction or infectious disease. Importantly, both the abundance and PBR are considered significantly underestimated in the SAR, as discussed above. NMFS will authorize one mortality in five years, and the resulting 0.2 annual mortality fell below 10 percent of residual PBR, under the insignificance threshold, and would be considerably even lower if compared against a more appropriate PBR. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 536 percent and 53 percent (Table 72). This information suggests that something less than half of the individuals are likely impacted, but that there is likely some repeat exposure (5 to 10 days within a year) of some subset of individuals within the U.S. EEZ if some animals spend extended time within the U.S. EEZ. Regarding the severity of those individual takes by Level B behavioral harassment, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB, with a portion up to 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Also, the Navy implements time/area mitigation in the Northeast that minimizes MTEs and total sonar hours in an area that significantly overlaps an important feeding area for minke whales, which will reduce the severity of impacts to minke whales by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities. Regarding the severity of TTS takes, we have explained that they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival. For similar reasons (described above) the five estimated Level A harassment takes by PTS for this stock are unlikely to have any effects on the reproduction or survival of any individuals.

Altogether, only a portion of the stock is impacted and any individual minke whale is likely to be disturbed at a low to moderate level, with likely many animals exposed only once or twice and a subset potentially disturbed across 5 to 10 likely non-sequential days, minimized in biologically important areas. Even given the potential for compromised health of some individuals, this low magnitude and severity of effects is not expected to result in impacts on the reproduction or survival of individuals, nor are these harassment takes combined with the authorized mortality expected to adversely affect this stock through impacts on annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on minke whales.

Fin whale (Western North Atlantic stock)—This stock spans the East Coast and up into the Newfoundland waters of Canada. There is no currently reported trend for the population and there are no specific issues with the status of the stock that cause particular concern (*e.g.,* UMEs), although the species is listed as endangered under the ESA. Importantly, both the abundance and PBR are considered underestimated in the SAR, as discussed above. NMFS will authorize 1 mortality over the 5 years of the rule, or 0.2 annually. With the addition of this 0.2 annual mortality, residual PBR is exceeded, which means the total human-caused mortality would exceed PBR by 0.2. However, if the PBR in the SAR reflected the actual abundance across the entire range of the stock, residual PBR would be significantly higher, and definitely not be exceeded. Further, the Atlantic Large Whale Take Reduction Plan directs multiple efforts and requirements towards reducing mortality from commercial fishing (via gear modifications, area closures, and other mechanisms) and NOAA Law Enforcement has reported high compliance rates. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 323 percent and 37 percent (Table 72). This information suggests that something less than a third of the individuals are likely impacted, but that there is likely some repeat exposure (2–6 days within a year) of some subset of individuals within the U.S. EEZ if some animals spend extended time within the U.S. EEZ. Regarding the severity of those individual takes by Level B behavioral harassment, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Also, the Navy implements time/area mitigation in the Northeast that minimizes major training exercises and total sonar hours in an area that significantly overlaps an important BIA feeding area for fin whales, which will reduce the severity of impacts to fin whales by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities. Regarding the severity of TTS takes, we have explained that they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere with fin whale communication or other important low-frequency cues—and that the associated lost opportunities and capabilities are not at a level that would impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, at the expected scale the 33 estimated Level A harassment takes by PTS for fin whales would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals.

Altogether, only a portion of the stock is impacted and any individual fin whale is likely to be disturbed at a low to moderate level, with likely many animals exposed only once or twice and a subset potentially disturbed across approximately 6 likely non-sequential days, minimized in biologically important areas. This low magnitude and severity of effects is not expected to result in impacts on reproduction or survival of individuals, nor are these harassment takes combined with the authorized mortality expected to adversely affect this stock through impacts on annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on fin whales.

Humpback whale (Gulf of Maine stock)—This feeding group stock of humpback whales is one of several associated with the larger, and increasing, West Indies DPS. Humpback whales in the Atlantic are currently experiencing a UME in which a portion of the whales have shown evidence of vessel strike. NMFS will authorize one mortality for the five-year period, which falls under the insignificance threshold of 10 percent of residual PBR for the Gulf of Maine stock. However, importantly, deaths of humpback whales along the Atlantic coast (whether by authorized ship strike or UME) must be considered within the context of the larger West Indies DPS, as animals along the coast could come from the Gulf of Maine stock or any of three or more other associated feeding groups. Specifically, the West Indies DPS numbers in excess of 10,000 whales and the associated PBR, if calculated, would be over 100.

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances (of any humpbacks) compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 141 percent and 16 percent (Table 72). This suggests that only a small portion of the humpback whales in the area are likely impacted, with perhaps some individuals taken on a few days of the year. It would be impossible to determine exactly what portion of the takes are from the Gulf of Maine stock. However, based on the information provided earlier, which suggested about one third of the humpback whales traversing the Atlantic Coast likely come from the Gulf of Maine stock, we estimate that approximately 250 of the 749 total humpback whale takes might be from the Gulf of Maine stock. Two hundred and fiftyrepresents about 28 percent of the minimum population estimate for the Gulf of Maine humpback whale abundance in NMFS' draft 2018 SAR, equating to an expectation that few animals would be repeatedly exposed. Regarding the severity of those individual takes by Level B behavioral harassment, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB with a portion above 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Also, the Navy implements time/area mitigation in the Northeast that minimizes MTEs and total sonar hours in an area that significantly overlaps with an important feeding area for humpbacks, which will reduce the severity of impacts to humpbacks by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities. Regarding the severity of TTS takes, we have explained that they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival. For similar reasons (described above) the three estimated Level A harassment takes by PTS for this stock are unlikely to have any effects on the reproduction or survival of any individuals.

Altogether, only a portion of the stock or DPS is impacted and any individual humpback whale is likely to be disturbed at a low-moderate level, with most animals exposed only once or twice, and minimized in biologically important areas. This low magnitude and severity of effects is not expected to result in impacts on the reproduction or survival of any individuals, nor are these harassment takes combined with the authorized mortality expected to adversely affect this stock through impacts on annual rates of recruitment or survival for the stock. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on humpback whales.

Sei whale (Nova Scotia stock)—This stock spans the northern East Coast and up to southern Newfoundland. There is no currently reported trend for the population and there are no specific issues with the status of the stock that cause particular concern (*e.g.,* UMEs), although the species is listed as endangered under the ESA. Importantly, both the abundance and PBR are considered underestimated in the SAR, as discussed above. NMFS will authorize one mortality over the 5 years covered by this rule, or 0.2 mortality annually. With the addition of this 0.2 annual mortality, residual PBR is exceeded, which means the total human-caused mortality would exceed PBR by 0.3. However, if the PBR in the SAR reflected the actual abundance across the entire range of the stock, residual PBR would be significantly higher, and PBR would not be exceeded. Further, the ALWTRP Plan directs multiple efforts and requirements towards reducing mortality from commercial fishing (via gear modifications, area closures, and other mechanisms) and NOAA Law Enforcement has reported high compliance rates. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 317 percent and 7 percent (Table 72). This information suggests that only a very small portion of individuals in the stock are likely impacted, but that there is likely some repeat exposure (several days within a year) of some subset of individuals within the U.S. EEZ if some animals spend extended time within the U.S. EEZ. Regarding the severity of those individual takes by Level B behavioral harassment, we have explained that the duration of any exposure is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB with a portion up to 178 dB (*i.e.,* of a moderate or lower level, less likely to evoke a severe response). Also, the Navy implements time/area mitigation in the Northeast that minimizes major training exercises and total sonar hours in an area that significantly overlaps an important BIA feeding area for sei whales, which will reduce the severity of impacts to sei whales by reducing interference in feeding that could result in lost feeding opportunities or necessitate additional energy expenditure to find other good opportunities. Regarding the severity of TTS takes, we have explained that they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival. For similar reasons (described above) the four estimated Level A harassment takes by PTS for this stock are unlikely to have any effects on the reproduction or survival of any individuals.

Altogether, only a small portion of the stock is impacted and any individual sei whale is likely to be disturbed at a low-moderate level, with likely many animals exposed only once or twice and a subset potentially disturbed across a few days, minimized in biologically important areas. This low magnitude and severity of harassment effects is not expected to result in impacts on individual reproduction or survival, nor are these harassment takes combined with the authorized mortality expected to adversely affect this stock through impacts on annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on sei whales.

Odontocetes

In this section, we include information here that applies to all of the odontocete species and stocks addressed below, which are further divided into the following subsections: Sperm whales, dwarf sperm whales, and pygmy sperm whales; Dolphins and small whales; Beaked whales; and Harbor porpoise. These sub-sections include more specific information about the group, as well as conclusions for each stock represented.

The majority of takes by harassment of odontocetes in the AFTT Study Area are caused by sources from the MF1 active sonar bin (which includes hull-mounted sonar) because they are high level sources at a frequency (1–10 kHz), which overlap a more sensitive portion (though not the most sensitive) of the MF hearing range, and of the sources expected to result in take, they are used in a large portion of exercises (see Table 1.5–5 in the Navy's rulemaking/LOA application). For odontocetes other than beaked whales or harbor porpoises (for which these percentages are indicated separately in their sections), most of the takes (97 percent) from the MF1 bin in the AFTT Study Area would result from received levels between 160 and 172 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF3 = 98 percent between 142 and 160, MF4 = 97 percent between 136 and 160, MF5 = 98 percent between 124 and 148, and HF4 = 93 percent between 100 and 148 dB SPL. These values may be derived from the information in Tables 6.4–8 through 6.4–12 in the Navy's rulemaking/LOA application (though they were provided directly to NMFS upon request). Based on this information, the majority of the takes by Level B behavioral harassment are expected to be low to sometimes moderate in nature, but still of a generally shorter duration.

For all odontocetes, takes from explosives (Level B behavioral harassment, TTS, or PTS if present) comprise a very small fraction of those caused by exposure to active sonar. Take from exposure to air guns or pile driving is limited to small numbers of a few dolphin species (bottlenose, Atlantic spotted, and Clymene).

The range of potential behavioral effects of sound exposure on marine mammals generally, and odontocetes specifically, has been discussed in detail previously. There are a couple of behavioral patterns that differentiate the likely impacts on odontocetes as compared to mysticetes. First, odontocetes echolocate to find prey, which means that they actively send out sounds to detect their prey. While there are many strategies for hunting, one common pattern, especially for deeper diving species, is many repeated deep dives within a bout, and multiple bouts within a day, to find and catch prey. As discussed above, there are many studies demonstrating the cessation of odontocete foraging dives in response to sound exposure. If enough foraging interruptions occur over multiple sequential days, and the individual either does not take in the necessary food, or must exert significant effort to find necessary food elsewhere, energy budget deficits can occur that could potentially result in impacts to reproductive success, such as increased cow/calf intervals (the time between successive calving). Alternately, many mysticetes rely on seasonal migratory patterns that position them in a geographic location at a specific time of the year to take advantage of ephemeral large abundances of prey (*i.e.,* invertebrates or small fish, which they eat by the thousands), whereas odontocetes forage more homogeneously one fish or squid at a time, which means that if they are interrupted while feeding, it is often possible to find more prey relatively nearby.

Because the majority of harassment take of odontocetes results from the sources in the MF1 bin (1–10 kHz), the vast majority of threshold shift caused by Navy sonar sources will typically occur in the range of 2–20 kHz. This frequency range falls directly within the range of most odontocete vocalizations. However, odontocete vocalizations typically span a much wider range than this, and alternately, threshold shift from active sonar will often be in a narrower band (reflecting the narrower band source that caused it), which means that TTS incurred by odontocetes would typically only interfere with communication within a portion of an odontocete's range (if it occurred during a time when communication with conspecifics was occurring) and as discussed earlier, it would only be expected to be of a short duration and relatively small degree. Odontocete echolocation occurs predominantly at frequencies significantly higher than 20 kHz, though there may be some small overlap at the lower part of their echolocating range for some species, which means that there is little likelihood that threshold shift, either temporary or permanent would interfere with feeding behaviors. Many of the other critical sounds that serve as cues for navigation and prey (*e.g.,* waves, fish, invertebrates) occur below a few kHz, which means that detection of these signals will not be inhibited by most threshold shift either. The low number of takes by threshold shifts that might be incurred by individuals exposed to explosives, pile driving, or air guns would likely be lower frequency (5 kHz or less) and spanning a wider frequency range, which could slightly lower an individual's sensitivity to navigational or prey cues, or a small portion of communication calls, for several minutes to hours (if temporary) or permanently. There is no reason to think that any of the individual odontocetes taken by TTS would incur these types of takes over more than a few days of the year (with the exception of North Atlantic Kogia, which are explicitly discussed below), at the most, and therefore they are unlikely to incur impacts on reproduction or survival.

Sperm Whales, Dwarf Sperm Whales, and Pygmy Sperm Whales—In this section, building on the broader discussion above (for marine mammals, and odontocetes in particular), we bring together the discussion of the different types and amounts of take that different stocks will incur, the applicable mitigation for each stock, and the status of the stocks to support the negligible impact determinations for each stock. We have also previously described the unlikelihood of any masking or habitat impacts to any groups that would rise to the level of affecting individual fitness. The discussion in this section fairly narrowly focuses some information that applies specifically to the sperm whale group, and then because there are multiple stock-specific factors in relation to differential Level B harassment effects and authorized mortality, we break out specific findings into a few groups—North Atlantic sperm whales (with authorized mortality and one instance of tissue damage from explosives), Western North Atlantic dwarf and pygmy sperm whales, and GOMEX sperm, dwarf sperm and pygmy sperm whales (which have lower level magnitude of Level B harassment takes, but lingering effects from the DWH oil spill).

In Table 73 below, for sperm whale, dwarf sperm whales, and pygmy sperm whales, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

Table 73. Annual takes of Level B and Level A harassment, mortality for sperm whales, dwarf sperm whales, and pygmy sperm whales in the AFTT Study Area and number indicating the instances of total take as a percentage of stock abundance.

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percentage of abundance	
		Level B Harassment		Level A Harassment								
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage	Mortality	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ
Suborder Odontoceti (toothed whales)												
Family Physeteridae (sperm whale)												
Sperm whale*	Gulf of Mexico Oceanic	1,107	25	0	0	0	1132	1132	2,114	2,114	54	54
	North Atlantic	24,703	662	3	1	0.2	21489	25369	3,950	61,700	544	41
Family Kogiidae (sperm whales)												
Dwarf sperm whale	Gulf of Mexico Oceanic	339	453	70	0	0	862	862	1,107	1,107	78	78
	Western North Atlantic	3,900	9,102	94	0	0	12852	13096	611	3,641	2105	360
Pygmy sperm whale	Northern Gulf of Mexico	339	453	70	0	0	862	862	1,107	1,107	78	78
	Western North Atlantic	3,900	9,102	94	0	0	12852	13096	611	3,641	2105	360

Note: Above we compare predicted takes to abundance estimates generated from the same underlying density estimate (as described in the *Estimated Take of Marine Mammals* section), versus abundance estimates directly from NMFS' SARs, which are not based on the same data and would not be appropriate for this purpose. Note that comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty and takes are notably greater) and across the whole Study Area (which offers a more comprehensive comparison for many stocks).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing plus take from one large ship shock trial.

The annual mortality of 0.2 is because we expect no more than one mortality over the course of five years from vessel strikes as previously described above.

As discussed above, the majority of Level B harassment behavioral takes of odontocetes, and thereby sperm whales, are expected to be in the form of low to occasionally moderate severity of a generally shorter duration. As mentioned earlier in this section, we anticipate more severe effects from takes when animals are exposed to higher received levels or for longer durations. Occasional milder Level B behavioral harassment is unlikely to cause long-term consequences for individual animals or populations, even if some smaller subset of the takes are in the form of a longer (several hours or a day) and more moderate response. However, impacts across higher numbers of days, especially where sequential, have an increased probability of resulting in energetic deficits that could accrue to effects on reproductive success.

We note here that *Kogia,* as an HF-sensitive species, has a lower PTS threshold than all other groups and therefore is likely to experience larger amounts of TTS and PTS, and NMFS will authorize higher numbers. However, *Kogia* whales are still likely to avoid sound levels that would cause higher levels of TTS (greater than 20 dB) or PTS. Even though the number of takes is high, all of the reasons described above for why TTS and PTS are not expected to impact reproduction or survival still apply. The Navy will implement a mitigation area that will avoid or reduce impacts to sperm whales (*Physeter microcephalus*). Nearly the entire important sperm whale habitat (Mississippi Canyon) is included in the GOMEX Planning Awareness Mitigation Areas where the Navy will not conduct MTEs, which are more likely to have more severe effects because of their multiple platforms, hull-mounted sonar, and longer-durations.

Below we compile and summarize the information that supports our determination that the Navy's activities will not adversely impact recruitment or survival for any of the affected stocks addressed in this section.

Sperm whale (North Atlantic stock)—This stock spans the East Coast out into oceanic waters well beyond the U.S. EEZ. There is no currently reported trend for the population and, although listed as endangered under the ESA, there are no specific issues with the status of the stock that cause particular concern (*e.g.,* UMEs). NMFS will authorize one mortality, which, when added to the other forward-projected mortality does not exceed the PBR insignificance threshold. One Level A harassment take by tissue damage will also be authorized which, as noted previously, could range in impact from minor to something just less than M/SI that could seriously impact fitness. However, given the Navy's mitigation and the sperm whale's large size, which improves detection by Lookouts, exposure at the closer to the source and more severe end of the spectrum is less likely and we cautiously assume some moderate impact for this single take that could lower one individual's fitness within the year such that a female (assuming a 50 percent chance of it being a female) might forego reproduction for one year. As noted previously, foregone reproduction has less of an impact on population rates than death (especially for one year) and one instance would not be expected to impact annual rates of recruitment or survival, even if it were a female. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 544 percent and 41 percent (Table 73). This information, combined with the known range of the stock, suggests that something less than a quarter of the individuals in the stock are likely impacted, but that there is likely some repeat exposure (2–11 days within a year) of some subset of individuals that remain within the U.S. EEZ for an extended time. Regarding the severity of those individual takes by Level B behavioral harassment, we have explained that the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound

levels largely between 160 and 172 dB (*i.e.,* of a lower, to occasionally moderate, level). Regarding the severity of TTS takes, as described previously they are expected to be low-level and of short duration and the associated lost opportunities and capabilities not at a level that would impact reproduction or survival. For similar reasons (described above) three estimated Level A harassment takes by PTS for this stock is unlikely to have any effects on the reproduction or survival of any individuals.

Altogether, only a small portion of the stock is impacted and any individual sperm whale is likely to be disturbed at a low-moderate level, with the majority of animals likely disturbed once or not at all, and a subset potentially disturbed across 2–11 likely non-sequential days. Even for an animal disturbed at the high end of this range (11 days over a year), given the low to moderate impact from each incident, and the fact that few days with take would likely be sequential, no impacts to individual fitness are expected. This low to occasionally moderate magnitude and severity of effects is not expected to result in impacts on reproduction or or survival, and nor are these harassment takes combined with the authorized mortality expected to adversely affect the stock through annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on North Atlantic sperm whales.

Sperm whale, dwarf sperm whale, and pygmy sperm whale (GOMEX stocks)—These stocks suffer from lingering health issues from the DWH oil spill (6–7 percent of individuals of these stocks with adverse health effects), which means that some could be more susceptible to exposure to other stressors, and negative population effects (21–42 years until the DWH oil-injured population trajectory is projected to catch up with the baseline population trajectory (*i.e.,* in the absence of DWH)), reported as years to recovery. Neither mortality nor tissue damage from explosives is anticipated or authorized for any of these three stocks, and sperm whales are not expected to incur PTS. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance is 54–78 percent (Table 73), which suggests that for each of the three species/stocks either this percentage of the individuals in these stocks are all taken by harassment on a single day, or a small subset may be taken on a few days. Regarding the severity of those individual takes by Level B behavioral harassment, we have explained that the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels are largely between 160 and 172 dB (*i.e.,* of a lower level, less likely to evoke a severe response). Additionally, the Navy is implementing mitigation areas for sperm whales that are expected to reduce impacts in important feeding areas, further lessening the severity of impacts. Regarding the severity of TTS takes, as described previously they are expected to be low-level, of short duration, and mostly not in a frequency band that would be expected to interfere significantly with conspecific communication, echolocation, or other important low-frequency cues. Also, there is no reason to believe that any individual would incur these TTS takes more than a few days in a year, and the associated lost opportunities and capabilities would not be expected to impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, 70 estimated Level A harassment takes by PTS for the two *Kogia* stocks in the GOMEX would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals.

Altogether, only a portion of these stocks are impacted and any individual sperm, dwarf sperm, or pygmy sperm whale is likely to be disturbed at a low to occasionally moderate level and no more than a few days per year. Even given the fact that some of the affected individuals may have compromised health, there is nothing to suggest that such a low magnitude and severity of effects would result in impacts on the reproduction or survival of individuals, much less annual rates of recruitment or survival for any of the stocks. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the GOMEX stocks of sperm whales, dwarf sperm whales, and pygmy sperm whales.

Pygmy and Dwarf sperm whales (Western North Atlantic stocks)—These stocks span the deeper waters of the East Coast north to Canada and out into oceanic waters beyond the U.S. EEZ. There is no currently reported trend for these populations and there are no specific issues with the status of the stocks that cause particular concern. Neither mortality nor tissue damage from explosives is anticipated or authorized for these stocks. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 2,105 percent and 360 percent (Table 73). This information, combined with the known range of the stock, suggests that while not all of the individuals in these stocks will most likely be taken (because they span well into oceanic waters) of those that are taken, most will be taken over several repeated days (though likely not sequential) and some subset that spends extended time within the U.S. EEZ will likely be taken over a larger amount of days (likely 15–42 days during a year), some of which could be sequential. Regarding the severity of the individual takes by Level B behavioral harassment, we have explained that the duration of any exposure response is expected to be between minutes and hours (and likely not more than 24 hours) and the received sound levels are largely between 160 and 172 dB (*i.e.,* of a lower level, less likely to evoke a severe response). Additionally, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity. Regarding the severity of TTS takes, as described previously they are expected to be low-level, of short duration and mostly not in a frequency band that would be expected to interfere significantly with conspecific communication, echolocation, or other important low-frequency cues. Also, there is no reason to believe that any individual would incur these TTS takes more than a few days in a year, and the associated lost opportunities and capabilities would not be expected to impact reproduction or survival. For these same reasons (low level and frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, at the expected scale the 94 estimated Level A harassment takes by PTS for the two *Kogia* stocks in the North Atlantic would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with

reproductive success or survival of any individuals.

Altogether, most of the stock will likely be taken (at a low to occasionally moderate level) over several days a year, and some smaller portion of the stock is expected to be taken on a relatively moderate to high number of days across the year, some of which could be sequential days. Though the majority of impacts are expected to be of a lower to sometimes moderate severity, the larger number of takes (in total and for certain individuals) makes it more likely (probabilistically) that a small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year (energetic impacts to males are generally meaningless to population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal). As noted previously, however, foregone reproduction (especially for one year) has far less of an impact on population rates than mortality and a small number of instances of foregone reproduction would not be expected to adversely impact annual rates of recruitment or survival, especially given that PBR for both of these stocks is 21. For these reasons, in consideration of all of the effects of the Navy's activities combined, we have determined that the authorized take will have a negligible impact on the West North Atlantic stocks of pygmy and dwarf sperm whales.

Dolphins and Small Whales—This section builds on the broader discussion above brings together the discussion of the different types and amounts of take that different stocks will incur, the applicable mitigation for each stock, and the status of the stocks to support the negligible impact determinations for each stock. None of these species are listed as endangered or threatened under the ESA. We have also described the unlikelihood of any masking or habitat impacts to any groups that would rise to the level of affecting individual fitness. The discussion below focuses on additional information that is specific to the dolphin taxa (in addition to the general information on odontocetes provided above, which is relevant to these species) and to support the summarized group-specific conclusions in the subsequent sections. Because of several factors, we break out specific findings into four groups: The two GOMEX (GOM) stocks with authorized mortality, the two Western North Atlantic stocks with authorized mortality, the remaining GOMEX stocks (which have a lower magnitude of Level B harassment takes, but also health issues related to the DWH oil spill), and the remaining Western North Atlantic stocks.

In Table 74 below, for dolphins and small whales, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

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Table 74. Annual takes of Level B and Level A harassment and mortality for dolphins and small whales in the AFTT Study Area and number indicating the instances of total take as a percentage of stock abundance.

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percentage of abundance	
		Level B Harassment		Level A Harassment								
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage	Mortality	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ
Family Delphinidae (dolphins)												
Atlantic spotted dolphin	Northern Gulf of Mexico	69,225	3,610	3	0	0	72,838	72,838	47,676	47,676	153	153
	Western North Atlantic	208,201	19,383	26	6	0	209,814	227,616	52,118	250,648	403	91
Atlantic white-sided dolphin	Western North Atlantic	44,077	2,207	7	3	0.2	44,210	46,294	14,332	137,305	308	34
Bottlenose dolphin	Choctawhatchee Bay	941	32	0	0	0	973	973	99	99	984	984
	Gulf of Mexico Eastern Coastal	42	0	0	0	0	42	42	9,888	9,888	0	0
	Gulf of Mexico Northern Coastal	15,644	834	2	0	0	16,480	16,480	8,476	8,476	194	194
	Gulf of Mexico Western Coastal	7,191	635	0	0	0	7,826	7,826	33,903	33,903	23	23
	Indian River Lagoon Estuarine System	255	31	0	0	0	286	286	36	36	790	790
	Jacksonville Estuarine System	74	13	0	0	0	87	87	27	27	320	320
	Mississippi Sound, Lake Borgne, Bay Boudreau	1	0	0	0	0	1	1	198	198	1	1
	Northern Gulf of Mexico Continental Shelf	121,223	6,287	15	1	0	127,526	127,526	72,043	72,043	177	177
	Northern Gulf of Mexico Oceanic	13,947	706	8	2	0	14,663	14,663	18,364	18,364	80	80
	Northern North Carolina Estuarine System	2,844	483	0	0	0	3,327	3,327	3,622	3,622	92	92
	Southern North Carolina Estuarine System	0	0	0	0	0	0	0	0	0	0	0
	Western North Atlantic Northern Florida Coastal	1,145	90	0	0	0	1,235	1,235	906	906	136	136
	Western North Atlantic Central Florida Coastal	7,100	513	0	0	0	7,613	7,613	4,528	4,528	168	168
	Western North Atlantic Northern Migratory Coastal	33,993	3,051	7	0	0	37,051	37,051	9,962	9,962	372	372
	Western North Atlantic Offshore	393,416	34,686	77	9	0	421,295	428,188	64,298	186,260	655	230
	Western North Atlantic South Carolina/Georgia Coastal	5,544	416	0	0	0	5,960	5,960	3,622	3,622	165	165
	Western North Atlantic Southern Migratory Coastal	15,411	1,305	2	0	0	16,718	16,718	7,245	7,245	231	231
Clymene dolphin	Northern Gulf of Mexico	4,174	99	4	2	0	4,279	4,279	10,942	10,942	39	39
	Western North Atlantic	97,952	7,816	10	3	0	92,364	105,781	15,370	171,202	601	62
False killer whale	Northern Gulf of Mexico	1,902	72	1	0	0	1,975	1,975	3,136	3,136	63	63
	Western North Atlantic	11,176	863	0	0	0	11,131	12,039	1,254	16,144	888	75
Fraser's dolphin	Northern Gulf of Mexico	1,123	58	2	1	0	1,184	1,184	1,637	1,637	72	72
	Western North Atlantic	4,931	291	0	0	0	3,914	5,222	411	17,588	952	30
Killer whale	Northern Gulf of Mexico	33	0	0	0	0	33	33	176	176	19	19
	Western North Atlantic	113	6	0	0	0	112	119	15	472	747	25
Long-finned pilot whale	Western North Atlantic	35,890	1,656	7	1	0	33,769	37,554	3,863	447,431	874	8
Melon-headed whale	Northern Gulf of Mexico	3,067	66	3	1	0	3,137	3,137	6,725	6,725	47	47
	Western North Atlantic	50,058	3,792	3	0	0	49,707	53,853	5,821	69,526	854	77
Pantropical spotted dolphin	Northern Gulf of Mexico	25,924	596	15	6	0.2	26,541	26,541	82,055	82,055	32	32
	Western North Atlantic	207,279	15,304	8	1	0	196,098	222,592	30,088	275,964	652	81
Pygmy killer whale	Northern Gulf of Mexico	720	16	1	0	0	737	737	2,062	2,062	36	36
	Western North Atlantic	8,702	629	0	0	0	8,507	9,331	1,052	12,296	809	76
Risso's dolphin	Northern Gulf of Mexico	1,647	43	1	0	0	1,691	1,691	3,096	3,096	55	55
	Western North Atlantic	38,887	2,220	2	0	0	40,144	41,109	5,601	39,085	717	105
Rough-toothed dolphin	Northern Gulf of Mexico	3,849	177	1	1	0	4,028	4,028	4,824	4,824	83	83
	Western North Atlantic	25,857	2,476	0	0	0	26,450	28,333	2,793	34,768	947	81
Short-beaked common dolphin	Western North Atlantic	540,662	30,561	101	36	1.2	571,100	571,361	73,481	520,317	777	110
Short-finned pilot whale	Northern Gulf of Mexico	1,835	26	3	0	0	1,864	1,864	2,032	2,032	92	92
	Western North Atlantic	45,724	2,639	5	1	0	34,760	48,369	6,578	450,146	528	11
Spinner dolphin	Northern Gulf of Mexico	7,803	277	31	14	0.2	8,125	8,125	13,653	13,653	60	60
	Western North Atlantic	98,665	8,382	5	1	0	98,817	107,053	11,280	135,573	876	79
Striped dolphin	Northern Gulf of Mexico	2,449	69	2	1	0	2,521	2,521	4,871	4,871	52	52
	Western North Atlantic	181,103	11,992	16	4	0	167,438	193,115	52,222	322,542	321	60
White-beaked dolphin	Western North Atlantic	80	4	0	0	0	84	84	42	42	200	200

Note: Above we compare predicted takes to abundance estimates generated from the same underlying density estimate (as described in the *Estimated Take of Marine Mammals* section), versus abundance estimates directly from NMFS' SARs, which are not based on the same data and

would not be appropriate for this purpose. Note that comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty and takes are notably greater) and across the whole Study Area (which offers a more comprehensive comparison for many stocks).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing plus take from one large ship shock trial.

For mortality takes there was an annual average of 0.2 dolphins from each dolphin species/stock listed above (*i.e.*, for those species or stocks where 1 take could potentially occur divided by 5 years to get the annual number of mortalities/serious injuries) or 1.2 dolphins in the case of short-beaked common dolphin (*i.e.*, where 6 takes could potentially occur divided by 5 years to get the annual number of mortalities/serious injuries).

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As described above, the large majority of Level B behavioral harassments to odontocetes, and thereby dolphins and small whales, from hull-mounted sonar (MF1) in the AFTT Study Area would result from received levels between 160 and 172 dB SPL. Therefore, the majority of Level B harassment takes are expected to be in the form of low to occasionally moderate responses of a generally shorter duration. As mentioned earlier in this section, we anticipate more severe effects from takes when animals are exposed to higher received levels. Occasional milder occurrences of Level B behavioral harassment are unlikely to cause long-term consequences for individual animals or populations that have any effect on reproduction or survival. Some behavioral responses could be in the form of a longer (several hours or a day) and more moderate response, but because they are not expected to be repeated over more than several sequential days at the most, impacts to reproduction or survival for most animals are not anticipated. Even where a few animals could experience effects on reproduction, for the reasons explained below this would not affect rates of recruitment or survival.

Research and observations show that if delphinids are exposed to sonar or other active acoustic sources they may react in a number of ways depending on their experience with the sound source and what activity they are engaged in at the time of the acoustic exposure. Delphinids may not react at all until the sound source is approaching within a few hundred meters to within a few kilometers depending on the environmental conditions and species. Some dolphin species (the more surface-dwelling taxa—typically those with ''dolphin'' in the common name, except Risso's dolphin, such as bottlenose dolphins, spotted dolphins, common dolphins, spinner dolphins, rough-toothed dolphins, etc), especially those residing in more industrialized or busy areas, have demonstrated more tolerance for disturbance and loud sounds and many of these species are known to approach vessels to bow-ride. These species are often considered generally less sensitive to disturbance. Deep-diving dolphins that reside in deeper waters and generally have fewer interactions with human activities are more likely to demonstrate more typical avoidance reactions and foraging interruptions as described above in the odontocete overview.

BIAs have been identified for several small and resident populations of bottlenose dolphin in the GOMEX and on the East Coast, but these identified areas are within bays and estuaries where the Navy does not use explosives and conducts limited activities by sonar and other transducers. For example, for the small resident population of Northern North Carolina Estuarine dolphins, for which there is a BIA, one-third of the takes are from sub-navigation and ship object avoidance, which are less impactful than sonar activity and shorter in duration (by about 30 min or less). The area of activity is at the northern edge of this BIA, which further reduces the possibility of modeled takes that would result in impacts that could affect reproduction or survival. The other two-thirds of the takes for the Northern North Carolina Estuarine dolphins are from Civilian Port Defense, which would occur at most only once in five years in the vicinity of that BIA. Similarly, for the small resident population of Indian River Lagoon Estuarine system bottlenose dolphins, for which there is also a BIA, all of the Level B harassment takes are also from the less impactful sonar activity of sub-navigation and ship object avoidance and are events of short duration (approximately 30 min). Two small and resident populations of bottlenose dolphin for which there are two BIAs (Northern North Carolina Estuarine System and Southern North Carolina Estuarine System) may be impacted during pile driving activities for the Elevated Causeway System at Marine Corps Base Camp Lejeune, North Carolina; however, only one modeled take of a Northern North Carolina Estuarine System bottlenose dolphin is predicted. There are no expected takes from any activities to the small resident population of Southern North Carolina Estuarine System bottlenose dolphins (for which there is a BIA) and only one expected take to the small resident population of Mississippi Sound bottlenose dolphins (for which there is a BIA) from sonar. Therefore, for these small resident populations of bottlenose dolphins, impacts from Level B harassment are expected to be short-term and minor, and mostly all in the form of behavioral disturbance. Abandonment of the area, or any other response that could affect reproduction or survival, is not anticipated for the small and resident bottlenose dolphin populations stocks with BIAs from the Navy's training and testing activities.

Animals from one of these stocks with a BIA, the bottlenose dolphin of Barataria Bay, Louisiana, which is still showing persistent impacts from the Cetacean UME in the Northern GOMEX, were recently fitted with satellite-linked transmitters, which showed that most dolphins remained within the bay, while those that entered nearshore coastal waters remained within 1.75 km (Wells *et al.,* 2017). With the Navy's activities very limited in this type of habitat, the Navy is not conducting training or testing where Barataria Bay dolphins inhabit and therefore no takes will occur to this stock.

Below we synthesize and summarize the information that supports our determination that the Navy's activities will not adversely impact recruitment or survival for any of the affected stocks addressed in this section:

Atlantic white-sided dolphin and short-beaked common dolphin (Western North Atlantic stocks)—There is no currently reported trend for these stocks and there are no specific issues with the status of these stocks that cause particular concern (*e.g.,* UMEs). We have authorized one and six mortalities over the course of five years for these two stocks, respectively. Given the large residual PBR values for these stocks (248 and 148), this number of mortalities falls well under the insignificance threshold. Some Level A harassment take by tissue damage from explosives has also been authorized for these stocks (3 and 36, respectively). As noted previously, tissue damage effects could range in impact from minor to

something just less than M/SI that could seriously impact fitness. However, given the Navy's mitigation, which makes exposure at the closer to the source and more severe end of the spectrum less likely, we cautiously assume some moderate impact for this category of take that could lower an individual's fitness within the year such that females (assuming a 50 percent chance that a take is a female) might forego reproduction for one year. As noted previously, foregone reproduction has less of an impact on population rates than death (especially for one year) and the number of takes anticipated for each stock would not be expected to impact annual rates of recruitment or survival, even if all of the takes were females (which would be highly unlikely), especially given the high residual PBRs of these stocks (in other words, if the stocks can absorb those numbers of mortalities without impacting ability to approach OSP, clearly they can absorb the significantly lesser effects of a one-year delay in calving).

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ for these four stocks, respectively, is 308–777 percent and 34–110 percent (Table 74). This information suggests that some portion of these stocks are likely not taken at all, but that there is likely some repeat exposure (2–15 days within a year) of some subset of individuals. Regarding the severity of those individual takes by Level B behavioral harassment, we have explained that the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower level, less likely to evoke a severe response). Additionally, while we do not have a specific reason to expect that these takes would occur sequentially on more than several days in row or be more severe in nature, the probability of this occurring increases the higher the total take numbers. Given the higher number of takes and the associated abundances (especially for short-beaked common dolphin) we acknowledge the possibility that some smaller subset of individuals could experience behavioral disruption of a degree that impacts energetic budgets such that reproduction could be delayed for a year. However, as discussed above in regards to PBR and Level A harassment by tissue damage, and in consideration of the potential reproductive effects of tissue damage and these takes by Level B behavioral harassment, and in combination with the authorized mortality—this degree of effects on a small subset of individuals is still not expected to adversely affect rates of recruitment or survival. Regarding the severity of TTS takes, as described previously they are expected to be low-level, of short duration, and not in a frequency band that would be expected to significantly interfere with dolphin communication, or echolocation or other important low-frequency cues—and, therefore, the associated lost opportunities and capabilities would not be expected to impact reproduction or survival. For these same reasons (low level and the likely frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the estimated Level A harassment takes by PTS for the two dolphin stocks addressed here (7 and 101, respectively) would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals.

Altogether, individual dolphins are likely to be taken at a low level, with some animals likely taken once or not at all, many potentially disturbed across 2–15 predominantly non-sequential days, and a small number potentially experiencing a level of effects that could curtail reproduction for one year. This magnitude and severity of effects (especially given the status of the stocks), including the consideration or the authorized mortality, is not expected to result in impacts on annual rates of recruitment or survival for either of the stocks. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on these two Western North Atlantic stocks of dolphins.

Pantropical spotted dolphin and spinner dolphin (GOM stocks)—As described above, the GOMEX dolphin stocks indicated in Table 71 suffer from lingering health issues resulting from the DWH oil spill (7 and 17 percent of individuals of these stocks, respectively, have adverse health effects), which means that some of them could be more susceptible to exposure to other stressors, as well as negative population effects (predicting it will take up to 39 and 105 years, respectively, for stocks to return to population growth rates predicted in the absence of DWH effects). We have authorized one mortality over the course of five years for each of these two stocks, respectively. Given the large residual PBR values for these stocks (402 and 62, respectively), this number of mortalities falls well under the insignificance threshold. Some Level A harassment take by tissue damage from explosives has also been authorized for these stocks (6 and 14, respectively). As noted previously, tissue damage effects could range in impact from minor to something just less than M/SI that could seriously impact fitness. However, given the Navy's mitigation, which makes exposure at the closer to the source and more severe end of the spectrum less likely, we cautiously assume some moderate impact for this category of take that could lower an individual's fitness within the year such that females (assuming a 50 percent chance that a take is a female) might forego reproduction for one year. As noted previously, foregone reproduction has less of an impact on population rates than death (especially for one year) and the number of takes anticipated for each stock would not be expected to impact annual rates of recruitment or survival, even if all of the takes were females (which would be highly unlikely), especially given the high residual PBRs of these stocks (in other words, if the stocks can absorb one mortality each without impacting ability to approach OSP, they can absorb the significantly lesser effect of a one-year delay in calving).

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance is 32 percent and 60 percent, respectively, reflecting that only a subset of each stock will be taken by Level B behavioral harassment within a year. Of that subset, those taken will likely be taken one time, but if taken more than that, the 2 or 3 days would not likely be sequential (Table 74). Regarding the severity of those individual takes by Level B behavioral harassment, we have explained that the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower to occasionally moderate severity).

Regarding the severity of TTS takes, as described previously they are expected to be low-level, of short duration, and not in a frequency band that would be expected to significantly interfere with dolphin communication, or echolocation or other important low-frequency cues. Therefore, the associated lost opportunities and

capabilities are not expected to impact reproduction or survival. For these same reasons (low level and the likely frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the estimated Level A harassment takes by PTS for the dolphin stocks addressed here (15 and 31, respectively) would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals.

Altogether, any individual dolphin is likely to be taken at a low to occasionally moderate level, with most animals likely not taken at all and with a subset of animals being taken up to a few non-sequential days. Even given the fact that some of the affected individuals may have compromised health, there is nothing to suggest that such a low magnitude and severity of effects, including the potential tissue damage, would result in impacts on annual rates of recruitment or survival for either of these two stocks. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the GOMEX stocks of pantropical spotted dolphins and spinner dolphins.

Western North Atlantic dolphin stocks (all stocks in Table 74 except Atlantic white-sided dolphin and short-beaked common dolphin)—There are no specific issues with the status of these stocks that cause particular concern (*e.g.,* UMEs). No mortality is expected nor has it been authorized for these stocks. For some of these stocks, some tissue damage has been authorized (0 for many, 1–9 for others). As noted previously, tissue damage effects could range in impact from minor to something just less than M/SI that could seriously impact fitness. However, given the Navy's mitigation, which makes exposure at the closer to the source and more severe end of the spectrum less likely, we cautiously assume some moderate impact for all these takes that could lower an individual's fitness within the year such that this small number of females (assuming a 50 percent chance of being a female) might forego reproduction for one year. As noted previously, foregone reproduction has less of an impact on population rates than death (especially for one year) and a few instances would not be expected to impact annual rates of recruitment or survival, even if all of the takes were females (which would be highly unlikely), especially given the higher residual PBRs, where known (the majority of stocks). For stocks with no calculated residual PBR or where abundance is unknown, the limited information available on population size indicates that the very low number of females who might forego reproduction would have no effect on rates of recruitment or survival. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance ranges up to 984 percent inside the U.S. EEZ (though some are significantly lower) and is generally much lower across the whole range of most stocks, reflecting that for many stocks only a subset of the stock will be impacted—although alternately for a few of the smaller bay stocks all individuals are expected to be taken across multiple days (Table 74). Generally, individuals of most stocks (especially bottlenose dolphins) might be taken no more than several times each, while the other species in this group will only accrue takes to a portion of the stock, but individuals might be taken across 2–20 days within a year. Regarding the severity of those individual takes by Level B behavioral harassment, we have explained that the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower level, less likely to evoke a severe response). While we do not have reason to expect that these takes would occur sequentially on more than several days in a row or be more severe in nature, the probability of this occurring increases the higher the total take numbers. Given higher percentages when compared to abundances, and especially where the absolute number of takes is higher *(e.g.,* spinner dolphin), we acknowledge the possibility that some smaller subset of individuals (especially in the larger stocks with higher total take numbers) could experience behavioral disruption of a degree that impacts energetic budgets such that reproduction could be delayed for a year. However, as discussed above in regards to tissue damage, and in consideration of the potential reproductive effects of Level A harassment by tissue damage and these takes by Level B behavioral harassment, this degree of effects on a small subset of individuals is still not expected to adversely affect rates of recruitment or survival. For the smaller Estuarine stocks with the potential repeated days of disturbance, we note that as described earlier, the activities that Navy conducts in inland areas (not MTEs, etc.) are expected to generally result in lower severity responses, further decreasing the likelihood that they would accrue to effects on reproduction or survival, even if accrued over several sequential days.

Regarding the severity of TTS takes, as described previously they are expected to be low-level, of short duration, and not in a frequency band that would be expected to significantly interfere with dolphin communication, or echolocation or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities would not be expected to impact reproduction or survival. For these same reasons (low level and the likely frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the estimated Level A harassment takes by PTS for the dolphin stocks addressed here (between 1 and 77) would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals.

Altogether, any individual dolphin is likely taken at a low to occasionally moderate level, with some animals likely taken once or not at all, and a subset potentially disturbed across 2–20 predominantly non-sequential days, and a small number potentially experiencing a level of effects that could curtail reproduction for one year. The magnitude and severity of effects described is not expected to result in impacts on annual rates of recruitment or survival for any of the stocks. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on these Western North Atlantic stocks of dolphins.

GOMEX dolphin stocks (all of the stocks indicated in Table 74 except Pantropical spotted dolphin and spinner dolphin)—As described above, the GOMEX stocks indicated in Table 71 suffer from lingering health issues resulting from the DWH oil spill (3–30 percent of individuals of these stocks have adverse health effects), which means that some of them could be more susceptible to exposure to other stressors, as well as negative population effects (predicting it will take up to 76 years, with number varying across stocks, for stocks to return to population growth rate e predicted in the absence of DWH effects). Of note, the Northern Coastal bottlenose dolphin adverse

effect statistics are about twice as high as the others (*i.e.,* all other stocks are below 17 percent). No mortality is authorized for these stocks, however a few Level A harassment takes by tissue damage from explosives (zero for most, 1–2 for a few, and 6 for the Atlantic spotted dolphin stock) are authorized. As noted previously, tissue damage effects could range in impact from minor to something just less than M/SI that could seriously impact fitness. However, given the Navy's mitigation, which makes exposure at the closer to the source and more severe end of the spectrum less likely, we cautiously assume some moderate impact for these Level A harassment takes that could lower an individual's fitness within the year such that a female (assuming a 50 percent chance of being a female) might forego reproduction for one year. As noted previously, foregone reproduction has less of an impact on population rates than death (especially for one year) and a few instances, even up to six, would not be expected to impact annual rates of recruitment or survival, even if all of the takes were of females (which is highly unlikely).

Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance ranges up to 177 percent, but is generally much lower for most stocks, reflecting that generally only a subset of each stock will be taken, with those in the subset taken only a few non-sequential days of the year (Table 74). Regarding the severity of those individual takes by Level B behavioral harassment, we have explained that the duration of any exposure response is expected to be between minutes and hours (*i.e.,* relatively short) and the received sound levels largely below 172 dB (*i.e.,* of a lower to occasionally moderate severity).

Regarding the severity of TTS takes, as described previously they are expected to be low-level, of short duration, and not in a frequency band that would be expected to significantly interfere with dolphin communication, or echolocation or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities would not be expected to impact reproduction or survival. For these same reasons (low level and the likely frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the estimated Level A harassment takes by PTS for the dolphin stocks addressed here (all 3 or below, with the exception of three stocks with much larger abundances with 4, 8, and 15 PTS takes) would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival of any individuals.

Altogether, any individual dolphin is likely to be taken at a low to occasionally moderate level, with many animals likely not taken at all and with a subset of animals being taken up to a few times. A very small number could potentially experience tissue damage that could curtail reproduction for one year. Even given the fact that some of the affected individuals may have compromised health, there is nothing to suggest that such a low magnitude and severity of effects would result in impacts on annual rates of recruitment or survival for any of the GOMEX stocks indicated in Table 74. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on these GOMEX stocks of dolphins.

Harbor Porpoise—In this section, we build on the broader Odontocete discussion above (*i.e.,* that information applies to harbor porpoises as well), except where we offer alternative information about the received levels for harbor porpoise Level B behavioral harassment. We bring together the discussion of the different types and amounts of take that the stock will incur, the applicable mitigation for the stock, and the status of the stock to support the negligible impact determination. Harbor porpoises are not listed as endangered or threatened under the ESA. The discussion below focuses on additional information that is specific to harbor porpoises (in addition to the general information on odontocetes provided above, which is relevant to this species) to support the summarized conclusion for this stock. We have also described previously the unlikelihood of any masking or habitat impacts to harbor porpoises that would affect reproduction or survival.

In Table 75, below for porpoises, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance. Since the proposed rule, the Navy has removed one of its testing activities in the Northeast Range Complex (four events—USWT), which decreased the number of Level B harassment takes by approximately 10,000 takes annually for harbor porpoise.

Table 75. Annual takes of Level B and Level A harassment and mortality for porpoises in the AFTT Study Area and number indicating the instances of total take as a percentage of stock abundance.

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percentage of abundance	
		Level B Harassment		Level A Harassment								
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage	Mortality	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ
Family Phocoenidae (porpoises)												
Harbor porpoise	Gulf of Maine/Bay of Fundy	133,396	21917	454	0	0	155,767	155,767	16,552	195727	941	80

Note: Above we compare predicted takes to abundance estimates generated from the same underlying density estimate (as described in the *Estimated Take of Marine Mammals* section), versus abundance estimates directly from NMFS' SARs, which are not based on the same data and would not be appropriate for this purpose. Note that comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty and takes are notably greater) and across the whole Study Area (which offers a more comprehensive comparison for many stocks).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing plus take from one large ship shock trial.

Note that this paragraph provides specific information that is in lieu of the parallel information provided for odontocetes as a whole. The majority of takes by harassment of harbor porpoises in the AFTT Study Area are caused by sources from the MF1 active sonar bin (which includes hull-mounted sonar) because they are high level sources at a frequency (1–10 kHz), which overlaps a more sensitive portion (though not the most sensitive) of the HF hearing range, and of the sources expected to result in take, they are used in a large portion of exercises (see Table 1.5–5 in the Navy's rulemaking/LOA application). Most of the takes (88 percent) from the MF1 bin in the AFTT Study Area would result from received levels between 154 and 166 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF3 = 98 percent between 136 and 154, MF4 = 95 percent between 130 and 148, MF5 = 93 percent between 118 and 136, and HF4 = 96 percent between 118 and 148 dB SPL. These values may be derived from the information in Tables 6.4–8 through 6.4–12 in the Navy's rulemaking/LOA application (though they were provided directly to NMFS upon request).

Harbor porpoises have been shown to be particularly sensitive to human activity (Tyack *et al.,* 2011; Pirotta *et al.,* 2012). The information currently available regarding harbor porpoises suggests a very low threshold level of response for both captive (Kastelein *et al.,* 2000; Kastelein *et al.,* 2005) and wild (Johnston, 2002) animals. Southall *et al.* (2007) concluded that harbor porpoises are likely sensitive to a wide range of anthropogenic sounds at low received levels (approximately 90 to 120 dB). Research and observations of harbor porpoises for other locations show that this species is wary of human activity and will display profound avoidance behavior for anthropogenic sound sources in many situations at levels down to 120 dB re 1 µPa (Southall, 2007). Harbor porpoises routinely avoid and swim away from large motorized vessels (Barlow *et al.,* 1988; Evans *et al.,* 1994; Palka and Hammond, 2001; Polacheck and Thorpe, 1990). Harbor porpoises may startle and temporarily leave the immediate area of the training or testing until after the event ends. Accordingly, harbor porpoises have been assigned a lower Level B behavioral harassment threshold, *i.e.,* a more distant distance cutoff (40 km for high source level, 20 km for moderate source level) and, as a result, the number of harbor porpoise taken by Level B behavioral harassment through exposure to LFAS/MFAS/HFAS in the AFTT Study Area is generally higher than the other species. Given the levels they are exposed to and their sensitivity, some responses would be of a lower severity, but many would likely be considered moderate. As mentioned earlier in the odontocete overview, we anticipate more severe effects from takes when animals are exposed to higher received levels or sequential days of impacts; occasional low to moderate behavioral reactions are unlikely to affect reproduction or survival. Some takes by Level B behavioral harassment could be in the form of a longer (several hours or a day) and more moderate response, but unless they are repeated over more than several sequential days, impacts to reproduction or survival for most animals are not anticipated. Even where some smaller number of animals could experience effects on reproduction (which could happen to a small number), for the reasons explained below this would not affect rates of recruitment or survival, especially given the status of the stock.

A BIA was identified for this small and resident population of harbor porpoises by LaBrecque *et al.* (2015a, 2015b). The population straddles the Northern border of the U.S. EEZ and AFTT Study Area, with perhaps approximately half located inside the border (noting that BIAs were only identified within the U.S. EEZ, so the whole BIA is in the AFTT Study Area). Navy testing activities that use sonar and other transducers could occur year round within the Northeast Range Complexes in the vicinity of the BIA. However, the harbor porpoise BIA is included in the Gulf of Maine Planning Awareness Mitigation Area where the Navy will not plan MTEs (Composite Training Unit or Fleet/Sustainment Exercises) and will not conduct more than 200 hrs of hull-mounted MFAS per year, both of which reduce the likely severity of potential Level B harassment by behavioral disturbance (*e.g.,* it is less likely that harbor porpoises would be displaced from the preferred habitat in the BIA and thereby suffer effects more likely to impact reproduction or survival).

In conclusion, the Gulf of Maine/Bay of Fundy stock of harbor porpoise is found predominantly in northern U.S. coastal waters (<150 m depth) and up into Canada's Bay of Fundy. No mortality or tissue damage by explosives are anticipated or authorized for this stock and there are no specific issues with the status of the stock that cause particular concern (*e.g.,* UMEs). Regarding the magnitude of Level B

harassment takes (TTS and behavioral disruption), the number of estimated instances compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ, respectively, is 941 percent and 80 percent (Table 75). This information, combined with the known range of the stock, suggests that only a portion of the individuals in the stock are likely impacted (*i.e.,* notably less than 80 percent given the likely repeats; in other words more than 20 percent taken zero times), but that there would likely be some amount of repeat exposures across days (perhaps 6–19 days within a year) for some subset of individuals that spend extended times within the U.S. EEZ. Regarding the severity of those individual takes by Level B behavioral harassment, the duration of any exposure response is expected to be from minutes to hours and not likely exceeding 24 hrs, and the received sound levels of the MF1 bin are largely between 154 and 166 dB, which, for a harbor porpoise (which have a lower Level B behavioral harassment threshold) would mostly be considered a moderate level.

Regarding the severity of TTS takes, as described previously they are expected to be low-level, of short duration, and not in a frequency band that would be expected to significantly interfere with harbor porpoise communication, or echolocation or other important low-frequency cues. Therefore, the associated lost opportunities and capabilities would not be expected to impact reproduction or survival. For these same reasons (low level and the likely frequency band), while a small permanent loss of hearing sensitivity may include some degree of energetic costs for compensating or may mean some small loss of opportunities or detection capabilities, the estimated 454 Level A harassment takes by PTS for harbor porpoise would be unlikely to impact behaviors, opportunities, or detection capabilities to a degree that would interfere with reproductive success or survival for most individuals. Because of the high number of PTS takes, we acknowledge that a few animals could potentially incur permanent hearing loss of a higher degree that could potentially interfere with their successful reproduction and growth. However, given the status of the stock, even if this occurred, it would not adversely impact rates of recruitment or survival.

Altogether, because harbor porpoises are particularly sensitive, it is likely that a fair number of the responses will be of a moderate nature. Additionally, as noted, some portion of the stock may be taken repeatedly on up to 19 days within a year, some of those may be sequential. Given this and the larger number of total takes (totally and to individuals), it is more likely (probabilistically) that some small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year (energetic impacts to males are generally meaningless to population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal). As noted previously, however, foregone reproduction (especially for one year) has far less of an impact on population rates than mortality and a small number of instances would not be expected to adversely impact annual rates of recruitment or survival, especially given that the residual PBR of harbor porpoises is 451 (and a one year delay in calving has a far less severe impact on population rates than death, and this stock could absorb more than 400 deaths without inhibiting its ability to approach OSP). All indications are that the number of times in which reproduction would be likely to be foregone will not affect the stock's annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on harbor porpoises.

Beaked Whales—In this section, we build on the broader Odontocete discussion above (*i.e.,* that information applies to beaked whales as well), except where we offer alternative information about the received levels for beaked whale Level B behavioral harassment. We bring together the discussion of the different types and amounts of take that different stocks will incur, the applicable mitigation for each stock, and the status of the stocks to support the negligible impact determinations for each stock. None of these species are listed as endangered or threatened under the ESA. For beaked whales, there is no predicted mortality or tissue damage from explosives for any stock. Broadly, we have also described the unlikelihood of any masking or habitat impacts to any groups that would rise to the level of affecting individual fitness. The discussion below focuses on additional information that is specific to beaked whales (in addition to the general information on odontocetes provided above, which is relevant to these species) to support the summarized conclusion for this stock. Because there are differential magnitudes of effect to the GOMEX stocks of beaked whales (lower magnitude of Level B harassment, but also lingering effects from the DWH oil spill) versus the Western North Atlantic beaked whales, we break out specific findings into those two groups.

In Table 76 below, for beaked whales, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

Table 76. Annual takes of Level B and Level A harassment and mortality for beaked whales in the AFTT Study Area and number indicating the instances of total take as a percentage of stock abundance.

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percentage of abundance	
		Level B Harassment		Level A Harassment								
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage	Mortality	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ
Suborder Odontoceti (toothed whales)												
Family Ziphiidae (beaked whales)												
Blainville's beaked whale	Northern Gulf of Mexico	1,420	8	0	0	0	1,428	1,428	966	966	148	148
	Western North Atlantic	22,902	197	1	0	0	19,959	23,100	1,274	14,277	1567	162
Cuvier's beaked whale	Northern Gulf of Mexico	1,487	8	0	0	0	1,495	1,495	966	966	155	155
	Western North Atlantic	84,460	724	3	0	0	73,799	85,187	4,704	52,716	1569	162
Gervais' beaked whale	Northern Gulf of Mexico	1,420	8	0	0	0	1,428	1,428	966	966	148	148
	Western North Atlantic	22,902	197	1	0	0	19,959	23,100	1,274	14,277	1567	162
Northern bottlenose whale	Western North Atlantic	2,040	4	0		0	1,836	2,044	100	688	1836	297
Sowersby's beaked whale	Western North Atlantic	22,930	197	1	0	0	19,987	23,128	1,274	14,277	1569	162
True's beaked whale	Western North Atlantic	22,930	197	1	0	0	19,987	23,128	1,274	14,277	1569	162

Note: Above we compare predicted takes to abundance estimates generated from the same underlying density estimate (as described in the *Estimated Take of Marine Mammals* section), versus abundance estimates directly from NMFS' SARs, which are not based on the same data and would not be appropriate for this purpose. Note that comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty and takes are notably greater) and across the whole Study Area (which offers a more comprehensive comparison for many stocks).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing plus take from one large ship shock trial.

Note that this first paragraph provides specific information that is in lieu of the parallel information provided for odontocetes as a whole. The majority of takes by harassment of beaked whales in the AFTT Study Area are caused by sources from the MF1 active sonar bin (which includes hull-mounted sonar) because they are high level sources at a frequency (1–10 kHz), which overlaps a more sensitive portion (though not the most sensitive) of the MF hearing range, and of the sources expected to result in take, they are used in a large portion of exercises (see Table 1.5–5 in the Navy's rulemaking/LOA application). Most of the takes (91 percent) from the MF1 bin in the AFTT Study Area would result from received levels between 148 and 160 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF3 = 94 percent between 136 and 148, MF4 = 96 percent between 124 and 148, MF5 = 96 percent between 100 and 142, and HF4 = 94 percent between 100 and 148 dB SPL. These values may be derived from the information in Tables 6.4–8 through 6.4–12 in the Navy's rulemaking/LOA application (though they were provided directly to NMFS upon request). Given the levels they are exposed to and their sensitivity, some responses would be of a lower severity, but many would likely be considered moderate.

As is the case with harbor porpoises, research has shown that beaked whales are especially sensitive to the presence of human activity (Tyack *et al.,* 2011; Pirotta *et al.,* 2012) and therefore have been assigned a lower harassment threshold, *i.e.,* a more distant distance cutoff (50 km for high source level, 25 km for moderate source level). Given the levels they are exposed to and their sensitivity, some responses would be of a lower severity, but many would likely be considered moderate.

Beaked whales have been documented to exhibit avoidance of human activity or respond to vessel presence (Pirotta *et al.,* 2012). Beaked whales were observed to react negatively to survey vessels or low altitude aircraft by quick diving and other avoidance maneuvers, and none were observed to approach vessels (Wursig *et al.,* 1998). It has been speculated for some time that beaked whales might have unusual sensitivities to sonar sound due to their likelihood of stranding in conjunction with MFAS use. Research and observations show that if beaked whales are exposed to sonar or other active acoustic sources they may startle, break off feeding dives, and avoid the area of the sound source to levels of 157 dB re 1 µPa, or below (McCarthy *et al.,* 2011). Acoustic monitoring during actual sonar exercises revealed some beaked whales continuing to forage at levels up to 157 dB re 1 µPa (Tyack *et al.* 2011). Stimpert *et al.* (2014) tagged a Baird's beaked whale, which was subsequently exposed to simulated MFAS. Changes in the animal's dive behavior and locomotion were observed when received level reached 127 dB re 1µPa. However, Manzano-Roth *et al.* (2013) found that for beaked whale dives that continued to occur during MFAS activity, differences from normal dive profiles and click rates were not detected with estimated received levels up to 137 dB re 1 µPa while the animals were at depth during their dives. And in research done at the Navy's fixed tracking range in the Bahamas, animals were observed to leave the immediate area of the anti-submarine warfare training exercise (avoiding the sonar acoustic footprint at a distance where the received level was ''around 140 dB'' SPL, according to Tyack *et al.* (2011)) but return within a few days after the event ended (Claridge and Durban, 2009; Moretti *et al.,* 2009, 2010; Tyack *et al.,* 2010, 2011; McCarthy *et al.,* 2011). Tyack *et al.* (2011) report that, in reaction to sonar playbacks, most beaked whales stopped echolocating, made long slow ascent to the surface, and moved away from the sound. A similar behavioral response study conducted in Southern California waters during the 2010–2011 field season found that Cuvier's beaked whales exposed to MFAS displayed behavior ranging from initial orientation changes to avoidance responses characterized by energetic fluking and swimming away from the source (DeRuiter *et al.,* 2013b). However, the authors did not detect similar responses to incidental exposure to distant naval sonar exercises at comparable received levels, indicating

that context of the exposures (*e.g.,* source proximity, controlled source ramp-up) may have been a significant factor. The study itself found the results inconclusive and meriting further investigation. Populations of beaked whales and other odontocetes on the Bahamas and other Navy fixed ranges, where Navy activities have been operating for decades, appear to be stable. Take by Level B behavioral harassment (most likely avoidance of the area of Navy activity) seem likely in most cases if beaked whales are exposed to anti-submarine sonar within a few tens of kilometers, especially for prolonged periods (a few hours or more) since this is one of the most sensitive marine mammal groups to anthropogenic sound of any species or group studied to date and research indicates beaked whales will leave an area where anthropogenic sound is present (Tyack *et al.,* 2011; De Ruiter *et al.,* 2013; Manzano-Roth *et al.,* 2013; Moretti *et al.,* 2014). Research involving tagged Cuvier's beaked whales in the SOCAL Range Complex reported on by Falcone and Schorr (2012, 2014) indicates year-round prolonged use of the Navy's training and testing area by these beaked whales and has documented movements in excess of hundreds of kilometers by some of those animals. Given that some of these animals may routinely move hundreds of kilometers as part of their normal pattern, leaving an area where sonar or other anthropogenic sound is present may have little, if any, cost to such an animal. Photo identification studies in the SOCAL Range Complex, have identified approximately 100 individual Cuvier's beaked whale individuals with 40 percent having been seen in one or more prior years, with re-sightings up to seven years apart (Falcone and Schorr, 2014). These results indicate long-term residency by individuals in an intensively used Navy training and testing area, which may also suggest a lack of adverse impact on rates of recruitment and survival in the areas a result of exposure to Navy's training and testing activities. Finally, results from passive acoustic monitoring estimated regional Cuvier's beaked whale densities were higher than indicated by NMFS' broad scale visual surveys for the U.S. West Coast (Hildebrand and McDonald, 2009).

As mentioned earlier in the odontocete overview, we anticipate more severe effects from takes when animals are exposed to higher received levels or sequential days of impacts. Occasional instances of take by Level B behavioral harassment of a low to moderate severity are unlikely to affect reproduction or survival. Here, some small number of takes by Level B behavioral harassment could be in the form of a longer (several hours or a day) and more moderate response, and/or some small number could be repeated over more than several sequential days. Impacts to reproduction could be possible for some small number of individuals, but given the information presented regarding beaked whale movement patterns, their return to areas within hours to a few days after a disturbance, and their continued presence and abundance in the area of instrumented Navy ranges, these impacts seem somewhat less likely. Nonetheless, even where some smaller number of animals could experience effects on reproduction, they would not be expected to adversely affect rates of recruitment or survival.

Below we synthesize and summarize the information that supports our determination that the Navy's activities will not adversely impact recruitment or survival for any of the affected stocks addressed in this section:

Beaked whales (Western North Atlantic stocks)—These stocks span the deeper waters of the East Coast north to Canada and out into oceanic waters beyond the U.S. EEZ. There is no currently reported trend for these populations and there are no specific issues with the status of the stocks that cause particular concern. Neither mortality nor tissue damage from explosives is anticipated or authorized for these stocks. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance within the U.S. EEZ and both in and outside of the U.S. EEZ is 1567–1836 percent and 148–297 percent, respectively (Table 76). This information, combined with the known range of the stock, suggests that while not all of the individuals in these stocks will most likely be taken (because they span well into oceanic waters), of those that are, most will be taken over a few days (though likely not sequential) and some subset that spends extended time within the U.S. EEZ will likely be taken over a larger amount of days (maybe 15–37) some of which could be sequential. Regarding the severity of those individual takes by Level B behavioral harassment, we have explained that the duration of any exposure response is expected to generally be between minutes and hours and largely between 148 and 160 dB, though with beaked whales, which are considered somewhat more sensitive, this could mean that some individuals will leave preferred habitat for a day or two. However, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity in the Western North Atlantic.

Regarding the severity of TTS takes, as described previously they are expected to be low-level, of short duration, and not in a frequency band that would adversely affect communication, inhibit echolocation, or otherwise interfere with other low frequency cues. Therefore any associated lost opportunities and capabilities would not impact reproduction or survival. For the same reasons (low level and frequency band) the one to three estimated Level A harassment takes by PTS for these stocks are unlikely to have any effects on the reproduction or survival of any individuals.

Altogether, a small portion of the stock will likely be taken (at a relatively moderate level) on a relatively moderate to high number of days across the year, some of which could be sequential. Though the majority of impacts are expected to be of a sometimes low, but more likely, moderate magnitude and severity, the sensitivity of beaked whales and larger number of takes makes it more likely (probabilistically) that a small number of individuals could be interrupted during foraging in a manner and amount such that impacts to the energy budgets of females (from either losing feeding opportunities or expending considerable energy to find alternative feeding options) could cause them to forego reproduction for a year (energetic impacts to males are generally meaningless to population rates unless they cause death, and it takes extreme energy deficits beyond what would ever be likely to result from these activities to cause the death of an adult marine mammal). As noted previously, however, foregone reproduction (especially for one year) has far less of an impact on population rates than mortality and a small number of instances would not be expected to adversely impact annual rates of recruitment or survival. Based on the abundance of these stocks in the area and the evidence of little, if any, known human-caused mortality, all indications here are that the small number of times in which reproduction would be likely to be foregone will not affect the stock's annual rates of recruitment or survival. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible

impact on the Western North Atlantic stocks of beaked whales.

Beaked whales (GOMEX stocks)—The animals in these stocks suffer from lingering health issues resulting from the DWH oil spill (four percent of individuals of these stocks have adverse health effects), which means that some of them could be more susceptible to exposure to other stressors, and negative population effects (10 years for their growth rate to recover to the rate predicted for the stock if it had not incurred spill impacts). Neither mortality nor tissue damage from explosives is anticipated or authorized for these stocks. Level A harassment take from PTS is also unlikely to occur. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance is 148–155 percent (Table 76). This information indicates that either the individuals in these stocks are all taken by harassment one or two days within a year, or that a subset are not taken at all and a small subset may be taken several times. Regarding the severity of those individual takes, we have explained that the duration of any exposure response is expected to generally be between minutes and hours and largely between 148 and 160 dB, though with beaked whales, which are considered somewhat more sensitive, this could mean that some individuals will leave preferred habitat for a day or two. However, while interrupted feeding bouts are a known response and concern for odontocetes, we also know that there are often viable alternative habitat options in the relative vicinity in the GOMEX. Regarding the severity of TTS takes, as described previously they are expected to be low-level, of short duration, and not in a frequency band that would adversely affect communication, inhibit echolocation, or otherwise interfere with other low frequency cues. Therefore any associated lost opportunities and capabilities would not impact reproduction or survival.

Altogether, likely only a portion of these stocks are impacted and any individual beaked whale is likely being disturbed moderate level no more than a few days per year. Even given the fact that some of the affected individuals may have compromised health, there is nothing to suggest that this magnitude and severity of effects would result in impacts on annual rates of recruitment or survival for any of the stocks. For these reasons, we have determined, in consideration of all of the effects of the Navy's activities combined, that the authorized take will have a negligible impact on the GOMEX stocks of beaked whales included in Table 76.

Pinnipeds

In this section, we build on the broader discussion above and bring together the discussion of the different types and amounts of take that different stocks will incur, the applicable mitigation for each stock, and the status of the stocks to support the negligible impact determinations for each stock. None of these species are listed as endangered or threatened under the ESA. For pinnipeds, there is no predicted mortality or tissue damage from explosives for any stock. Broadly, we have already described above why we believe the incremental addition of the small number of low-level PTS takes in predominantly narrow frequency bands will not have any meaningful effect towards inhibiting reproduction or survival. We have also described the unlikelihood of any masking or habitat impacts to any groups that would rise to the level of affecting individual fitness. Much of the discussion below focuses on the behavioral effects. A UME has been designated for harbor seals and gray seals, which is addressed below, but because of the small magnitude and severity of effects for all of the species, it is not necessary to break out the findings by species or stock.

In Table 77 below for pinnipeds, we indicate the total annual mortality, Level A and Level B harassment, and a number indicating the instances of total take as a percentage of abundance.

Table 77: Annual takes of Level B and Level A harassment and mortality for pinnipeds in the AFTT Study Area and number indicating the instances of total take as a percentage of stock abundance.

		Instances of indicated types of incidental take (not all takes represent separate individuals, especially for disturbance)					Total takes		Abundance		Instances of total take as percentage of abundance	
		Level B Harassment		Level A Harassment								
Species	Stock	Behavioral Disturbance	TTS (may also include disturbance)	PTS	Tissue Damage	Mortality	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ	In EEZ	Inside and Outside EEZ
Suborder Pinnipedia												
Family Phocidae (true seals)												
Gray seal	Western North Atlantic	810	1,528	2	0	0	2,340	2,340	2,472	2,472	95	95
Harbor seal	Western North Atlantic	1,312	2,477	4	0	0	3,793	3,793	11,122	11,122	34	34
Harp seal	Western North Atlantic	6,339	9,955	3	0	0	16,297	16,297	7,242	7,242	225	225
Hooded seal	Western North Atlantic	448	466	0	0	0	914	914	880	880	104	104

Note: Above we compare predicted takes to abundance estimates generated from the same underlying density estimate (as described in the *Estimated Take of Marine Mammals* section), versus abundance estimates directly from NMFS' SARs, which are not based on the same data and would not be appropriate for this purpose. Note that comparisons are made both within the U.S. EEZ only (where density estimates have lesser uncertainty and takes are notably greater) and across the whole Study Area (which offers a more comprehensive comparison for many stocks).

Total takes inside and outside U.S. EEZ represent the sum of annual Level A and Level B harassment from training and testing plus take from one large ship shock trial.

The majority of takes by harassment of pinnipeds in the AFTT Study Area are caused by sources from the MF1 active sonar bin (which includes hull-mounted sonar) because they are high level sources at a frequency (1–10 kHz), which overlaps the most sensitive portion of the pinniped hearing range, and of the sources expected to result in take, they are used in a large portion of exercises (see Table 1.5–5 in the Navy's rulemaking/LOA application). Most of the takes (76 percent) from the MF1 bin in the AFTT Study Area would result from received levels between 166 and 172 dB SPL, while another 23 percent would result from exposure between 172 and 178 dB SPL. For the remaining active sonar bin types, the percentages are as follows: LF3 = 97 percent between 148 and 166, MF4 = 97 percent between 142 and 166, MF5 = 97 percent between 130 and 160, and HF4 = 96 percent between 118 and 166 dB SPL. These values may be derived from the information in Tables 6.4–8 through 6.4–12 in the Navy's rulemaking/LOA application (though they were provided directly to NMFS upon request). Exposures at these levels would be considered of low to occasionally moderate severity. As mentioned earlier in this section, we anticipate more severe effects from takes when animals are exposed to higher received levels. Occasional milder takes by Level B behavioral harassment are unlikely to cause long-term consequences for individual animals or populations, especially when they are not expected to be repeated over sequential multiple days. For all pinnipeds, harassment takes from explosives (behavioral, TTS, or PTS if present) comprise a very small fraction of those caused by exposure to active sonar. No take of pinnipeds is expected to result from pile driving, and take from exposure to airguns is limited to single digits of gray and harbor seals.

Because the majority of harassment take of pinnnipeds results from the sources in the MF1 bin (1–10 kHz), the vast majority of threshold shift caused by Navy sonar sources will typically occur in the range of 2–20 kHz. This frequency range falls within the range of pinniped hearing, however, odontocete vocalizations typically span a somewhat lower range than this (<0.2 to 10 kHz) and threshold shift from active sonar will often be in a narrower band (reflecting the narrower band source that caused it), which means that TTS incurred by pinnipeds would typically only interfere with communication within a portion of an pinniped's range (if it occurred during a time when communication with conspecifics was occurring). As discussed earlier, it would only be expected to be of a short duration and relatively small degree. Many of the other critical sounds that serve as cues for navigation and prey (*e.g.,* waves, fish, invertebrates) occur below a few kHz, which means that detection of these signals will not be inhibited by most threshold shift either. The very low number of takes by threshold shifts that might be incurred by individuals exposed to explosives or airguns would likely be lower frequency (5 kHz or less) and spanning a wider frequency range, which could slightly lower an individual's sensitivity to navigational or prey cues, or a small portion of communication calls, for several minutes to hours (if temporary) or permanently.

Regarding behavioral disturbance, research and observations show that pinnipeds in the water may be tolerant of anthropogenic noise and activity (a review of behavioral reactions by pinnipeds to impulsive and non-impulsive noise can be found in Richardson *et al.,* 1995 and Southall *et al.,* 2007). Available data, though limited, suggest that exposures between approximately 90 and 140 dB SPL do not appear to induce strong behavioral responses in pinnipeds exposed to non-pulse sounds in water (Jacobs and Terhune, 2002; Costa *et al.,* 2003; Kastelein *et al.,* 2006c). Based on the limited data on pinnipeds in the water exposed to multiple pulses (small explosives, impact pile driving, and seismic sources), exposures in the approximately 150 to 180 dB SPL range generally have limited potential to induce avoidance behavior in pinnipeds (Harris *et al.,* 2001; Blackwell *et al.,* 2004; Miller *et al.,* 2004). If pinnipeds are exposed to sonar or other active acoustic sources they may react in a number of ways depending on their experience with the sound source and what activity they are engaged in at the time of the acoustic exposure. Pinnipeds may not react at all until the sound source is approaching within a few hundred meters and then may alert, ignore the stimulus, change their behaviors, or avoid the immediate area by swimming away or diving. Effects on pinnipeds in the AFTT Study Area that are taken by Level B harassment, on the basis of reports in the literature as well as Navy monitoring from past activities, will likely be limited to reactions such as increased swimming speeds, increased surfacing time, or decreased foraging (if such activity were occurring). Most likely, individuals will simply move away from the sound source and be temporarily displaced from those areas, or not respond at all, which would have no effect on reproduction or survival. In areas of repeated and frequent acoustic disturbance, some animals may habituate or learn to tolerate the new baseline or fluctuations in noise level. Habituation can occur when an animal's response to a stimulus wanes with repeated exposure, usually in the absence of unpleasant associated events (Wartzok *et al.,* 2003). While some animals may not return to an area, or may begin using an area differently due to training and testing activities, most animals are expected to return to their usual locations and behavior. Given their documented tolerance of anthropogenic sound (Richardson *et al.,* 1995 and Southall *et al.,* 2007), repeated exposures of individuals of any of these species to levels of sound that may cause Level B harassment are unlikely to result in hearing impairment or to significantly disrupt foraging behavior.

Thus, even repeated Level B harassment of some small subset of an overall stock is unlikely to result in any significant realized decrease in fitness to those individuals that would result in any adverse impact on rates of recruitment or survival for the stock as a whole. Evidence from areas where the Navy extensively trains and tests provides some indication of the possible consequences resulting from those planned activities. Specifically, almost all of the impacts to pinnipeds estimated by the quantitative assessment are due to navigation and object avoidance (detection) activities in navigation lanes entering Groton, Connecticut. Navigation and object avoidance (detection) activities normally involve a single ship or submarine using a limited amount of sonar, therefore significant reactions are unlikely, especially in phocid seals. The use of sonar from navigation and object avoidance in Groton, Connecticut likely exposes the same sub-population of animals multiple times throughout the year. However, phocid seals are likely to have only minor and short-term behavioral reactions to these types of activities and significant behavioral reactions leading to impacts on reproduction or survival would not be expected, even if some smaller groups were repeatedly taken. Below we synthesize and summarize the information that supports our determination that the Navy's activities will not adversely impact recruitment or survival for any of the affected species and stocks addressed in this section.

In conclusion, the Western North Atlantic pinnipeds (harp seal, harbor seal, hooded seal, and gray seal) stocks

are northern, but highly migratory species. While harp seals are limited to the northern portion of the U.S. EEZ, gray and harbor seals may be found as far south as the Chesapeake in late Fall and hooded seals migrate as far south as Puerto Rico. A UME has been designated for gray seals and harbor seals and the main pathogen found on the seals that have been tested is phocine distemper virus. Neither mortality nor tissue damage from explosives is anticipated or authorized for any of these stocks. Regarding the magnitude of Level B harassment takes (TTS and behavioral disruption), the number of estimated instances of harassment compared to the abundance that is expected within the AFTT Study area is 34–225 percent, which suggests that only a subset of the animals in the AFTT Study area would be taken, but that a few might be taken on several days within the year (1–5), but not on sequential days. When the fact that some of these seals are residing in areas near Navy activities is considered, we can estimate that perhaps some of those individuals might be taken some higher number of days within the year (up to approximately 10), but still with no reason to think that these takes would occur on sequential days, which means that we would not expect effects on reproduction or survival. Regarding the severity of those individual Level B behavioral harassment takes, we have explained that the duration of any exposure response is expected to be between minutes and hours *(i.e.,* relatively short) and the received sound levels are largely below 172 dB, with some up to 178 dB (*i.e.,* of a lower to moderate level, less likely to evoke a severe response) and therefore there is no indication that the expected takes by Level B behavioral harassment would have any effect on annual rates of recruitment or survival.

Regarding the severity of TTS takes, they are expected to be low-level, of short duration, and not in a frequency band that would adversely affect communication, inhibit echolocation, or otherwise interfere with other low frequency cues. Therefore any associated lost opportunities and capabilities would not impact reproduction or survival. For the same reasons (low level and frequency band) the two to four estimated Level A harassment takes by PTS for these stocks are unlikely to have any effects on the reproduction or survival of any individuals.

Even given the fact that some of the affected harbor seal individuals may have compromised health due to the UME, there is nothing to suggest that such a low magnitude and severity of effects would result in impacts on annual rates of recruitment or survival, especially given that the stock abundance in NMFS SAR is 75,839 with a residual PBR of 1,651. Similarly, given the low magnitude and severity of effects, there is no indication that these activities would affect reproduction or survival of harp or hooded seals, much less adversely affect rates of recruitment or survival, especially given that harp seal abundance is estimated at 6.9 million and hooded seal residual PBR is 13,950. Gray seals are experiencing a UME as well as an exceedance of more than 4,299 M/SI above PBR. However, given the low magnitude (take compared to abundance is 95 percent, meaning the subset of individuals taken may be taken a few times on non-sequential days) and low to occasionally moderate severity of impacts, no impacts to individual reproduction or survival are expected, and therefore no effects on annual rates of recruitment or survival will occur. For these reasons, in consideration of all of the effects of the Navy's activities combined, we have determined that the authorized take will have a negligible impact on the Western North Atlantic stocks of gray seals, harbor seals, hooded seals, and harp seals.

Determination

Based on the analysis contained herein of the potential and likely effects of the specified activities 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 specified activities will have a negligible impact on all affected marine mammal species and stocks.

Subsistence Harvest of Marine Mammals

There are no subsistence uses or harvest of marine mammals in the geographic area affected by the specified activities. Therefore, NMFS has determined that the total taking affecting species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

ESA

There are five marine mammal species under NMFS jurisdiction that are listed as endangered or threatened under the ESA with confirmed or possible occurrence in the AFTT Study Area: Blue whale (Western North Atlantic stock), fin whale (Western North Atlantic stock), sei whale (Nova Scotia), sperm whale (GOMEX Oceanic stock and North Atlantic stock), and NARW (Western North Atlantic stock). In addition, the GOMEX Bryde's whale is proposed for listing under the ESA. The Navy consulted with NMFS pursuant to section 7 of the ESA, and NMFS also consulted internally on the issuance of these regulations and LOAs under section 101(a)(5)(A) of the MMPA for AFTT activities. NMFS issued a Biological and Conference Opinion concluding that the issuance of the rule and subsequent LOAs are likely to adversely affect, but are not likely to jeopardize, the continued existence of the threatened and endangered species under NMFS' jurisdiction and are not likely to result in the destruction or adverse modification of critical habitat in the AFTT Study Area. The Biological and Conference Opinion for this action is available at *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

National Marine Sanctuaries Act

Federal agency actions that are likely to injure national marine sanctuary resources are subject to consultation with the Office of National Marine Sanctuaries (ONMS) under section 304(d) of the National Marine Sanctuaries Act (NMSA).

On December 15, 2017, the Navy initiated consultation with ONMS and submitted a Sanctuary Resource Statement (SRS) that discussed the effects of the U.S. Navy's AFTT activities in the vicinity of Stellwagen Bank, Gray's Reef, and Florida Keys National Marine Sanctuaries on sanctuary resources. NMFS worked with the Navy in the development of the SRS to ensure that it could serve jointly as an SRS for NMFS' action as well.

On December 20, 2017, NMFS OPR initiated consultation with ONMS on NMFS' proposed MMPA Incidental Take Regulations for the Navy's AFTT activities. NMFS requested that ONMS consider the description and assessment of the effects of the Navy's activities, which included an assessment of the effects on marine mammals, included in the joint SRS submitted by the Navy as satisfying NMFS' need to provide an SRS.

ONMS reviewed the SRS, as well as an addendum the Navy provided on April 3, 2018. On April 12, 2018, ONMS found the SRS addendum sufficient for the purposes of making an injury determination to develop recommended alternatives as required by the NMSA. On May 15, 2018, ONMS recommended two reasonable and prudent measures to

Navy and NMFS (one of which applied to NMFS) in accordance with the NMSA to minimize injury and to protect sanctuary resources. ONMS subsequently provided a slight modification of those recommendations to the Navy and NMFS on August 1, 2018.

On August 17, 2018, the Navy agreed to implement both ONMS recommendations. On October 30, 2018, NMFS agreed to implement the recommendation that applied to NMFS, thus concluding our consultation with ONMS.

NEPA

NMFS participated as a cooperating agency on the AFTT FEIS/OEIS, which was published on September 14, 2018, and is available at *http://www.aftteis.com.* In accordance with 40 CFR 1506.3, NMFS independently reviewed and evaluated the AFTT FEIS/OEIS and determined that it is adequate and sufficient to meet our responsibilities under NEPA for the issuance of this rule and associated LOAs. NOAA therefore adopted the Navy's AFTT FEIS/OEIS. NMFS has prepared a separate Record of Decision. NMFS' Record of Decision for adoption of the AFTT FEIS/OEIS and issuance of this final rule and subsequent LOAs can be found at: *https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

Classification

The Office of Management and Budget has determined that this final rule is not significant for purposes of Executive Order 12866.

Pursuant to the Regulatory Flexibility Act (RFA), the Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this final rule will not have a significant economic impact on a substantial number of small entities. The RFA requires Federal agencies to prepare an analysis of a rule's impact on small entities whenever the agency is required to publish a notice of proposed rulemaking. However, a Federal agency may certify, pursuant to 5 U.S.C. 605(b), that the action will not have a significant economic impact on a substantial number of small entities. The Navy is the sole entity that will be affected by this rulemaking, and the Navy is not a small governmental jurisdiction, small organization, or small business, as defined by the RFA. Any requirements imposed by an LOA issued pursuant to these regulations, and any monitoring or reporting requirements imposed by these regulations, are applicable only to the Navy. NMFS does not expect the issuance of these regulations or the associated LOAs to result in any impacts to small entities pursuant to the RFA. Because this action will directly affect the Navy and not a small entity, NMFS concludes the action will not result in a significant economic impact on a substantial number of small entities.

Waiver of Delay in Effective Date

NMFS has determined that there is good cause under the Administrative Procedure Act (5 U.S.C 553(d)(3)) to waive the 30-day delay in the effective date of this final rule. No individual or entity other than the Navy is affected by the provisions of these regulations. The Navy has informed NMFS that it requests that this final rule take effect by November 14, 2018, to accommodate the Navy's current Letters of Authorization expiring November 13, 2018, so as to not cause a disruption in training and testing activities. NMFS was unable to accommodate the 30-day delay of effectiveness period due to the need for additional time to consider additional mitigation measures presented by the Navy as well as new analysis of information showing that incidental mortality and serious injury of two stocks previously analyzed is unlikely to occur. The waiver of the 30-day delay of the effective date of the final rule will ensure that the MMPA final rule and Letters of Authorization are in place by the time the previous authorizations expire. Any delay in finalizing the rule would result in either: (1) A suspension of planned naval training and testing, which would disrupt vital training and testing essential to national security; or (2) the Navy's procedural non-compliance with the MMPA (should the Navy conduct training and testing without LOAs), thereby resulting in the potential for unauthorized takes of marine mammals. Moreover, the Navy is ready to implement the rule immediately. For these reasons, NMFS finds good cause to waive the 30-day delay in the effective date. In addition, the rule authorizes incidental take of marine mammals that would otherwise be prohibited under the statute. Therefore the rule is granting an exception to the Navy and relieving restrictions under the MMPA, which is a separate basis for waiving the 30-day effective date for the rule.

List of Subjects in 50 CFR Part 218

Exports, Fish, Imports, Incidental take, Indians, Labeling, Marine mammals, Navy, Penalties, Reporting and recordkeeping requirements, Seafood, Sonar, Transportation.

Dated: October 30, 2018.

Samuel D. Rauch III,

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

For reasons set forth in the preamble, 50 CFR part 218 is amended as follows:

PART 218—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

■ 1. The authority citation for part 218 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.,* unless otherwise noted.

■ 2. Revise subpart I of part 218 to read as follows:

Subpart I—Taking and Importing Marine Mammals; U.S. Navy's Atlantic Fleet Training and Testing (AFTT)

Sec.

Subpart I—Taking and Importing Marine Mammals; U.S. Navy's Atlantic Fleet Training and Testing (AFTT)

§ 218.80 Specified activity and specified geographical region.

(a) Regulations in this subpart apply only to the U.S. Navy for the taking of marine mammals that occurs in the area described in paragraph (b) of this section and that occurs incidental to the activities listed in paragraph (c) of this section.

(b) The taking of marine mammals by the Navy under this subpart may be authorized in Letters of Authorization (LOAs) only if it occurs within the Atlantic Fleet Training and Testing (AFTT) Study Area, which includes areas of the western Atlantic Ocean along the East Coast of North America, portions of the Caribbean Sea, and the Gulf of Mexico. The AFTT Study Area begins at the mean high tide line along the U.S. East Coast and extends east to the 45-degree west longitude line, north to the 65-degree north latitude line, and south to approximately the 20-degree

north latitude line. The AFTT Study Area also includes Navy pierside locations, bays, harbors, and inland waterways, and civilian ports where training and testing occurs.

(c) The taking of marine mammals by the Navy is only authorized if it occurs incidental to the Navy conducting training and testing activities, including:

(1) *Training.* (i) Amphibious warfare.

(ii) Anti-submarine warfare.

(iii) Electronic warfare.

(iv) Expeditionary warfare.

(v) Mine warfare.

(vi) Surface warfare.

(2) *Testing.* (i) Naval Air Systems Command Testing Activities.

(ii) Naval Sea System Command Testing Activities.

(iii) Office of Naval Research Testing Activities.

§ 218.81 Effective dates.

Regulations in this subpart are effective November 14, 2018 through November 13, 2023.

§ 218.82 Permissible methods of taking.

(a) Under LOAs issued pursuant to §§ 216.106 of this chapter and 218.86, the Holder of the LOAs (hereinafter ''Navy'') may incidentally, but not intentionally, take marine mammals within the area described in § 218.80(b) by Level A harassment and Level B harassment associated with the use of active sonar and other acoustic sources and explosives as well as serious injury or mortality associated with ship shock trials and vessel strikes provided the activity is in compliance with all terms, conditions, and requirements of these regulations in this subpart and the applicable LOAs.

(b) The incidental take of marine mammals by the activities listed in § 218.80(c) is limited to the following species:

TABLE 1 TO § 218.82

Species	Stock
Suborder Mysticeti (baleen whales)	
Family Balaenidae (right whales):	
North Atlantic right whale *	Western.
Family Balaenopteridae (roquals):	
Blue whale *	Western North Atlantic (Gulf of St. Lawrence)
Bryde's whale	Northern Gulf of Mexico.
	NSD.
Minke whale	Canadian East Coast.
Fin whale *	Western North Atlantic.
Humpback whale	Gulf of Maine.
Sei whale *	Nova Scotia.
Suborder Odontoceti (toothed whales)	
Family Physeteridae (sperm whale):	
Sperm whale *	Gulf of Mexico Oceanic.
	North Atlantic.
Family Kogiidae (sperm whales):	
Dwarf sperm whale	Gulf of Mexico Oceanic.
	Western North Atlantic.
Pygmy sperm whale	Northern Gulf of Mexico.
	Western North Atlantic.
Family Ziphiidae (beaked whales):	
Blainville's beaked whale	Northern Gulf of Mexico.
	Western North Atlantic.
Cuvier's beaked whale	Northern Gulf of Mexico.
	Western North Atlantic.
Gervais' beaked whale	Northern Gulf of Mexico.
	Western North Atlantic.
Northern bottlenose whale	Western North Atlantic.
Sowersby's beaked whale	Western North Atlantic.
True's beaked whale	Western North Atlantic.
Family Delphinidae (dolphins):	
Atlantic spotted dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
Atlantic white-sided dolphin	Western North Atlantic.
Bottlenose dolphin	Choctawhatchee Bay.
	Gulf of Mexico Eastern Coastal.
	Gulf of Mexico Northern Coastal.
	Gulf of Mexico Western Coastal.
	Indian River Lagoon Estuarine System.
	Jacksonville Estuarine System.
	Mississippi Sound, Lake Borgne, Bay Boudreau.
	Northern Gulf of Mexico Continental Shelf.
	Northern Gulf of Mexico Oceanic.
	Northern North Carolina Estuarine System.
	Southern North Carolina Estuarine System.
	Western North Atlantic Northern Florida Coastal.
	Western North Atlantic Central Florida Coastal.
	Western North Atlantic Northern Migratory Coastal.
	Western North Atlantic Offshore.
	Western North Atlantic South Carolina/Georgia Coastal.

TABLE 1 TO § 218.82—Continued

Species	Stock
	Western North Atlantic Southern Migratory Coastal.
Clymene dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
False killer whale	Northern Gulf of Mexico.
	Western North Atlantic.
Fraser's dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
Killer whale	Northern Gulf of Mexico.
	Western North Atlantic.
Long-finned pilot whale	Western North Atlantic.
Melon-headed whale	Northern Gulf of Mexico.
	Western North Atlantic.
Pantropical spotted dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
Pygmy killer whale	Northern Gulf of Mexico.
	Western North Atlantic.
Risso's dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
Rough-toothed dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
Short-beaked common dolphin	Western North Atlantic.
Short-finned pilot whale	Northern Gulf of Mexico.
	Western North Atlantic.
Spinner dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
Striped dolphin	Northern Gulf of Mexico.
	Western North Atlantic.
White-beaked dolphin	Western North Atlantic.
Family Phocoenidae (porpoises):	
Harbor porpoise	Gulf of Maine/Bay of Fundy.
Suborder Pinnipedia	
Family Phocidae (true seals):	
Gray seal	Western North Atlantic.
Harbor seal	Western North Atlantic.
Harp seal	Western North Atlantic.
Hooded seal	Western North Atlantic.

§ 218.83 Prohibitions.

Notwithstanding incidental takings contemplated in § 218.82(a) and authorized by LOAs issued under §§ 216.106 of this chapter and 218.86, no person in connection with the activities listed in § 218.80(c) may:

(a) Violate, or fail to comply with, the terms, conditions, and requirements of this subpart or an LOA issued under §§ 216.106 of this chapter and 218.86;

(b) Take any marine mammal not specified in § 218.82(b);

(c) Take any marine mammal specified § 218.82(b) in any manner other than as specified in the LOAs; or

(d) Take a marine mammal specified § 218.82(b) if NMFS determines such taking results in more than a negligible impact on the species or stocks of such marine mammal.

§ 218.84 Mitigation requirements.

When conducting the activities identified in § 218.80(c), the mitigation measures contained in any LOAs issued under §§ 216.106 of this chapter and 218.86 must be implemented. These mitigation measures include, but are not limited to:

(a) *Procedural mitigation.* Procedural mitigation is mitigation that the Navy must implement whenever and wherever an applicable training or testing activity takes place within the AFTT Study Area for each applicable activity category or stressor category and includes acoustic stressors (*i.e.,* active sonar, air guns, pile driving, weapons firing noise), explosive stressors (*i.e.,* sonobuoys, torpedoes, medium-caliber and large-caliber projectiles, missiles and rockets, bombs, sinking exercises, mines, anti-swimmer grenades, line charge testing and ship shock trials), and physical disturbance and strike stressors *(i.e.,* vessel movement, towed in-water devices, small-, medium-, and large-caliber non-explosive practice munitions, non-explosive missiles and rockets, non-explosive bombs and mine shapes).

(1) *Environmental awareness and education.* Appropriate personnel (including civilian personnel) involved in mitigation and training or testing activity reporting under the specified activities will complete one or more modules of the U.S. Navy Afloat Environmental Compliance Training Series, as identified in their career path training plan. Modules include: Introduction to the U.S. Navy Afloat Environmental Compliance Training Series, Marine Species Awareness Training, U.S. Navy Protective Measures Assessment Protocol, and U.S. Navy Sonar Positional Reporting System and Marine Mammal Incident Reporting.

(2) *Active sonar.* Active sonar includes low-frequency active sonar, mid-frequency active sonar, and high-frequency active sonar. For vessel-based active sonar activities, mitigation applies only to sources that are positively controlled and deployed from manned surface vessels (*e.g.,* sonar sources towed from manned surface platforms). For aircraft-based active sonar activities, mitigation applies only to sources that are positively controlled and deployed from manned aircraft that do not operate at high altitudes (*e.g.,* rotary-wing aircraft). Mitigation does

not apply to active sonar sources deployed from unmanned aircraft or aircraft operating at high altitudes (*e.g.,* maritime patrol aircraft).

(i) *Number of Lookouts and observation platform*—(A) *Hull-mounted sources.* One Lookout for platforms with space or manning restrictions while underway (at the forward part of a small boat or ship) and platforms using active sonar while moored or at anchor (including pierside); two Lookouts for platforms without space or manning restrictions while underway (at the forward part of the ship); and four Lookouts for pierside sonar testing activities at Port Canaveral, Florida and Kings Bay, Georgia.

(B) *Non-hull mounted sources.* One Lookout on the ship or aircraft conducting the activity.

(ii) *Mitigation zones and requirements.* During the activity, at 1,000 yard (yd) the Navy must power down 6 decibels (dB), at 500 yd the Navy must power down an additional 4 dB (for a total of 10 dB), and at 200 yd the Navy must shut down for low-frequency active sonar ≥200 dB and hull-mounted mid-frequency active sonar; or at 200 yd the Navy must shut down for low-frequency active sonar <200 dB, mid-frequency active sonar sources that are not hull-mounted, and high-frequency active sonar.

(A) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if observed, Navy personnel must relocate or delay the start of active sonar transmission.

(B) During low-frequency active sonar at or above 200 dB and hull-mounted mid-frequency active sonar, Navy personnel must observe the mitigation zone for marine mammals and power down active sonar transmission by 6 dB if observed within 1,000 yd of the sonar source; power down by an additional 4 dB (10 dB total) if observed within 500 yd of the sonar source; and cease transmission if observed within 200 yd of the sonar source.

(C) During low-frequency active sonar below 200 dB, mid-frequency active sonar sources that are not hull mounted, and high-frequency active sonar, Navy personnel must observe the mitigation zone for marine mammals and cease active sonar transmission if observed within 200 yd of the sonar source.

(D) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing or powering up active sonar transmission) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the sonar source; the mitigation zone has been clear from any additional sightings for 10 minutes (min) for aircraft-deployed sonar sources or 30 min for vessel-deployed sonar sources; for mobile activities, the active sonar source has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting; or for activities using hull-mounted sonar, the ship concludes that dolphins are deliberately closing in on the ship to ride the ship's bow wave, and are therefore out of the main transmission axis of the sonar (and there are no other marine mammal sightings within the mitigation zone).

(3) *Air guns*—(i) *Number of Lookouts and observation platform*. One Lookout must be positioned on a ship or pierside.

(ii) *Mitigation zone and requirements.* 150 yd around the air gun.

(A) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if observed, Navy personnel must relocate or delay the start of air gun use.

(B) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if observed, Navy personnel must cease use of air guns.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing air gun use) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the air gun; the mitigation zone has been clear from any additional sightings for 30 min; or for mobile activities, the air gun has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(4) *Pile driving.* Pile driving and pile extraction sound during Elevated Causeway System training.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on the shore, the elevated causeway, or a small boat.

(ii) *Mitigation zone and requirements.* 100 yd around the pile driver.

(A) Prior to the initial start of the activity (for 30 min), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if observed, Navy personnel must delay the start of pile driving or vibratory pile extraction.

(B) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if observed, Navy personnel must cease impact pile driving or vibratory pile extraction.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing pile driving or pile extraction) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the pile driving location; or the mitigation zone has been clear from any additional sightings for 30 min.

(5) *Weapons firing noise.* Weapons firing noise associated with large-caliber gunnery activities.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on the ship conducting the firing. Depending on the activity, the Lookout could be the same as the one provided for under ''Explosive medium-caliber and large-caliber projectiles'' or under ''Small-, medium-, and large-caliber non-explosive practice munitions'' in paragraphs (a)(8)(i) and (a)(19)(i) of this section.

(ii) *Mitigation zone and requirements.* Thirty degrees on either side of the firing line out to 70 yd from the muzzle of the weapon being fired.

(A) Prior to the initial start of the activity, Navy personnel must observe the mitigation zone for floating vegetation; if resources observed, relocate or delay the start until the mitigation zone is clear. Navy personnel

also must observe the mitigation zone for marine mammals; if observed, Navy personnel must relocate or delay the start of weapons firing.

(B) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if observed, Navy personnel must cease weapons firing.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing weapons firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the firing ship; the mitigation zone has been clear from any additional sightings for 30 min; or for mobile activities, the firing ship has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(6) *Explosive sonobuoys*—(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft or on small boat. If additional platforms are participating in the activity, personnel positioned in those assets (*e.g.,* safety observers, evaluators) will support observing the mitigation zone for applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 600 yd around an explosive sonobuoy.

(A) Prior to the initial start of the activity (*e.g.,* during deployment of a sonobuoy field, which typically lasts 20–30 min), Navy personnel must observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. Navy personnel must conduct passive acoustic monitoring for marine mammals and use information from detections to assist visual observations. Navy personnel also must visually observe the mitigation zone for marine mammals; if observed, Navy personnel must relocate or delay the start of sonobuoy or source/receiver pair detonations.

(B) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if observed, Navy personnel must cease sonobuoy or source/receiver pair detonations.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the sonobuoy; or the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints (*e.g.,* helicopter), or 30 min when the activity involves aircraft that are not typically fuel constrained.

(D) After completion of the activity (*e.g.,* prior to maneuvering off station), when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(7) *Explosive torpedoes*—(i) *Number of Lookouts and observation platform.* One Lookout positioned in an aircraft. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 2,100 yd around the intended impact location.

(A) Prior to the initial start of the activity (*e.g.,* during deployment of the target), Navy personnel must observe the mitigation zone for floating vegetation; if observed, relocate or delay the start until the mitigation zone is clear. Navy personnel also must conduct passive acoustic monitoring for marine mammals and use the information from detections to assist visual observations. Navy personnel must visually observe the mitigation zone for marine mammals and jellyfish aggregations; if observed, Navy personnel must relocate or delay the start of firing.

(B) During the activity, Navy personnel must observe for marine mammals and jellyfish aggregations; if observed, Navy personnel must cease firing.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(D) After completion of the activity *(e.g.,* prior to maneuvering off station)—when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(8) *Explosive medium-caliber and large-caliber projectiles.* Gunnery activities using explosive medium-caliber and large-caliber projectiles. Mitigation applies to activities using a surface target.

(i) *Number of Lookouts and observation platform.* One Lookout must be on the vessel or aircraft conducting the activity. For activities using explosive large-caliber projectiles, depending on the activity, the Lookout could be the same as the one described in weapons firing noise in paragraph (a)(5)(i) of this section. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 200 yd around the intended impact location for air-to-surface activities using explosive medium-caliber projectiles.

(B) 600 yd around the intended impact location for surface-to-surface activities using explosive medium-caliber projectiles.

(C) 1,000 yd around the intended impact location for surface-to-surface

activities using explosive large-caliber projectiles.

(D) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if observed, Navy personnel must relocate or delay the start of firing.

(E) During the activity, Navy personnel must observe for marine mammals; if observed, Navy personnel must cease firing.

(F) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; the mitigation zone has been clear from any additional sightings for 10 min for aircraft-based firing or 30 min for vessel-based firing; or for activities using mobile targets, the intended impact location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(G) After completion of the activity (*e.g.,* prior to maneuvering off station)—when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(9) *Explosive missiles and rockets.* Aircraft-deployed explosive missiles and rockets. Mitigation applies to activities using a surface target.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 900 yd around the intended impact location for missiles or rockets with 0.6–20 lb net explosive weight.

(B) 2,000 yd around the intended impact location for missiles with 21–500 lb net explosive weight.

(C) Prior to the initial start of the activity (*e.g.,* during a fly-over of the mitigation zone), Navy personnel must observe the mitigation zone for floating vegetation; if resource observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if resources observed, Navy personnel must relocate or delay the start of firing.

(D) During the activity, Navy personnel must observe for marine mammals; if observed, Navy personnel must cease firing.

(E) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(F) After completion of the activity (*e.g.,* prior to maneuvering off station)—when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(10) *Explosive bombs*—(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft conducting the activity. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 2,500 yd around the intended target.

(A) Prior to the initial start of the activity (*e.g.,* when arriving on station), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if observed, Navy personnel must relocate or delay the start of bomb deployment.

(B) During the activity (*e.g.,* during target approach), Navy personnel must observe for marine mammals; if observed, Navy personnel must cease bomb deployment.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing bomb deployment) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended target; the mitigation zone has been clear from any additional sightings for 10 min; or for activities using mobile targets, the intended target has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(D) After completion of the activity (*e.g.,* prior to maneuvering off station), when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(11) *Sinking exercises*—(i) *Number of Lookouts and observation platform.* Two Lookouts (one must be positioned in an aircraft and one must be positioned on a vessel). If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the

mitigation zone for applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 2.5 nautical miles (nmi) around the target ship hulk.

(A) Prior to the initial start of the activity (90 min prior to the first firing), Navy personnel must conduct aerial observations of the mitigation zone for floating vegetation and delay the start until the mitigation zone is clear. Navy personnel also must conduct aerial observations of the mitigation zone for marine mammals and jellyfish aggregations; if observed, Navy personnel must delay the start of firing.

(B) During the activity, Navy personnel must conduct passive acoustic monitoring for marine mammals and use information from detections to assist visual observations. Navy personnel must visually observe the mitigation zone for marine mammals from the vessel; if observed, Navy personnel must cease firing. Immediately after any planned or unplanned breaks in weapons firing of longer than two hours, Navy personnel must observe the mitigation zone for marine mammals from the aircraft and vessel; if observed, Navy personnel must delay recommencement of firing.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the target ship hulk; or the mitigation zone has been clear from any additional sightings for 30 min.

(D) After completion of the activity (for two hours after sinking the vessel or until sunset, whichever comes first), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(12) *Explosive mine countermeasure and neutralization activities*—(i) *Number of Lookouts and observation platform.* (A) One Lookout must be positioned on a vessel or in an aircraft when implementing the smaller mitigation zone (using up to 0.1–5 lb net explosive weight charges).

(B) Two Lookouts (one must be in an aircraft and one must be on a small boat) when implementing the larger mitigation zone (using up to 6–650 lb net explosive weight charges).

(C) If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) will support observing the mitigation zone for applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 600 yd around the detonation site for activities using 0.1–5 lb net explosive weight.

(B) 2,100 yd around the detonation site for activities using 6–650 lb net explosive weight (including high explosive target mines).

(C) Prior to the initial start of the activity (*e.g.,* when maneuvering on station; typically, 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if observed, Navy personnel must relocate or delay the start of detonations.

(D) During the activity, Navy personnel must observe the mitigation zone for marine mammals; if observed, the Navy must cease detonations.

(E) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to detonation site; or the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(F) After completion of the activity (typically 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets will assist in the visual observation of the area where detonations occurred.

(13) *Explosive mine neutralization activities involving Navy divers*—(i) *Number of Lookouts and observation platform.* (A) Two Lookouts (two small boats with one Lookout each, or one Lookout must be on a small boat and one must be in a rotary-wing aircraft) when implementing the smaller mitigation zone.

(B) Four Lookouts (two small boats with two Lookouts each), and a pilot or member of an aircrew must serve as an additional Lookout if aircraft are used during the activity, when implementing the larger mitigation zone.

(C) All divers placing the charges on mines must support the Lookouts while performing their regular duties and must report applicable sightings to their supporting small boat or Range Safety Officer.

(D) If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* (A) 500 yd around the detonation site during activities under positive control using 0.1–20 lb net explosive weigh.

(B) 1,000 yd around the detonation site during all activities using time-delay fuses (0.1–20 lb net explosive weight) and during activities under positive control using 21–60 lb net explosive weight charges.

(C) Prior to the initial start of the activity (*e.g.,* when maneuvering on station for activities under positive control; 30 min for activities using time-delay firing devices), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if resource observed, Navy personnel must relocate or delay the start of detonations or fuse initiation.

(D) During the activity, Navy personnel must observe for marine mammals; if observed, Navy personnel must cease detonations or fuse initiation. To the maximum extent practicable depending on mission

requirements, safety, and environmental conditions, boats must position themselves near the mid-point of the mitigation zone radius (but outside of the detonation plume and human safety zone), must position themselves on opposite sides of the detonation location (when two boats are used), and must travel in a circular pattern around the detonation location with one Lookout observing inward toward the detonation site and the other observing outward toward the perimeter of the mitigation zone. If used, aircraft must travel in a circular pattern around the detonation location to the maximum extent practicable. Navy personnel must not set time-delay firing devices (0.1–20 lb. net explosive weight) to exceed 10 min.

(E) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the detonation site; or the mitigation zone has been clear from any additional sightings for 10 min during activities under positive control with aircraft that have fuel constraints, or 30 min during activities under positive control with aircraft that are not typically fuel constrained and during activities using time-delay firing devices.

(F) After completion of an activity (for 30 min), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(14) *Maritime security operations—anti-swimmer grenades*—(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on the small boat conducting the activity. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 200 yd around the intended detonation location.

(A) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if observed, Navy personnel must relocate or delay the start of detonations.

(B) During the activity, Navy personnel must observe for marine mammals; if observed, Navy personnel must cease detonations.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended detonation location; the mitigation zone has been clear from any additional sightings for 30 min.; or the intended detonation location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(D) After completion of the activity (*e.g.,* prior to maneuvering off station), when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets must assist in the visual observation of the area where detonations occurred.

(15) *Line charge testing*—(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on a vessel. If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must support observing the mitigation zone for applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 900 yd around the intended detonation location.

(A) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if observed, Navy personnel must delay the start of detonations.

(B) During the activity, Navy personnel must observe for marine mammals; if observed, Navy personnel must cease detonations.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended detonation location; or the mitigation zone has been clear from any additional sightings for 30 min.

(D) After completion of the activity (*e.g.,* prior to maneuvering off station), when practical (*e.g.,* when platforms are not constrained by fuel restrictions or mission-essential follow-on commitments), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets will assist in the visual observation of the area where detonations occurred.

(16) *Ship shock trials*—(i) *Number of Lookouts and observation platform.* (A) A minimum of ten Lookouts or trained marine species observers (or a combination thereof) must be positioned either in an aircraft or on multiple vessels (*i.e.,* a Marine Animal Response Team boat and the test ship).

(*1*) If aircraft are used, Lookouts or trained marine species observers must be in an aircraft and on multiple vessels.

(*2*) If aircraft are not used, a sufficient number of additional Lookouts or trained marine species observers must be used to provide vessel-based visual observation comparable to that achieved by aerial surveys.

(B) If additional platforms are participating in the activity, Navy personnel positioned in those assets (*e.g.,* safety observers, evaluators) must

support observing the mitigation zone for applicable biological resources while performing their regular duties.

(ii) *Mitigation zone and requirements.* 3.5 nmi around the ship hull.

(A) The Navy must not conduct ship shock trials in the Jacksonville Operating Area during North Atlantic right whale calving season from November 15 through April 15.

(B) The Navy must develop detailed ship shock trial monitoring and mitigation plans approximately one-year prior to an event and must continue to provide these to NMFS for review and approval.

(C) Pre-activity planning must include selection of one primary and two secondary areas where marine mammal populations are expected to be the lowest during the event, with the primary and secondary locations located more than 2 nmi from the western boundary of the Gulf Stream for events in the Virginia Capes Range Complex or Jacksonville Range Complex.

(D) If it is determined during pre-activity surveys that the primary area is environmentally unsuitable (*e.g.,* observations of marine mammals or presence of concentrations of floating vegetation), the shock trial can be moved to a secondary site in accordance with the detailed mitigation and monitoring plan provided to NMFS.

(E) Prior to the initial start of the activity at the primary shock trial location (in intervals of 5 hrs, 3 hrs, 40 min, and immediately before the detonation), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if observed, Navy personnel must delay triggering the detonation.

(F) During the activity, Navy personnel must observe for marine mammals, large schools of fish, jellyfish aggregations, and flocks of seabirds; if observed, Navy personnel must cease triggering the detonation. After completion of each detonation, Navy personnel must observe the mitigation zone for marine mammals; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures and halt any remaining detonations until Navy personnel can consult with NMFS and review or adapt the mitigation, if necessary.

(G) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing detonations) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the ship hull; or the mitigation zone has been clear from any additional sightings for 30 min.

(H) After completion of the activity (during the following two days at a minimum, and up to seven days at a maximum), Navy personnel must observe for marine mammals in the vicinity of where detonations occurred; if any injured or dead marine mammals are observed, Navy personnel must follow established incident reporting procedures. If additional platforms are supporting this activity (*e.g.,* providing range clearance), these Navy assets will assist in the visual observation of the area where detonations occurred.

(17) *Vessel movement.* The mitigation will not be applied if: the vessel's safety is threatened; the vessel is restricted in its ability to maneuver (*e.g.,* during launching and recovery of aircraft or landing craft, during towing activities, when mooring, etc.); or the vessel is operated autonomously.

(i) *Number of Lookouts and observation platform.* One Lookout must be on the vessel that is underway.

(ii) *Mitigation zone and requirements.* (A) 500 yd around whales.

(B) 200 yd around all other marine mammals (except bow-riding dolphins and pinnipeds hauled out on man-made navigational structures, port structures, and vessels).

(C) During the activity, when underway, Navy personnel must observe the mitigation zone for marine mammals; if observed, Navy personnel must maneuver to maintain distance.

(D) Additionally, Navy personnel must broadcast awareness notification messages with North Atlantic right whale Dynamic Management Area information (*e.g.,* location and dates) to applicable Navy assets operating in the vicinity of the Dynamic Management Area. The information will alert assets to the possible presence of a North Atlantic right whale to maintain safety of navigation and further reduce the potential for a vessel strike. Platforms will use the information to assist their visual observation of applicable mitigation zones during training and testing activities and to aid in the implementation of procedural mitigation, including but not limited to, mitigation for vessel movement. If a marine mammal vessel strike occurs, Navy personnel must follow the established incident reporting procedures.

(18) *Towed in-water devices.* Mitigation applies to devices that are towed from a manned surface platform or manned aircraft. The mitigation will not be applied if the safety of the towing platform or in-water device is threatened.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on a manned towing platform.

(ii) *Mitigation zone and requirements.* 250 yd around marine mammals. During the activity, when towing an in-water device, Navy personnel must observe for marine mammals; if observed, Navy personnel must maneuver to maintain distance.

(19) *Small-, medium-, and large-caliber non-explosive practice munitions.* Mitigation applies to activities using a surface target.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned on the platform conducting the activity. Depending on the activity, the Lookout could be the same as the one described for weapons firing noise in paragraph (a)(5)(i) of this section.

(ii) *Mitigation zone and requirements.* 200 yd around the intended impact location.

(A) Prior to the initial start of the activity (*e.g.,* when maneuvering on station), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if observed, Navy personnel must relocate or delay the start of firing.

(B) During the activity, Navy personnel must observe for marine mammals; if observed, Navy personnel must cease firing.

(C) Commencement/recommencement conditions after a marine mammal sighting before or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; the mitigation zone has been clear from any additional sightings for 10 min for aircraft-based firing or 30 min for vessel-based firing; or for

activities using a mobile target, the intended impact location has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(20) *Non-explosive missiles and rockets.* Aircraft-deployed non-explosive missiles and rockets. Mitigation applies to activities using a surface target.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft.

(ii) *Mitigation zone and requirements.* 900 yd around the intended impact location.

(A) Prior to the initial start of the activity (*e.g.,* during a fly-over of the mitigation zone), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if observed, Navy personnel must relocate or delay the start of firing.

(B) During the activity, Navy personnel must observe for marine mammals; if observed, Navy personnel must cease firing.

(C) Commencement/recommencement conditions after a marine mammal sighting prior to or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing firing) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended impact location; or the mitigation zone has been clear from any additional sightings for 10 min when the activity involves aircraft that have fuel constraints, or 30 min when the activity involves aircraft that are not typically fuel constrained.

(21) *Non-explosive bombs and mine shapes.* Non-explosive bombs and non-explosive mine shapes during mine laying activities.

(i) *Number of Lookouts and observation platform.* One Lookout must be positioned in an aircraft.

(ii) *Mitigation zone and requirements.* 1,000 yd around the intended target.

(A) Prior to the initial start of the activity (*e.g.,* when arriving on station), Navy personnel must observe the mitigation zone for floating vegetation; if observed, Navy personnel must relocate or delay the start until the mitigation zone is clear. Navy personnel also must observe the mitigation zone for marine mammals; if observed, Navy personnel must relocate or delay the start of bomb deployment or mine laying.

(B) During the activity (*e.g.,* during approach of the target or intended minefield location), Navy personnel must observe the mitigation zone for marine mammals; if observed, Navy personnel must cease bomb deployment or mine laying.

(C) Commencement/recommencement conditions after a marine mammal sighting prior to or during the activity: Navy personnel must allow a sighted marine mammal to leave the mitigation zone prior to the initial start of the activity (by delaying the start) or during the activity (by not recommencing bomb deployment or mine laying) until one of the following conditions has been met: The animal is observed exiting the mitigation zone; the animal is thought to have exited the mitigation zone based on a determination of its course, speed, and movement relative to the intended target or minefield location; the mitigation zone has been clear from any additional sightings for 10 min; or for activities using mobile targets, the intended target has transited a distance equal to double that of the mitigation zone size beyond the location of the last sighting.

(b) *Mitigation areas.* In addition to procedural mitigation, the Navy must implement mitigation measures within mitigation areas to avoid potential impacts on marine mammals.

(1) *Mitigation areas off the Northeastern United States for sonar, explosives, and physical disturbance and strikes*—(i) *Mitigation area requirements.* (A) Northeast North Atlantic Right Whale Mitigation Area (year-round):

(*1*) Navy personnel must report the total hours and counts of active sonar and in-water explosives used in the mitigation area (which includes North Atlantic right whale ESA-designated critical habitat) in its annual training and testing activity reports submitted to NMFS.

(*2*) Navy personnel must minimize the use of low-frequency active sonar, mid-frequency active sonar, and high-frequency active sonar to the maximum extent practicable within the mitigation area.

(*3*) Navy personnel must not use Improved Extended Echo Ranging sonobuoys in or within 3 nmi of the mitigation area or use explosive and non-explosive bombs, in-water detonations, and explosive torpedoes within the mitigation area.

(*4*) For activities using non-explosive torpedoes within the mitigation area, Navy personnel must conduct activities during daylight hours in Beaufort sea state 3 or less. The Navy must use three Lookouts (one positioned on a vessel and two positioned in an aircraft during dedicated aerial surveys) to observe the vicinity of the activity. An additional Lookout must be positioned on the submarine, when surfaced. Immediately prior to the start of the activity, Navy personnel will observe for floating vegetation and marine mammals; if observed, Navy personnel will not commence the activity until the vicinity is clear or the activity is relocated to an area where the vicinity is clear. During the activity, Navy personnel will observe for marine mammals; if observed, Navy personnel will cease the activity. To allow a sighted marine mammal to leave the area, Navy personnel must not recommence the activity until one of the following conditions has been met: The animal is observed exiting the vicinity of the activity; the animal is thought to have exited the vicinity of the activity based on a determination of its course, speed, and movement relative to the activity location; or the area has been clear from any additional sightings for 30 min. During transits and normal firing, ships will maintain a speed of no more than 10 knots (kn). During submarine target firing, ships must maintain speeds of no more than 18 kn. During vessel target firing, vessel speeds may exceed 18 kn for brief periods of time (*e.g.,* 10–15 min).

(*5*) For all activities, before vessel transits within the mitigation area, Navy personnel must conduct a web query or email inquiry to the National Oceanographic and Atmospheric Administration Northeast Fisheries Science Center's North Atlantic Right Whale Sighting Advisory System to obtain the latest North Atlantic right whale sightings information. Navy personnel on vessels must use the sightings information to reduce potential interactions with North Atlantic right whales during transits. Navy personnel on vessels must implement speed reductions within the mitigation area after observing a North Atlantic right whale, if transiting within 5 nmi of a sighting reported to the North Atlantic Right Whale Sighting Advisory System within the past week, and if transiting at night or during periods of reduced visibility.

(B) Gulf of Maine Planning Awareness Mitigation Area (year-round):

(*1*) Navy personnel must report the total hours and counts of active sonar and in-water explosives used in the

mitigation area in its annual training and testing activity reports submitted to NMFS.

(*2*) Navy personnel must not conduct greater than 200 hrs of hull-mounted mid-frequency active sonar per year within the mitigation area.

(*3*) Navy personnel must not conduct major training exercises (Composite Training Unit Exercises or Fleet Exercises/Sustainment Exercises) within the mitigation area. If the Navy needs to conduct a major training exercise within the mitigation area in support of training requirements driven by national security concerns, Navy personnel must confer with NMFS to verify that potential impacts are adequately addressed.

(C) Northeast Planning Awareness Mitigation Areas (year-round):

(*1*) Navy personnel will avoid planning major training exercises (Composite Training Unit Exercises or Fleet Exercises/Sustainment Exercises) within the mitigation area to the maximum extent practicable.

(*2*) Navy personnel must not conduct more than four major training exercises per year (all or a portion of the exercise) within the mitigation area.

(*3*) If the Navy needs to conduct additional major training exercises in the mitigation area in support of training requirements driven by national security concerns, Navy personnel must provide NMFS with advance notification and include the information in its annual training and testing activity reports submitted to NMFS.

(ii) [Reserved]

(2) *Mitigation areas off the Mid-Atlantic and Southeastern United States for sonar, explosives, and physical disturbance and strikes*—(i) *Mitigation area requirements.* (A) Southeast North Atlantic Right Whale Mitigation Area (November 15 through April 15):

(*1*) Navy personnel must report the total hours and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS.

(*2*) The Navy must not conduct: Low-frequency active sonar (except as noted in paragraph (b)(2)(i)(A)(*3*) of this section), mid-frequency active sonar (except as noted in paragraph (b)(2)(i)(A)(*3*) of this section), high-frequency active sonar, missile and rocket activities (explosive and non-explosive), small-, medium-, and large-caliber gunnery activities, Improved Extended Echo Ranging sonobuoy activities, explosive and non-explosive bombing activities, in-water detonations, and explosive torpedo activities within the mitigation area.

(*3*) To the maximum extent practicable, Navy personnel must minimize the use of: Helicopter dipping sonar, low-frequency active sonar and hull-mounted mid-frequency active sonar used for navigation training, and low-frequency active sonar and hull-mounted mid-frequency active sonar used for object detection exercises within the mitigation area.

(*4*) Before transiting or conducting training or testing activities within the mitigation area, Navy personnel must initiate communication with the Fleet Area Control and Surveillance Facility, Jacksonville to obtain Early Warning System North Atlantic right whale sightings data. The Fleet Area Control and Surveillance Facility, Jacksonville must advise Navy personnel on vessels of all reported whale sightings in the vicinity to help Navy personnel on vessels and aircraft reduce potential interactions with North Atlantic right whales. Commander Submarine Force U.S. Atlantic Fleet must coordinate any submarine activities that may require approval from the Fleet Area Control and Surveillance Facility, Jacksonville. Navy personnel on vessels must use the sightings information to reduce potential interactions with North Atlantic right whales during transits.

(*5*) Navy personnel on vessels must implement speed reductions after they observe a North Atlantic right whale, if they are within 5 nmi of a sighting reported within the past 12 hrs, or when operating in the mitigation area at night or during periods of poor visibility.

(*6*) To the maximum extent practicable, Navy personnel on vessels must minimize north-south transits in the mitigation area.

(B) Southeast North Atlantic Right Whale Critical Habitat Special Reporting Area (November 15 through April 15):

(*1*) Navy personnel must report the total hours and counts of active sonar and in-water explosives used in the Special Reporting Area (which includes southeast North Atlantic right whale ESA-designated critical habitat) in its annual training and testing activity reports submitted to NMFS.

(*2*) [Reserved]

(C) Jacksonville Operating Area (November 15 through April 15):

(*1*) Navy units conducting training or testing activities in the Jacksonville Operating Area must initiate communication with the Fleet Area Control and Surveillance Facility, Jacksonville to obtain Early Warning System North Atlantic right whale sightings data. The Fleet Area Control and Surveillance Facility, Jacksonville must advise Navy personnel on vessels of all reported whale sightings in the vicinity to help Navy personnel on vessels and aircraft reduce potential interactions with North Atlantic right whales. Commander Submarine Force U.S. Atlantic Fleet must coordinate any submarine activities that may require approval from the Fleet Area Control and Surveillance Facility, Jacksonville. Navy personnel must use the reported sightings information as they plan specific details of events (*e.g.,* timing, location, duration) to minimize potential interactions with North Atlantic right whales to the maximum extent practicable. Navy personnel must use the reported sightings information to assist visual observations of applicable mitigation zones and to aid in the implementation of procedural mitigation.

(*2*) [Reserved]

(D) Navy Cherry Point Range Complex Nearshore Mitigation Area (March through September):

(*1*) Navy personnel must not conduct explosive mine neutralization activities involving Navy divers in the mitigation area.

(*2*) To the maximum extent practicable, Navy personnel must not use explosive sonobuoys, explosive torpedoes, explosive medium-caliber and large-caliber projectiles, explosive missiles and rockets, explosive bombs, explosive mines during mine countermeasure and neutralization activities, and anti-swimmer grenades in the mitigation area.

(E) Mid-Atlantic Planning Awareness Mitigation Areas (year-round):

(*1*) Navy personnel will avoid planning major training exercises (Composite Training Unit Exercises or Fleet Exercises/Sustainment Exercises) to the maximum extent practicable.

(*2*) Navy personnel must not conduct more than four major training exercises per year (all or a portion of the exercise) within the mitigation area.

(*3*) If the Navy needs to conduct additional major training exercises in the mitigation area in support of training requirements driven by national security concerns, Navy personnel will provide NMFS with advance notification and include the information in its annual training and testing activity reports submitted to NMFS.

(ii) [Reserved]

(3) *Mitigation areas in the Gulf of Mexico for sonar*—(i) *Mitigation area requirements.* (A) Gulf of Mexico Planning Awareness Mitigation Areas (year-round):

(*1*) Navy personnel must not conduct major training exercises within the mitigation area (all or a portion of the exercise).

(*2*) If the Navy needs to conduct a major training exercise within the mitigation areas in support of training requirements driven by national security concerns, Navy personnel must confer with NMFS to verify that potential impacts are adequately addressed.

(B) Bryde's Whale Mitigation Area (year-round):

(*1*) Navy personnel must report the total hours and counts of active sonar and in-water explosives used in the mitigation area in its annual training and testing activity reports submitted to NMFS.

(*2*) Navy personnel must not conduct greater than 200 hrs of hull-mounted mid-frequency active sonar per year within the mitigation area.

(*3*) The Navy must not use explosives (except during mine warfare activities) within the mitigation area.

(ii) [Reserved]

§ 218.85 Requirements for monitoring and reporting.

(a) *Unauthorized take.* The Navy must notify NMFS immediately (or as soon as operational security considerations allow) if the specified activity identified in § 218.80 is thought to have resulted in the mortality or serious injury of any marine mammals, or in any Level A or Level B harassment take of marine mammals not identified in this subpart.

(b) *Monitoring and reporting under the LOAs.* The Navy must conduct all monitoring and required reporting under the LOAs, including abiding by the AFTT Study Area monitoring program. Details on program goals, objectives, project selection process, and current projects are available at *www.navymarinespeciesmonitoring.us.*

(c) *Notification of injured, live stranded, or dead marine mammals.* The Navy must consult the Notification and Reporting Plan, which sets out notification, reporting, and other requirements when dead, injured, or live stranded marine mammals are detected. The Notification and Reporting Plan is available at *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-military-readiness-activities.*

(d) *Annual AFTT Study Area marine species monitoring report.* The Navy must submit an annual report of the AFTT Study Area monitoring describing the implementation and results from the previous calendar year. Data collection methods must be standardized across range complexes and study areas to allow for comparison in different geographic locations. The report must be submitted to the Director, Office of Protected Resources of NMFS either 90 days after the calendar year, or 90 days after the conclusion of the monitoring year to be determined by the Adaptive Management process. This report will describe progress of knowledge made with respect to monitoring plan study questions across all Navy ranges associated with the Integrated Comprehensive Monitoring Program. Similar study questions must be treated together so that progress on each topic can be summarized across all Navy ranges. The report need not include analyses and content that does not provide direct assessment of cumulative progress on the monitoring plan study questions.

(e) *Annual AFTT Study Area training and testing reports.* Each year, the Navy must submit a preliminary report (Quick Look Report) detailing the status of authorized sound sources within 21 days after the anniversary of the date of issuance of each LOA to the Director, Office of Protected Resources, NMFS. Each year, the Navy must submit a detailed report within 3 months after the anniversary of the date of issuance of each LOA to the Director, Office of Protected Resources, NMFS. The annual reports must contain information on Major Training Exercises (MTEs), Sinking Exercise (SINKEX) events, and a summary of all sound sources used, including within specified mitigation reporting areas, as described in paragraph (e)(3) of this section. The analysis in the detailed report must be based on the accumulation of data from the current year's report and data collected from the previous report. The detailed reports must contain information identified in paragraphs (e)(1) through (5) of this section.

(1) *MTEs.* This section of the report must contain the following information for MTEs conducted in the AFTT Study Area:

(i) Exercise Information (for each MTE):

(A) Exercise designator.

(B) Date that exercise began and ended.

(C) Location.

(D) Number and types of active sonar sources used in the exercise.

(E) Number and types of passive acoustic sources used in exercise.

(F) Number and types of vessels, aircraft, and other platforms, participating in exercise.

(G) Total hours of all active sonar source operation.

(H) Total hours of each active sonar source bin.

(I) Wave height (high, low, and average) during exercise.

(ii) Individual marine mammal sighting information for each sighting in each exercise when mitigation occurred:

(A) Date/Time/Location of sighting.

(B) Species (if not possible, indication of whale/dolphin/pinniped).

(C) Number of individuals.

(D) Initial Detection Sensor (*e.g.,* sonar, Lookout).

(E) Indication of specific type of platform observation made from (including, for example, what type of surface vessel or testing platform).

(F) Length of time observers maintained visual contact with marine mammal.

(G) Sea state.

(H) Visibility.

(I) Sound source in use at the time of sighting.

(J) Indication of whether animal was less than 200 yd, 200 to 500 yd, 500 to 1,000 yd, 1,000 to 2,000 yd, or greater than 2,000 yd from sonar source.

(K) Mitigation implementation. Whether operation of sonar sensor was delayed, or sonar was powered or shut down, and how long the delay was.

(L) If source in use was hull-mounted, true bearing of animal from the vessel, true direction of vessel's travel, and estimation of animal's motion relative to vessel (opening, closing, parallel).

(M) Observed behavior. Lookouts must report, in plain language and without trying to categorize in any way, the observed behavior of the animal(s) (such as animal closing to bow ride, paralleling course/speed, floating on surface and not swimming, etc.) and if any calves were present.

(iii) An evaluation (based on data gathered during all of the MTEs) of the effectiveness of mitigation measures designed to minimize the received level to which marine mammals may be exposed. This evaluation must identify the specific observations that support any conclusions the Navy reaches about the effectiveness of the mitigation.

(2) *SINKEXs.* This section must include the following information for each SINKEX completed that year:

(i) Exercise information (gathered for each SINKEX):

(A) Location.

(B) Date and time exercise began and ended.

(C) Total hours of observation by Lookouts before, during, and after exercise.

(D) Total number and types of explosive source bins detonated.

(E) Number and types of passive acoustic sources used in exercise.

(F) Total hours of passive acoustic search time.

(G) Number and types of vessels, aircraft, and other platforms participating in exercise.

(H) Wave height in feet (high, low, and average) during exercise.

(J) Narrative description of sensors and platforms utilized for marine mammal detection and timeline illustrating how marine mammal detection was conducted.

(ii) Individual marine mammal observation (by Navy Lookouts) information (gathered for each marine mammal sighting) for each sighting where mitigation was implemented:

(A) Date/Time/Location of sighting.

(B) Species (if not possible, indicate whale, dolphin, or pinniped).

(C) Number of individuals.

(D) Initial detection sensor (*e.g.,* sonar or Lookout).

(E) Length of time observers maintained visual contact with marine mammal.

(F) Sea state.

(G) Visibility.

(H) Whether sighting was before, during, or after detonations/exercise, and how many minutes before or after.

(I) Distance of marine mammal from actual detonations: Less than 200 yd, 200 to 500 yd, 500 to 1,000 yd, 1,000 to 2,000 yd, or greater than 2,000 yd (or target spot if not yet detonated).

(J) Observed behavior. Lookouts must report, in plain language and without trying to categorize in any way, the observed behavior of the animal(s) (such as animal closing to bow ride, paralleling course/speed, floating on surface and not swimming etc.), including speed and direction and if any calves were present.

(K) Resulting mitigation implementation. The report must indicate whether explosive detonations were delayed, ceased, modified, or not modified due to marine mammal presence and for how long.

(L) If observation occurred while explosives were detonating in the water, indicate munition type in use at time of marine mammal detection.

(3) *Summary of sources used.* This section must include the following information summarized from the authorized sound sources used in all training and testing events:

(i) Total annual hours or quantity (per the LOA) of each bin of sonar or other acoustic sources (pile driving and air gun activities); and

(ii) Total annual expended/detonated ordnance (missiles, bombs, sonobuoys, etc.) for each explosive bin.

(4) *Geographic information presentation.* The reports must present an annual (and seasonal, where practical) depiction of training and testing bin usage (as well as pile driving activities) geographically across the AFTT Study Area.

(5) *Sonar exercise notification.* The Navy must submit to NMFS (contact as specified in the LOA) an electronic report within fifteen calendar days after the completion of any MTE indicating:

(i) Location of the exercise;

(ii) Beginning and end dates of the exercise; and

(iii) Type of exercise.

(f) *Five-year close-out comprehensive training and testing report.* This report must be included as part of the 2023 annual training and testing report. This report must provide the annual totals for each sound source bin with a comparison to the annual allowance and the five-year total for each sound source bin with a comparison to the five-year allowance. Additionally, if there were any changes to the sound source allowance, this report must include a discussion of why the change was made and include the analysis to support how the change did or did not result in a change in the EIS and final rule determinations. The draft report must be submitted three months after the expiration of this subpart to the Director, Office of Protected Resources, NMFS. NMFS must submit comments on the draft close-out report, if any, within three months of receipt. The report will be considered final after the Navy has addressed NMFS' comments, or 3 months after the submittal of the draft if NMFS does not provide comments.

§ 218.86 Letters of Authorization.

(a) To incidentally take marine mammals pursuant to the regulations in this subpart, the Navy must apply for and obtain Letters of Authorization (LOAs) in accordance with § 216.106 of this chapter.

(b) LOAs, unless suspended or revoked, may be effective for a period of time not to exceed the expiration date of the regulations in this subpart.

(c) If an LOA expires prior to the expiration date of the regulations in this subpart, the Navy may apply for and obtain a renewal of the LOA.

(d) In the event of projected changes to the activity or to mitigation, monitoring, or reporting (excluding changes made pursuant to the adaptive management provision of § 218.87(c)(1)) as required by an LOA issued under this subpart, the Navy must apply for and obtain a modification of the LOA as described in § 218.87.

(e) Each LOA will set forth:

(1) Permissible methods of incidental taking;

(2) Specified geographic areas for incidental taking;

(3) Means of effecting the least practicable adverse impact (*i.e.,* mitigation) on the species or stocks of marine mammals and their habitat; and

(4) Requirements for monitoring and reporting.

(f) Issuance of the LOA(s) will be based on a determination that the level of taking must be consistent with the findings made for the total taking allowable under the regulations in this subpart.

(g) Notice of issuance or denial of the LOA(s) will be published in the **Federal Register** within 30 days of a determination.

§ 218.87 Renewals and modifications of Letters of Authorization.

(a) An LOA issued under §§ 216.106 of this chapter and 218.86 may be renewed or modified upon request by the applicant, provided that:

(1) The planned specified activity and mitigation, monitoring, and reporting measures, as well as the anticipated impacts, are the same as those described and analyzed for the regulations in this subpart (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section); and

(2) NMFS determines that the mitigation, monitoring, and reporting measures required by the previous LOA(s) under the regulations in this subpart were implemented.

(b) For LOA modification or renewal requests by the applicant that include changes to the activity or to the mitigation, monitoring, or reporting measures (excluding changes made pursuant to the adaptive management provision in paragraph (c)(1) of this section) that do not change the findings made for the regulations or result in no more than a minor change in the total estimated number of takes (or distribution by species or stock or years), NMFS may publish a notice of planned LOA in the **Federal Register**, including the associated analysis of the change, and solicit public comment before issuing the LOA.

(c) An LOA issued under §§ 216.106 of this chapter and 218.86 may be modified by NMFS under the following circumstances:

(1) *Adaptive management.* After consulting with the Navy regarding the practicability of the modifications, NMFS may modify (including adding or removing measures) the existing mitigation, monitoring, or reporting measures if doing so creates a reasonable likelihood of more effectively accomplishing the goals of the mitigation and monitoring.

(i) Possible sources of data that could contribute to the decision to modify the

mitigation, monitoring, or reporting measures in an LOA include:

(A) Results from the Navy's monitoring from the previous year(s);

(B) Results from other marine mammal and/or sound research or studies; or

(C) Any information that reveals marine mammals may have been taken in a manner, extent, or number not authorized by the regulations in this subpart or subsequent LOAs.

(ii) If, through adaptive management, the modifications to the mitigation, monitoring, or reporting measures are substantial, NMFS will publish a notice of planned LOA in the **Federal Register** and solicit public comment.

(2) *Emergencies.* If NMFS determines that an emergency exists that poses a significant risk to the well-being of the species or stocks of marine mammals specified in LOAs issued pursuant to §§ 216.106 of this chapter and 218.86, an LOA may be modified without prior notice or opportunity for public comment. Notice would be published in the **Federal Register** within thirty days of the action.

§§ 218.88–218.89 [Reserved]

[FR Doc. 2018–24042 Filed 11–13–18; 8:45 am]

BILLING CODE 3510–22–P

FEDERAL REGISTER

Vol. 83 Wednesday,
No. 220 November 14, 2018

Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services
42 CFR Parts 438 and 457
Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 438 and 457

[CMS–2408–P]

RIN 0938–AT40

Medicaid Program; Medicaid and Children's Health Insurance Plan (CHIP) Managed Care

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule advances CMS' efforts to streamline the Medicaid and Children's Health Insurance Plan (CHIP) managed care regulatory framework and reflects a broader strategy to relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care. These proposed revisions of the Medicaid and CHIP managed care regulations are intended to ensure that the regulatory framework is efficient and feasible for states to implement in a cost-effective manner and ensure that states can implement and operate Medicaid and CHIP managed care programs without undue administrative burdens.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 14, 2019.

ADDRESSES: In commenting, please refer to file code CMS–2408–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2408–P, P.O. Box 8016, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2408–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

John Giles, (410) 786–1255, for Medicaid Managed Care Operations.

Jennifer Sheer, (410) 786–1769, for the Medicaid Managed Care Quality provisions.

Melissa Williams, (410) 786–4435, for the CHIP provisions.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Medicaid Managed Care

A. Background

States may implement a managed care delivery system using four types of federal authorities—sections 1915(a), 1915(b), 1932(a), and 1115(a) of the Social Security Act (the Act); each is described briefly below.

Under section 1915(a) of the Act, states can implement a voluntary managed care program by executing a contract with organizations that the state has procured using a competitive procurement process. To require beneficiaries to enroll in a managed care program to receive services, a state must obtain approval from CMS under two primary authorities:

- Through a state plan amendment that meets standards set forth in section 1932(a) of the Act, states can implement a mandatory managed care delivery system. This authority does not allow states to require beneficiaries who are dually eligible for Medicare and Medicaid (dually eligible), American Indians/Alaska Natives (except as permitted in section 1932(a)(2)(C) of the Act), or children with special health care needs to enroll in a managed care program. State plans, once approved, remain in effect until modified by the state.
- We may grant a waiver under section 1915(b) of the Act, permitting a state to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, or children with special health care needs. After approval, a state may operate a section 1915(b) waiver for a 2-year period (certain waivers can be operated for up to 5 years if they include dually eligible beneficiaries) before requesting a renewal for an additional 2- (or 5-) year period.

We may also authorize managed care programs as part of demonstration projects under section 1115(a) of the Act that include waivers permitting the state to require all Medicaid beneficiaries to enroll in a managed care delivery system, including dually eligible beneficiaries, American Indians/Alaska Natives, and children with special health care needs. Under this authority, states may seek additional flexibility to demonstrate and evaluate innovative policy approaches for delivering Medicaid benefits, as well as the option to provide services not typically covered by Medicaid. Such flexibility is approvable only if the objectives of the Medicaid statute are likely to be met, and the demonstration is subject to evaluation.

These authorities may permit states to operate their programs without complying with the following standards of Medicaid law outlined in section of 1902 of the Act:

- *Statewideness* [section 1902(a)(1) of the Act]: States may implement a managed care delivery system in specific areas of the State (generally counties/parishes) rather than the whole state;
- *Comparability of Services* [section 1902(a)(10) of the Act]: States may provide different benefits to people enrolled in a managed care delivery system; and
- *Freedom of Choice* [section 1902(a)(23)(A) of the Act]: States may generally require people to receive their Medicaid services only from a managed care plan's network of providers or primary care provider.

In the May 6, 2016 **Federal Register** (81 FR 27498), we published the ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP

Delivered in Managed Care, and Revisions Related to Third Party Liability'' final rule (hereinafter referred to as ''the 2016 final rule'') that modernized the Medicaid and CHIP managed care regulations to reflect changes in the use of managed care delivery systems. The 2016 final rule aligned many of the rules governing Medicaid and CHIP managed care with those of other major sources of coverage; implemented applicable statutory provisions; strengthened actuarial soundness payment provisions to promote the accountability of managed care program rates; strengthened efforts to reform delivery systems that serve Medicaid and CHIP beneficiaries; and enhanced policies related to program integrity.

In the January 18, 2017 **Federal Register** (82 FR 5415), we published the ''Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems'' final rule (the 2017 pass-through payments final rule) that made changes to the pass-through payment transition periods and the maximum amount of pass-through payments permitted annually during the transition periods under Medicaid managed care contract(s) and rate certification(s). That final rule prevented increases in pass-through payments and the addition of new pass-through payments beyond those in place when the pass-through payment transition periods were established in the final Medicaid managed care regulations.

Since publication of the 2016 final rule, the landscape for healthcare delivery continues to change, and states are continuing to work toward reforming healthcare delivery systems to address the unique challenges and needs of their local citizens. To that end, the Department of Health and Human Services (HHS) and CMS issued a letter [1] to the nation's Governors on March 14, 2017, affirming the continued HHS and CMS commitment to partnership with states in the administration of the Medicaid program, and noting key areas where we would improve collaboration with states and move toward more effective program management. In that letter, we committed to a thorough review of the managed care regulations to prioritize beneficiary outcomes and state priorities.

Since our issuance of that letter, stakeholders have expressed that the current federal regulations are overly prescriptive and add costs and administrative burden to state Medicaid programs with little improvements in outcomes for beneficiaries. As part of the agency's broader efforts to reduce administrative burden, we undertook a review to analyze the current managed care regulations to ascertain if there were ways to achieve a better balance between appropriate federal oversight and state flexibility, while also maintaining critical beneficiary protections, ensuring fiscal integrity, and improving the quality of care for Medicaid beneficiaries. This proposed rule is the result of that review and seeks to streamline the managed care regulations by reducing unnecessary and duplicative administrative burden and further reducing federal regulatory barriers to help ensure that state Medicaid agencies are able to work efficiently and effectively to design, develop, and implement Medicaid managed care programs that best meet each state's local needs and populations.

B. Provisions of the Proposed Rule

This preamble discusses our proposed changes in the context of the current law. Throughout this document, the term ''PAHP'' is used to mean a prepaid ambulatory health plan that does not exclusively provide non-emergency medical transportation services. Whenever this document is referencing a PAHP that exclusively provides non-emergency medical transportation services, it would be specifically addressed as a ''Non-Emergency Medical Transportation (NEMT) PAHP.''

1. Standard Contract Requirements (§ 438.3)

In the 2016 final rule, we added a new provision at 42 CFR 438.3(t) requiring that contracts with a managed care organization (MCO), prepaid inpatient health plan (PIHP), or PAHP that cover Medicare-Medicaid dually eligible enrollees provide that the MCO, PIHP, or PAHP sign a Coordination of Benefits Agreement (COBA) and participate in the automated crossover claim process administered by Medicare. The purpose of this provision was to promote efficiencies for providers by allowing providers to bill once, rather than sending separate claims to Medicare and the Medicaid MCO, PIHP, or PAHP.

Since publication of the 2016 final rule, we have heard from a number of states that, prior to the rule, had effective processes in place to identify and send appropriate crossover claims to their managed care plans from the crossover file the states received from us. Medicaid beneficiaries can be enrolled in multiple managed care plans and/or the state's fee-for-service (FFS) program. For example, a beneficiary may have medical care covered by an MCO, dental care covered by a PAHP, and behavioral health care covered by the state's FFS program. However, when a managed care plan enters into a crossover agreement with Medicare, as required in § 438.3(t), we then send crossover claims for Medicaid managed care enrollees of that plan to the managed care plans, as well as to the state Medicaid agency. When this occurs, the managed care plan(s) may receive claims for services that are not the contractual responsibility of the managed care plan. Additionally, states noted that having all claims sent to the managed care plan(s) can result in some claims being sent to the wrong plan when beneficiaries change plans. These states have expressed that to discontinue existing effective processes for routing crossover claims to their managed care plans to comply with this provision adds unnecessary costs and burden to the state and plans, creates confusion for payers and providers, and delays provider payments.

To address these concerns, we propose to revise § 438.3(t) to remove the requirement that managed care plans must enter into a COBA directly and instead would require contracts with managed care plans to specify the methodology by which the state would ensure that the managed care plans receive all appropriate crossover claims for which they are responsible. Under this proposal, states would be able to determine the method that best meets the needs of their program, whether by requiring the managed care plans to enter into a COBA and participate in the automated claims crossover process directly or by using an alternative method by which the state forwards appropriate crossover claims it receives from Medicare to each MCO, PIHP, or PAHP. Additionally, we propose to include a requirement that, if the state elects to use a methodology other than requiring the MCO, PIHP, or PAHP to enter into a COBA with Medicare, that methodology must ensure that the submitting provider is promptly informed on the state's remittance advice that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration.

2. Actuarial Soundness Standards (§ 438.4)

a. Option To Develop and Certify a Rate Range (§ 438.4(c))

As noted in the 2016 final rule, before the 2016 final rule was published, we

[1] Letter to the nation's Governors on March 14, 2017: *https://www.hhs.gov/sites/default/files/sec-price-admin-verma-ltr.pdf*.

considered any capitation rate paid to a managed care plan that fell anywhere within the certified rate range to be actuarially sound (81 FR 27567). However, to make the rate setting and the rate approval process more transparent, we changed that process in the 2016 final rule at § 438.4 to require that states develop and certify as actuarially sound each individual rate paid per rate cell to each MCO, PIHP, or PAHP with enough detail to understand the specific data, assumptions, and methodologies behind that rate (81 FR 27567). We noted that states could continue to use rate ranges to gauge an appropriate range of payments on which to base negotiations with an MCO, PIHP, or PAHP, but would have to ultimately provide certification to CMS of a specific rate for each rate cell, rather than a rate range (81 FR 27567). We believed that this change would enhance the integrity of the Medicaid rate-setting process and align Medicaid policy more closely with actuarial practices used in setting rates for non-Medicaid plans (81 FR 27568).

Since publication of the 2016 final rule, we have heard from stakeholders that the requirement to certify a capitation rate per rate cell, rather than to certify a rate range, has the potential to diminish states' ability to obtain the best rates when contracts are procured through competitive bidding. For example, we heard from one state that historically competitively bid the administrative component of the capitation rate that the requirement to certify a capitation rate per rate cell would not permit the state, and therefore, the federal government, to realize a lower rate that could have been available through the state's previous procurement process. States that negotiate dozens of managed care plans' rates annually have also cited the potential burden associated with losing the flexibility to certify rate ranges. Our 2016 Medicaid Managed Care Enrollment Report shows that 15 states submitted rate certifications on 20 plans or more, and one state (California) submitted rate certifications for 130 plans.[2] States have claimed that the elimination of rate ranges could potentially increase administrative costs and burden to submit separate rate certifications and justifications for each capitation rate paid per rate cell.

To address states' concerns while ensuring that rates are actuarially sound and federal resources are spent appropriately, we propose to add § 438.4(c) to provide an option for states to develop and certify a rate range per rate cell within specified parameters. We have designed our proposal to address our previously articulated concerns over the lack of transparency when large rate ranges were used by states to increase or decrease rates paid to the managed care plans without providing further notification to CMS or the public of the change. The proposed rate range option at new paragraph (c) would allow states to certify a rate range per rate cell subject to specific limits and would require the submission of a rate recertification if the state determines that changes are needed within the rate range during the rate year. Under our proposal, an actuary must certify the upper and lower bounds of the proposed rate range as actuarially sound.

Specifically in § 438.4(c)(1), we propose the specific parameters for the use of rate ranges: (1) The rate certification identifies and justifies the assumptions, data, and methodologies specific to both the upper and lower bounds of the rate range; (2) the upper and lower bounds of the rate range are certified as actuarially sound consistent with the requirements of part 438; (3) the upper bound of the rate range does not exceed the lower bound of the rate range multiplied by 1.05; (4) the rate certification documents the state's criteria for paying MCOs, PIHPs, and PAHPs at different points within the rate range; and (5) compliance with specified limits on the state's ability to pay managed care plans at different points within the rate range. States using this option would be prohibited from paying MCOs, PIHPs, and PAHPs at different points within the certified rate range based on the willingness or agreement of the MCOs, PIHPs, or PAHPs to enter into, or adhere to, intergovernmental transfer (IGT) agreements, or the amount of funding the MCOs, PIHPs, or PAHPs provide through IGTs. We are proposing these specific conditions and limitations on the use of rate ranges to address our concerns noted above; that is, that rates are actuarially sound and ensure appropriate stewardship of federal resources, while also permitting limited state flexibility to use certified rate ranges. We believe that the conditions and limitations on the use of rate ranges as set forth in this proposed rule strike the appropriate balance between prudent fiscal and program integrity and state flexibility. We invite comment on these specific proposals and whether additional conditions should be considered to ensure that rates are actuarially sound. Finally, we would like to emphasize that this proposal would require states to demonstrate in their rate certification how the upper and lower bounds of the rate range are actuarially sound.

Under proposed § 438.4(c)(2)(i), states certifying a rate range would be required to document the capitation rates, prior to the start of the rating period for the applicable MCO, PIHP, and PAHP, at points within the certified rate range consistent with the state's criteria in proposed paragraph (c)(1)(iv). States electing to use a rate range would have to submit rate certifications to CMS prior to the start of the rating period and they must comply with all other regulatory requirements including § 438.4, except § 438.4(b)(4) as specified. During the contract year, states using the rate range option in § 438.4(c)(1) would not be able to modify capitation rates within the plus or minus 1.5 percent range allowed under § 438.7(c)(3); we propose to codify this as § 438.4(c)(2)(ii). This proposed provision would enable CMS to give states the flexibility and administrative simplification to use certified rate ranges. While the use of rate ranges is not standard practice in rate development, this proposed change aligns with standard rate development practices by requiring recertification when states elect to modify capitation rates within a rate range during the rating year. States wishing to modify the capitation rates within a rate range during the rating year would be required, in proposed § 438.4(c)(2)(iii), to provide a revised rate certification demonstrating that the criteria for initially setting the rate within the range, as described in the initial rate certification, were not applied accurately; that there was a material error in the data, assumptions, or methodologies used to develop the initial rate certification and that the modifications are necessary to correct the error; or that other adjustments are appropriate and reasonable to account for programmatic changes.

We acknowledge that our proposal has the potential to reintroduce some of the risks that were identified in the 2016 final rule related to the use of rate ranges in the Medicaid program. In the 2016 final rule, we generally prohibited the use of rate ranges, including changes limited to a de minimis plus or minus 1.5 percent range permitted under § 438.7(c)(3) that was finalized in the rule to provide some administrative relief to states with respect to small changes in the capitation rates, to eliminate any potential ambiguity in

[2] *See* 2016 Medicaid Managed Care Enrollment Report, Table 5 Enrollment by Program and Plan as of 2016, pages 24–84, *available at https://www.medicaid.gov/medicaid/managed-care/enrollment/index.html.*

rate setting and to be consistent with our goal to make the rate setting and rate approval processes more transparent. We specifically noted in the 2016 final rule that states have used rate ranges to increase or decrease rates paid to the managed care plans without providing further notification to CMS or the public of the change or certification that the change was based on actual experience incurred by the MCOs, PIHPs, or PAHPs that differed in a material way from the actuarial assumptions and methodologies initially used to develop the capitation rates (81 FR 27567–27568).

We further noted in the 2016 final rule that the prohibition on rate ranges was meant to enhance the integrity and transparency of the rate setting process in the Medicaid program, and to align Medicaid policy more closely with the actuarial practices used in setting rates for non-Medicaid health plans. We noted that the use of rate ranges was unique to Medicaid managed care and that other health insurance products that are subject to rate review submit and justify a specific premium rate. We stated in the 2016 final rule our belief that once a managed care plan has entered into a contract with the state, any increase in funding for the contract should correspond with something of value in exchange for the increased capitation payments. We also provided additional context that our policy on rate ranges was based on the concern that some states have used rate ranges to increase capitation rates paid to managed care plans without changing any obligations within the contract or certifying that the increase was based on managed care plans' actual expenses during the contract period. In the 2016 final rule, we reiterated that the prohibition on rate ranges was consistent with the contracting process where managed care plans are agreeing to meet obligations under the contract for a fixed payment amount (81 FR 27567–27568).

The specific risks described above are still concerns for CMS, as such we have proposed specific conditions and limitations on the use of rate ranges in this proposed rule to address our concerns. Our rate range proposal is intended to prevent states from using rate ranges to shift costs to the federal government. There are some states that currently make significant retroactive changes to the contracted rates at or after the end of the rating period. As we noted in the 2016 final rule, we do not believe that these changes are made to reflect changes in the underlying assumptions used to develop the rates (for example, the utilization of services, the prices of services, or the health status of the enrollee), but rather we are concerned that these changes are used to provide additional reimbursements to the plans or to some providers (81 FR 27834). Additionally, we believe the rate ranges compliant with our proposal will be actuarially sound, unlike the rate ranges that were permissible prior to the 2016 final rule. As noted in the 2016 final rule, 14 states used rate ranges with a width of 10 percent or smaller (that is, the low end and the high end of the range were within 5 percent of the midpoint of the range), but in some states, the ranges were as wide as 30 percent (81 FR 27834). We believe that our proposal would limit excessive ranges because proposed § 438.4(c)(1)(i) and (ii) would require the upper and lower bounds of the rate range to be certified as actuarially sound and that the rate certification would identify and justify the assumptions, data, and methodologies used to set the bounds. While we believe that this proposal would strike the right balance between state flexibility and our statutory responsibility to ensure that managed care capitation rates are actuarially sound, we also understand that our proposed approach may reintroduce undue risk in Medicaid rate-setting.

Therefore, we are requesting public comments on our proposal in general and on our proposed approach. We request public comment on the value of the additional state flexibility described in this proposal relative to the potential for the identified risks described here and in the 2016 final rule, including other unintended consequences that could arise from this proposal that we have not yet identified or described. We request public comment on whether additional conditions or limitations on the use of rate ranges would be appropriate to help mitigate the risks we have identified. We also request public comment from states on the utility of state flexibility in this area—specifically, we are asking states to provide specific comments about their policy needs and clear explanations describing how utilizing rate ranges effectively meets these needs or whether current regulatory requirements on rate ranges are sufficiently flexible to meet their needs. We are also asking states to provide quantitative data to help CMS quantify the benefits and risks associated with this proposal. We also encourage states and other stakeholders to comment on the need, benefits, risks, and proposed risk mitigations described in this proposed revision.

b. Capitation Rate Development Practices That Increase Federal Costs and Vary With the Rate of Federal Financial Participation (FFP) (§ 438.4(b)(1) and (d))

In the 2016 final rule, at § 438.4(b), we set forth the standards that capitation rates must meet to be approved as actuarially sound capitation rates eligible for FFP under section 1903(m) of the Act. Section 438.4(b)(1) requires that capitation rates be developed in accordance with generally accepted actuarial principles and practices and meet the standards described in § 438.5 dedicated to rate development standards. In the 2016 final rule (81 FR 27566), we acknowledged that states may desire to establish minimum provider payment rates in the contract with the managed care plan. We also explained that because actuarially sound capitation rates must be based on the reasonable, appropriate, and attainable costs under the contract, minimum provider payment expectations included in the contract would necessarily be built into the relevant service components of the rate. However, we finalized in the regulation at § 438.4(b)(1) a prohibition on different capitation rates based on the FFP associated with a particular population as part of the standards for capitation rates to be actuarially sound. We explained in the 2015 proposed rule (80 FR 31120) that different capitation rates based on the FFP associated with a particular population represented cost-shifting from the state to the federal government and were not based on generally accepted actuarial principles and practices.

In the 2016 final rule (81 FR 27566), we adopted § 438.4(b)(1) largely as proposed and provided additional guidance and clarification in response to public comments. We stated that the practice intended to be prohibited in § 438.4(b)(1) was variance in capitation rates per rate cell that was due to the different rates of FFP associated with the covered populations. We also provided an example in the 2016 final rule. In the example, we explained that we have seen rate certifications that set minimum provider payment requirements or established risk margins for the managed care plans only for covered populations eligible for higher percentages of FFP. We provided in the final rule that such practices, when not supported by the application of valid rate development standards, were not permissible. We further explained that the regulation would not prohibit the state from having different capitation rates per rate cell based on differences

in the projected risk of populations under the contract or based on different payment rates to providers that were required by federal law (for example, section 1932(h) of the Act). In the 2016 final rule, we stated that, as finalized, § 438.4(b)(1) provided that any differences among capitation rates according to covered populations must be based on valid rate development standards and not on network provider reimbursement requirements that apply only to covered populations eligible for higher percentages of FFP (81 FR 27566).

Since publication of the 2016 final rule, we have continued to hear from stakeholders that more guidance is needed regarding the regulatory standards finalized in § 438.4(b)(1). At least one state has indicated that if arrangements that vary provider reimbursement pre-date the differences in FFP for different covered populations, the regulation should not be read to prohibit the resulting capitation rates. While we believe that the existing text of § 438.4(b)(1) is sufficiently clear, we also want to be responsive to the comments from stakeholders and to eliminate any potential loophole in the regulation. Therefore, we are proposing to revise § 438.4(b)(1) and to add a new paragraph § 438.4(d) to clearly specify our standards for actuarial soundness. First and foremost, we are not changing the existing regulatory standard or text in § 438.4(b)(1) that capitation rates must have been developed in accordance with the standards specified in § 438.5 and generally accepted actuarial principles and practices. We are proposing to revise the remainder of § 438.4(b)(1).

We are proposing that any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations must be based on valid rate development standards that represent actual cost differences in providing covered services to the covered populations. Further, we are proposing that any differences in the assumptions, methodologies, or factors used to develop capitation rates must not vary with the rate of FFP associated with the covered populations in a manner that increases federal costs consistent with proposed § 438.4(d) described below. This proposal is intended to eliminate any ambiguity in the regulation and clearly specify our intent that variation in the assumptions, methodologies, and factors used to develop rates must be tied to actual cost differences and not to any differences that increase federal costs and vary with the rate of FFP. We intend the phrase ''assumptions, methodologies, and factors'' to cover the methods and data used to develop the actuarially sound capitation rates.

In conjunction with our proposed revisions to § 438.4(b)(1), we are also proposing a new paragraph (d) in this section to provide specificity regarding the rate development practices that increase federal costs and vary with the rate of FFP. We are proposing in § 438.4(d) a regulatory requirement that requires an evaluation of any differences in the assumptions, methodologies, or factors used to develop capitation rates for MCOs, PIHPs, and PAHPs that increase federal costs and vary with the rate of FFP associated with the covered populations. This evaluation must be conducted for the entire managed care program and include all managed care contracts for all covered populations. We are proposing to require this evaluation across the entire managed care program and all managed care contracts for all covered populations to protect against state managed care contracting practices that may cost-shift to the federal government. Specifically, this would entail comparisons of each managed care contract to others in the state's managed care program to ensure that variation among contracts does not include rate setting methods or policies that would be prohibited under this proposal.

Additionally, we are proposing at § 438.4(d)(1) regulation text to clearly list certain rate development practices that increase federal costs and are prohibited under our proposal for § 438.4(b)(1) and (d): (1) A state may not use higher profit margin, operating margin, or risk margin when developing capitation rates for any covered population, or contract, than the profit margin, operating margin, or risk margin used to develop capitation rates for the covered population, or contract, with the lowest average rate of FFP; (2) a state may not factor into the development of capitation rates the additional cost of contractually required provider fee schedules, or minimum levels of provider reimbursement, above the cost of similar provider fee schedules, or minimum levels of provider reimbursement, used to develop capitation rates for the covered population, or contract, with the lowest average rate of FFP; and (3) a state may not use a lower remittance threshold for a medical loss ratio for any covered population, or contract, than the remittance threshold used for the covered population, or contract, with the lowest average rate of FFP. We are proposing § 438.4(d)(1) to be explicitly clear about certain rate development practices that increase federal costs and vary with the rate of FFP. We note that this proposal would explicitly prohibit these specific rate development practices under any and all scenarios, and under this proposal, we would find these rate development practices to be in violation of our regulatory standards for actuarially sound capitation rates; we also note that the rate development practices proposed under § 438.4(d)(1) are not intended to represent an exhaustive list of practices that increase federal costs and vary with the rate of FFP, as we recognize that there may be additional capitation rate development practices that have the same effect and would also be prohibited under this proposed rule. We believe that this proposal will ensure that our regulatory standards for actuarial soundness are consistent with our intent, and that cost-shifting from the state to the federal government does not occur.

Finally, in proposed § 438.4(d)(2), we are proposing to specify that CMS may require a state to provide written documentation and justification, during our review of a state's capitation rates, that any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations or contracts, not otherwise referenced in proposed (d)(1), represent actual cost differences based on the characteristics and mix of the covered services or the covered populations. This proposal is consistent with our proposal at § 438.7(c)(3), to add regulatory text to specify that the adjustments to capitation rates would also be subject to the requirements at § 438.4(b)(1), and to require a state to provide documentation for adjustments permitted under proposed § 438.7(c)(3) to ensure that modifications to a final certified capitation rate comply with our proposed regulatory requirements. We are specifically requesting public comments on these proposed revisions to § 438.4(b)(1) and new proposed § 438.4(d), including on whether these proposed changes are sufficiently clear regarding the rate development practices that are prohibited in § 438.4(b)(1).

3. Rate Development Standards: Technical Correction (§ 438.5(c)(3)(ii))

In the 2016 final rule, we finalized at § 438.5(c)(3) an exception to the base data standard at § 438.5(c)(2) in recognition of circumstances where states may not be able to meet the standard at (c)(2). We explained in the 2016 final rule preamble (81 FR 27574) that states requesting the exception under § 438.5(c)(3) must submit a description of why the exception is

needed and a corrective action plan detailing how the state would bring their base data into compliance no more than 2 years after the rating period in which the deficiency was discovered.

Regrettably, the regulation text regarding the corrective action timeline at § 438.5(c)(3)(ii) was not as consistent with the preamble or as clear as we intended. The regulation text finalized in 2016 provides that the state must adopt a corrective action plan to come into compliance ''no later than 2 years from the rating period for which the deficiency was identified.'' The preamble text described the required corrective action plan as detailing how the problems ''would be resolved in no more than 2 years after the rating period in which the deficiency was discovered.'' This discrepancy resulted in ambiguity that confused some stakeholders as to when the corrective action plan must be completed and their base data must be in compliance. To remove this ambiguity, we propose to replace the word ''from'' at § 438.5(c)(3)(ii) with the phrase ''after the last day of.'' We also note that the preamble used the term ''discovered'', while the regulatory text used the term ''identified.'' We propose to retain the term ''identified'' in the regulatory text since we believe this term is more appropriate in this context. We believe that this proposed change would clarify the corrective action plan timeline for states to achieve compliance with the base data standard; that is, states would have the rating year for which the corrective action period request is made, plus 2 years following that rating year to develop rates using the required base data. For example, if the state's rate development for calendar year 2018 does not comply with the base data requirements, the state would have 2 calendar years after the last day of the 2018 rating period to come into compliance. This means that the state's rate development for calendar year 2021 would need to use base data that is compliant with § 438.5(c)(2).

We solicit comment on our proposal and whether any additional clarification is necessary.

4. Special Contract Provisions Related to Payment (§ 438.6)

a. Risk-Sharing Mechanism Basic Requirements (§ 438.6(b))

In the ''Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability'' proposed rule (the 2015 proposed rule) (80 FR 31098, June 1, 2015), we proposed to redesignate the basic requirements for risk contracts previously in § 438.6(c)(2) as § 438.6(b). In § 438.6(b)(1), we proposed a non-exhaustive list of risk-sharing mechanisms (for example, reinsurance, risk corridors, and stop-loss limits) and required that all such mechanisms be specified in the contract. In the preamble, we stated our intent to interpret and apply § 438.6(b)(1) to any mechanism or arrangement that has the effect of sharing risk between the MCO, PIHP, or PAHP, and the state (80 FR 31122). We did not receive comments on paragraph (b)(1) and finalized the paragraph as proposed in the 2016 final rule (81 FR 27578) with one modification.

In the 2016 final rule, we included at § 438.6(c)(5)(i) the standard from the then-current rule (adopted in 2002 in the ''Medicaid Program; Medicaid Managed Care: New Provisions'' final rule (67 FR 40989, June 14, 2002) (hereinafter referred to as the ''2002 final rule'')) that risk-sharing mechanisms must be computed on an actuarially sound basis. That element of the 2016 final rule was inadvertently omitted in the 2015 proposed rule. As managed care contracts are risk-based contracts, mechanisms that share or distribute risk between the state and the managed care plan are inherently part of the capitation rates paid to plans for bearing the risk. Therefore, the risk-sharing mechanisms should be developed in conjunction with the capitation rates and using the same actuarially sound principles and practices.

Risk-sharing mechanisms are intended to address the uncertainty inherent in setting capitation rates prospectively. As such, we expected states to identify and apply risk-sharing requirements prior to the start of the rating period. Because we believed that the final rule was clear on the prospective nature of risk-sharing and our expectations around the use of risk-sharing mechanisms, we did not specifically prohibit retroactive use. However, since publication of the 2016 final rule, we have found that some states have applied new or modified risk-sharing mechanisms retrospectively; for example, some states have sought approval to change rates after the claims experience for a rating period became known to the state and the managed care plan. We acknowledge the challenges in setting prospective capitation rates and encourage the use of appropriate risk-sharing mechanisms. In selecting and designing risk-sharing mechanisms, states and their actuaries are required to only use permissible strategies, use appropriate utilization and price data, and establish reasonable risk-sharing assumptions.

Despite a state's best efforts to set accurate and appropriate capitation rates, unexpected events can occur during a rating period that necessitate a retroactive adjustment to the previously paid rates. When this occurs, § 438.7(c)(2) provides the requirements for making a retroactive rate adjustment. Section 438.7(c)(2) clarifies that the retroactive adjustment must be supported by an appropriate rationale and that sufficient data, assumptions, and methodologies used in the development of the adjustment must be described in sufficient detail and submitted in a new rate certification along with the contract amendment.

To address the practice of adopting or amending risk-sharing mechanisms retroactively, we propose to amend § 438.6(b)(1) to require that risk-sharing mechanisms be documented in the contract and rate certification documents prior to the start of the rating period. As described in the 2017 Medicaid Managed Care Rate Development Guide,[3] we believe it is important to include a description in the rate certification, especially if the development of risk-sharing mechanisms has any implications for the Medical Loss Ratio (MLR) and items that factor into the assumptions for certification of the final capitation rate for each risk contract. To ensure clarity, we are also proposing to amend the regulation at § 438.6(b)(1) to explicitly prohibit retroactively adding or modifying risk-sharing mechanisms described in the contract or rate certification documents after the start of the rating period.

We acknowledge that our proposed requirement that risk-sharing mechanisms be documented in a state's contract and rate certification documents prior to the start of the rating period means, as a practical matter, that states electing to use risk-sharing mechanisms would have to submit contracts and rate certifications to CMS prior to the start of the rating period. We note here that section 1903(m)(2)(A)(iii) of the Act, as well as implementing regulations at § 438.806, require that the Secretary must provide prior approval for MCO contracts that meet certain value thresholds before states can claim FFP. This longstanding requirement is

[3] Centers for Medicare & Medicaid Services. 2017 Medicaid Managed Care Rate Development Guide. *https://www.medicaid.gov/medicaid/managed-care/downloads/2017-medicaid-managed-care-rate-development-guide.pdf.*

implemented in the regulation at § 438.806(c), which provides that FFP is not available for an MCO contract that does not have prior approval from CMS. CMS has, since the early 1990s, interpreted and applied this requirement by not awarding FFP until the contract has been approved and permitting FFP back to the initial date of a contract approved after the start of the rating period if an approvable contract were in place between the state and the managed care plan. This practice is reflected in the State Medicaid Manual, § 2087.

Lastly, the proposed change would make § 438.6(b)(1) more consistent with § 438.7(b)(5), which requires the rate certification to describe all risk-adjustment methodologies. While risk mitigation methodologies (which address which parties bear the risk of financial loss under the contract) are not risk-adjustment methodologies (which address compensation based on the health status of enrollees), we believe they have a similar impact on payment to the managed care plan and that the same rules about being described in the rate certification should apply. The current regulation text in § 438.6(b)(1) is not explicit that risk mitigation methodologies be in the rate certification and our proposal would revise the regulation to explicitly include this requirement.

We solicit comments on these proposed changes.

b. Delivery System and Provider Payment Initiatives Under MCO, PIHP, or PAHP Contracts (§ 438.6(a) and (c))

As finalized in the 2016 final rule, § 438.6(c)(1) permits states to, under the circumstances enumerated in § 438.6(c)(1)(i) through (iii), direct the managed care plan's expenditures under the contract. Among other criteria, such directed payment arrangements require prior approval by CMS, per § 438.6(c)(2); our approval is based on meeting the standards listed in § 438.6(c)(2), including that the state expects the directed payment to advance at least one of the goals and objectives in the state's quality strategy for its Medicaid managed care program. We have been reviewing and approving directed payment arrangements submitted by states since the 2016 final rule, and we have observed that a significant number of them require managed care plans to adopt minimum rates, and that most commonly, these minimum rates are those specified under an approved methodology in the Medicaid state plan. Additionally, most of these types of directed payment arrangements seek to accomplish the same goal in the state's quality strategy—to ensure adequate access to providers.

Due to the frequency and similarities of these types of directed payment arrangements, we believe that they should be specifically addressed in § 438.6(c)(1)(iii). Therefore, at § 438.6(a), we propose to add a definition for ''state plan approved rates'' to mean amounts calculated as a per unit price of services described under CMS approved rate methodologies in the state plan. We also propose to revise § 438.6(c)(1)(iii)(A) to specifically reference a directed payment arrangement that is based on an approved state plan rate methodology. As with all directed payment arrangements under § 438.6(c), a directed payment arrangement established under proposed paragraph (c)(1)(iii)(A) would have to be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices.

We note here that supplemental payments contained in a state plan are not, and do not constitute, state plan approved rates as proposed in § 438.6(a); we propose to include a statement to this effect under proposed paragraph (c)(1)(iii)(A). For the purposes of this proposed rule, a rate described in the approved rate methodology section of the state plan would reflect only the per unit price of particular services. Supplemental payments are not calculated or paid based on the number of services rendered, and therefore, are separate and distinct from state plan approved rates under this proposed rule. We also propose to define supplemental payments in § 438.6(a) as amounts paid by the State in its FFS Medicaid delivery system to providers that are described and approved in the state plan or under a waiver and are in addition to the amounts calculated through an approved state plan rate methodology.

Further, we propose to redesignate current paragraph § 438.6(c)(1)(iii)(A) as (c)(1)(iii)(B) and to include a revision to distinguish a minimum fee schedule for network providers that provide a particular service from use of the state plan approved rates. Proposed paragraphs (c)(1)(iii)(A) and (B) would now recognize two distinct minimum fee schedule directed payment arrangements. To accommodate our proposal, we also propose to redesignate current paragraphs (c)(1)(iii)(B) and (C) as paragraphs (c)(1)(iii)(C) and (D), respectively.

As we have reviewed and approved directed payment arrangements submitted by states since publication of the 2016 final rule, we have observed that our regulation does not explicitly address some types of potential directed payments that states are seeking to implement. For example, some states are experimenting with payment models that use a cost-based reimbursement, a Medicare equivalent reimbursement, an average commercial rate reimbursement, or reimbursement based on another market-based standard. To encourage states to continue developing payment models that produce optimal results for their local markets and to clarify how the regulatory standards apply in such cases, we are also proposing to add a new paragraph § 438.6(c)(1)(iii)(E) that would allow states to require managed care plans to adopt a cost-based rate, a Medicare equivalent rate, a commercial rate, or other market-based rate for network providers that provide a particular service under the contract. We believe that authorizing these additional types of payment models for states to implement would eliminate any need for states to modify their payment models as only minimum or maximum fee schedules to fit neatly into the construct of the current rule. In addition, adopting regulation text specific to these other methodologies for specific fee schedules is consistent with our policy to provide flexibility to the state where possible.

Along with the proposed changes in § 438.6(c)(1)(iii)(A), we are also proposing a corresponding change to the approval requirements in § 438.6(c)(2). In the 2016 final rule, we established an approval process that requires states to demonstrate in writing that payment arrangements adopted under § 438.6(c)(1)(i) through (iii) meet the criteria specified in § 438.6(c)(2) prior to implementation. Since implementing this provision of the 2016 final rule, states have noted that the approval process for contract arrangements that include only minimum rate methodologies that are already approved by CMS and included in the Medicaid state plan are substantially the same as the approval requirements under the Medicaid state plan. Some states have stated that the written approval process in § 438.6(c)(2) is unnecessary given that a state would have already justified the rate methodology associated with particular services in the Medicaid state plan (or a state plan amendment) to receive approval by CMS that the rates are efficient, economical, and assure quality of care under section 1902(a)(30)(A) of the Act.

Therefore, to avoid unnecessary and duplicative federal approval processes, we propose to eliminate the prior

approval requirement for payment arrangements that are based on state plan approved rates. To do so, we propose to redesignate existing paragraph (c)(2)(ii) as (c)(2)(iii), add a new paragraph (c)(2)(ii), and to redesignate paragraphs § 438.6(c)(2)(i)(A) through (F) as (c)(2)(ii)(A) through (F), respectively. We also propose to revise the remaining paragraph at § 438.6(c)(2)(i) to require, as in the current regulation, that all contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices; we propose to delete the remaining regulatory text from current paragraph (c)(1)(i).

In proposed new paragraph (c)(2)(ii), we would specify prior approval requirements for payment arrangements under paragraphs (c)(1)(i), (ii), and (iii)(B) through (E). For reasons discussed above, the amended paragraph (c)(2)(ii) would also explicitly provide that payment arrangements under paragraph (c)(1)(iii)(A) do not require prior approval from CMS; although, we propose to retain the requirement that such payment arrangements continue to meet the criteria in paragraphs (c)(2)(ii)(A) through (F). We believe that this proposed revision would reduce administrative burden for many states by eliminating the need to obtain written approval prior to implementation of this specific directed payment arrangement that utilizes previously approved rates in the state plan. With the redesignation of paragraph (c)(2)(ii)(A) through (F), we propose to keep in place the existing requirements for CMS approval to be granted.

In the 2016 final rule, we specified at paragraph § 438.6(c)(2)(ii)(C) that contract arrangements which direct expenditures made by the MCO, PIHP, or PAHP under paragraphs (c)(1)(i) or (c)(1)(ii) for delivery system or provider payment initiatives may not direct the amount or frequency of expenditures by managed care plans. We believed that this requirement was necessary to deter states from requiring managed care plans to reimburse particular providers specified amounts with specified frequencies. However, based on our experience in reviewing and approving directed payment arrangements since the 2016 final rule, we now recognize that this provision may have created unintended barriers to states pursuing innovative payment models. Some states have adopted or are pursuing payment models, such as global payment initiatives, which are designed to move away from a volume-driven system to a system focused on value and population health. Moreover, some of these payment models attempt to build on existing pay for performance or integrated care programs, or align with programs implemented by other payers at the state level. These innovative payment models can require that the state direct the amount or frequency of expenditures by the managed care plan to achieve the state's goals for improvements in quality, care, and outcomes under the payment model.

We believe that these innovative payment models necessitate acknowledging the complexity and variation in local market forces and that states need more flexible parameters to effectively negotiate these complex payment arrangements and achieve a more comprehensive transition from volume to value. Therefore, we propose to delete existing § 438.6(c)(2)(ii)(C) which would permit states to direct the amount or frequency of expenditures made by managed care plans under paragraphs (c)(1)(i) or (c)(1)(ii). As a conforming change, we would redesignate existing § 438.6(c)(2)(ii)(D) as § 438.6(c)(2)(iii)(C).

In the 2016 final rule at existing § 438.6(c)(2)(i)(F) (redesignated to paragraph § 438.6(c)(2)(ii)(F) in this proposed rule), we established that a contract arrangement directing a managed care plan's expenditures may not be renewed automatically. While § 438.6(c)(2)(i)(F) does not permit for the automatic renewal of a contract arrangement described in paragraph (c)(1), it does not prohibit states from including payment arrangements in a contract for more than one rating period. We have received numerous payment arrangement proposals from states requesting a multi-year approval of their payment arrangement to align with their delivery system reform efforts or contract requirements.

To provide additional guidance to states on the submission and approval process for directed payments, on November 2, 2017, we issued a CMCS Informational Bulletin (CIB) entitled ''Delivery System and Provider Payment Initiatives under Medicaid Managed Care Contracts'' (available at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib11022017.pdf*). The CIB explained that based on our experience with implementation of § 438.6(c)(2), we recognize that some states are specifically pursuing multi-year payment arrangements to transform their health care delivery systems. The CIB also described that states can develop payment arrangements under § 438.6(c)(1)(i) and (ii), which are intended to pursue delivery system reform, over a period of time that is longer than one year so long as the state explicitly identifies and describes how the payment arrangement would vary or change over the term of the arrangement.

We understand that some payment arrangements, particularly value-based purchasing arrangements or those tied to larger delivery system reform efforts, can be more complex and may take longer for a state to implement. Setting the payment arrangement for longer than a one-year term would provide a state with more time to implement and evaluate whether the arrangement meets the state's goals and objectives to advance its quality strategy under § 438.340. As stated in the CIB, we interpret the regulatory requirements under § 438.6(c) to permit multi-year payment arrangements when certain criteria are met. We set out the criteria in the CIB for multi-year approvals of certain directed payment arrangements, and we now propose to codify those criteria in a new § 438.6(c)(3).

Specifically, we propose in new paragraph (c)(3)(i) that we would condition a multi-year approval for a payment arrangement under paragraphs (c)(1)(i) and (ii) on the following criteria: (1) The state has explicitly identified and described the payment arrangement in the contract as a multi-year payment arrangement, including a description of the payment arrangement by year, if the payment arrangement varies by year; (2) the state has developed and described its plan for implementing a multi-year payment arrangement, including the state's plan for multi-year evaluation, and the impact of a multi-year payment arrangement on the state's goal(s) and objective(s) in the state's quality strategy in § 438.340; and (3) the state has affirmed that it will not make any changes to the payment methodology, or magnitude of the payment, described in the contract for all years of the multi-year payment arrangement without CMS prior approval. If the state determines that changes to the payment methodology, or magnitude of the payment, are necessary, the state must obtain prior approval of such changes using the process in paragraph (c)(2). We note that in addition to codifying criteria for the approval of multi-year payment arrangements, the proposed new paragraph (c)(3)(i) addresses any potential ambiguity in the 2016 final rule regarding the permissibility of states to enter into multi-year payment arrangements with managed care plans. However, the proposed paragraph

(c)(3)(i) would not change the requirement that a payment arrangement that directs a managed care plan's expenditures must meet all of the approval requirements in § 438.6(c)(2), including that the payment arrangement must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices.

Finally, in alignment with our guidance in the November CIB, we propose to specify at paragraph (c)(3)(ii) that the approval of a payment arrangement under paragraph (c)(1)(iii) of this section would be for one rating period. As explained above, while we understand and acknowledge that value-based purchasing payment arrangements or those tied to larger delivery system reform efforts can be more complex and may take longer for a state to implement, we believe that more traditional payment arrangements and fee schedules under paragraph (c)(1)(iii) should continue to be reviewed and evaluated on an annual basis by both states and CMS. We believe that it is important to continue ensuring that such payment arrangements under paragraph (c)(1)(iii) continue to be consistent with states' and our goals and objectives for directed payments under Medicaid managed care contracts.

We solicit comments on these proposals.

c. Pass-Through Payments Under MCO, PIHP, and PAHP Contracts (§ 438.6(d))

In the 2016 final rule, and the 2017 pass-through payment final rule (82 FR 5415), we finalized a policy to limit state direction of payments, including pass-through payments, at § 438.6(c) and (d). We defined pass-through payments at § 438.6(a) as any amount required by the state, and considered in calculating the actuarially sound capitation rate, to be added to the contracted payment rates paid by the MCO, PIHP, or PAHP to hospitals, physicians, or nursing facilities that is not for the following purposes: A specific service or benefit provided to a specific enrollee covered under the contract; a provider payment methodology permitted under § 438.6(c)(1)(i) through (iii) for services and enrollees covered under the contract; a subcapitated payment arrangement for a specific set of services and enrollees covered under the contract; graduate medical education (GME) payments; or federally-qualified health center (FQHC) or rural health clinic (RHC) wrap around payments. We noted in our 2017 pass-through payment final rule that a distinguishing characteristic of a pass-through payment is that a managed care plan is contractually required by the state to pay providers an amount that is disconnected from the amount, quality, or outcomes of services delivered to enrollees under the contract during the rating period of the contract (82 FR 5416).[4] When managed care plans only serve as a conduit for passing payments to providers independent of delivered services, such payments reduce managed care plans' ability to control expenditures, effectively use value-based purchasing strategies, implement provider-based quality initiatives, and generally use the full capitation payment to manage the care of enrollees.

In the 2016 final rule, we also noted that section 1903(m)(2)(A) of the Act requires that capitation payments to managed care plans be actuarially sound and clarified our interpretation of that standard as meaning that payments under the managed care contract must align with the provision of services to beneficiaries covered under the contract. We clarified the statutory and regulatory differences between payments made on a FFS basis and on a managed care basis (81 FR 27588). We provided an analysis and comparison of section 1902(a)(30)(A) of the Act regarding FFS payments and implementing regulations that impose aggregate upper payment limits (UPL) on rates for certain types of services or provider types to section 1903(m)(2)(A) regarding the requirement that capitation payments in managed care contracts be actuarially sound and implementing regulations that require payments to align with covered services delivered to eligible populations. Based on that analysis, we concluded that pass-through payments are not consistent with our regulatory standards for actuarially sound rates because they do not tie provider payments with the provision of services. Despite this conclusion, we acknowledged in the 2016 final rule that, for many states, pass-through payments have been approved in the past as part of Medicaid managed care contracts and served as a critical source of support for safety-net providers caring for Medicaid beneficiaries (81 FR 27589). We therefore adopted a transition period for states that had already transitioned services or eligible populations into managed care and had pass-through payments in their managed care contracts as part of the regulations that generally prohibit the use of pass-through payments in actuarially sound capitation rates. Although § 438.6(d) is not explicitly limited to pass-through payments in the context of an established managed care program, the use of pass-through payments in place as of the 2016 final rule as an upper limit on permitted pass-through payments during the transition periods described in § 438.6(d) effectively precludes new managed care programs from adopting pass-through payments.

We used the 2016 final rule to identify the pass-through payments in managed care contract(s) and rate certification(s) that are eligible for the pass-through payment transition period. We provided a detailed description of the policy rationale (81 FR 27587 through 27592) for why we established pass-through payment transition periods and limited pass-through payments to hospitals, nursing facilities, and physicians, and this policy rationale has not changed. We focused on the three provider types identified in § 438.6(d) because these are the most common provider types to which states make supplemental payments within federal UPLs under state plan authority.

Since implementation of the 2016 and 2017 final rules, we have worked with many states that have not transitioned some or all services or eligible populations from their FFS delivery system into a managed care program. Data from the CMS Medicaid Managed Care Data Collection System (MMCDCS) show that a large and growing majority of states contract with MCOs and that states are also rapidly expanding their use of MCOs to reach larger geographic areas, serve more medically complex beneficiaries, and deliver long-term services and supports (LTSS). Nationally, two-thirds (68.1 percent) of all Medicaid beneficiaries were enrolled in comprehensive MCOs in 2016, up from 65.5 percent in 2015. According to MMCDCS data, as of July 2016, 37 states have 50 percent or more of their Medicaid populations enrolled in a comprehensive MCO, up from 34 states in 2015; while 26 states have 20 percent or more of their Medicaid populations in FFS, and three of those states have 100 percent (Alaska and Connecticut) or almost 100 percent (Wyoming) of their Medicaid populations in FFS.[5]

Some states would like to begin to transition some services or eligible

[4] Medicaid Program; The Use of New or Increased Pass-Through Payments in Medicaid Managed Care Delivery Systems, Final Rule, (82 FR 5415–5429, January 18, 2017).

[5] Medicaid Managed Care Enrollment and Program Characteristics, 2016; Updated Spring 2018. Available at *https://www.medicaid.gov/medicaid/managed-care/downloads/enrollment/2016-medicaid-managed-care-enrollment-report.pdf.*

populations from FFS to managed care, but would also like to continue to make supplemental payments to hospitals, physicians, or nursing facilities. We recognize the challenges associated with transitioning supplemental payments into payments based on the delivery of services or value-based payment structures. The transition from one payment structure to another requires robust provider and stakeholder engagement, broad agreement on approaches to care delivery and payment, establishing systems for measuring outcomes and quality, planning, and evaluating the potential impact of change on Medicaid financing mechanisms. We also recognize that implementing value-based payment structures or other, delivery system reform initiatives, and addressing transition issues, including ensuring adequate base rates, is central to both delivery system reform and to strengthening access, quality, and efficiency in the Medicaid program.

To address states' requests to continue making supplemental payments for certain services and assist states with transitioning some or all services or eligible populations from a FFS delivery system into a managed care delivery system, we propose to add a new § 438.6(d)(6) that would allow states to make pass-through payments under new managed care contracts during a specified transition period if certain criteria are met. Here and in the regulation text proposed at § 438.6(d)(6), we refer to transitioning services from FFS Medicaid to Medicaid managed care plan(s); this phrasing refers both to when a state expands the scope of its managed care program in terms of services (for example, offering behavioral health services in Medicaid managed care that were previously provided under Medicaid FFS for populations that are already enrolled in managed care) and populations (that is, adding new populations to Medicaid managed care when previously those populations received all Medicaid services through FFS).

Specifically, we propose in § 438.6(d)(6)(i) through (iii) that states may require managed care plans to make pass-through payments, as defined in § 438.6(a), to network providers that are hospitals, nursing facilities, or physicians, when Medicaid populations or services are initially transitioning or moving from a Medicaid FFS delivery system to a Medicaid managed care delivery system, provided the following requirements are met: (1) The services will be covered for the first time under a Medicaid managed care contract and were previously provided in a Medicaid FFS delivery system prior to the first rating period, as defined in § 438.2, of the specified pass-through payment transition period; (2) the state made supplemental payments, as defined in § 438.6(a), to hospitals, nursing facilities, or physicians for those specific services that will be covered for the first time under a Medicaid managed care contract during the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period (this 12-month period is the same standard that is currently codified in existing pass-through payment regulations at § 438.6(d)(2) in relation to the calculation of the base amount for hospital pass-through payments under § 438.6(d)(3)); and (3) the aggregate amount of the pass-through payments that the state requires the managed care plan to make is less than or equal to the amounts calculated in proposed paragraphs (d)(6)(iii)(A), (B), or (C) for the relevant provider type for each rating period of the pass-through payment transition period—this requirement means that the aggregate amount of the pass-through payments for each rating period of the specified pass-through payment transition period that the state requires the managed care plan to make must be less than or equal to the payment amounts attributed to and actually paid as FFS supplemental payments to hospitals, nursing facilities, or physicians during the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period for each applicable provider type.

We also propose at § 438.6(d)(6)(iv) that the state may require the MCO, PIHP, or PAHP to make pass-through payments for Medicaid populations or services that are transitioning from a FFS delivery system to a managed care delivery system for up to 3 years from the beginning of the first rating period in which the services were transitioned from payment in a FFS delivery system to a managed care contract, provided that during the 3 years, the services continue to be provided under a managed care contract with an MCO, PIHP, or PAHP.

We propose paragraphs (d)(6)(iii)(A), (B) and (C) to address the maximum aggregate pass-through payment amounts to hospitals, nursing facilities, and physicians for each rating period of the specified 3-year pass-through payment transition period; that is, we propose three paragraphs to determine the maximum aggregate amount of the pass-through payments for each rating period of the 3-year pass-through payment transition period that the state can require the managed care plan to make to ensure that pass-through payments under proposed § 438.6(d)(6) are less than or equal to the payment amounts attributed to and actually paid as FFS supplemental payments to hospitals, nursing facilities, or physicians, respectively, during the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period for each applicable provider type. This means that the aggregate pass-through payments under the new 3-year pass-through payment transition period must be less than or equal to the payment amounts attributed to and actually paid as FFS supplemental payments in Medicaid FFS.

To include pass-through payments in the managed care contract(s) and capitation rates(s) under proposed new paragraph (d)(6), the state would have to calculate and demonstrate that the aggregate amount of the pass-through payments for each rating period of the pass-through payment transition period is less than or equal to the amounts calculated in proposed paragraphs (d)(6)(iii)(A), (B), or (C) for the relevant provider type. In § 438.6(d)(6)(iii), we propose that for determining the amount of each component for the calculations contained in proposed paragraphs (d)(6)(iii)(A), (B), and (C), the state must use the amounts paid for services during the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period. As a practical matter, the proposed calculation would require the state to use Medicaid Management Information System (MMIS) adjudicated claims data from the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period. This timeframe and use of 2-year old data was chosen so that the state has complete utilization data for the service type that would be subject to the pass-through payments. The proposed calculation would also require the state to restrict the amount used in each component of the calculation to the amount actually paid through a supplemental payment for each applicable provider type. We note that our proposal would generally refer to the same provider types as Medicaid FFS specified under 42 CFR part 447. The calculation process under these proposed paragraphs would involve 4 basic steps:

- *Step 1:* For each applicable provider type, identify the actual payment amounts that were attributed to and actually paid as FFS supplemental payments during the 12-month period

immediately 2 years prior to the first rating period of the pass-through payment transition period.

- *Step 2:* Divide (a) the payment amounts paid through payment rates for the services that are being transitioned from payment in FFS to the managed care contract for each applicable provider type by (b) the total payment amounts paid through payment rates for services provided in FFS for each applicable provider type to determine the ratio. In determining these amounts, the state must use the amounts paid for each provider type during the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period.
- *Step 3:* Multiply the amount in Step 1 by the ratio produced by Step 2.
- *Step 4:* The aggregate amount of pass-through payments that the state may require the MCO, PIHP, or PAHP to make for each rating period of the 3-year pass-through payment transition period must be demonstrated to be less than or equal to the result achieved in Step 3.

Following the above steps, we offer the following formula to help illustrate the aggregate amount of pass-through payments for each rating period of the pass-through payment transition period for each applicable provider type:

$$\textit{Permissible Aggregate Payment Amounts}$$

$$= (\textit{Medicaid FFS Supplemental Payments Paid to Provider Type X})$$

$$\times \left(\frac{\textit{Amounts Paid in Medicaid FFS to Provider Type X through Medicaid for Transitioning Services}}{\textit{Total Amounts Paid in Medicaid FFS to Provider Type X for All Services}}\right)$$

To demonstrate how the calculation is performed, we provide the following example in which we assume that a state Medicaid program paid $60 million in claims in FFS for inpatient hospital services in CY 2016. To acknowledge the Medicaid FFS UPL, we assume that those same services would have been reimbursed at $100 million using Medicare payment principles. The difference between the amount that Medicare would have paid and the amount Medicaid actually paid in claims is $40 million. For Step 1, of the $40 million difference, the state actually paid $20 million in supplemental payments to inpatient hospitals in CY 2016. For this example, we assume that CY 2016 is the 12-month period immediately 2 years prior to the first rating period of the pass-through payment transition period in which inpatient hospital services will be transitioned to a managed care contract; therefore, we assume the pass-through payments are for CY 2018. This transition to managed care could be either by moving Medicaid beneficiaries from FFS to coverage under managed care contracts that cover inpatient hospital services or by moving inpatient hospital services into coverage under managed care contracts.

Next, in Step 2, the state determines the ratio of the payment amounts paid in FFS for inpatient hospital services that will be transitioned from payment in a FFS delivery system to the managed care contract within the specific provider category and requisite period in relation to the total payment amounts paid in FFS for all inpatient hospital services within the same provider category during the same period. For example, if the state paid $36 million in FFS for inpatient hospital services for a specific population out of the $60 million in total claims paid in FFS for inpatient hospital services during 2016, and the state wants to transition the population associated with the $36 million in paid claims to the managed care contract, then the ratio is $36 million divided by $60 million, or 60 percent.

In Step 3, the state would multiply the $20 million in actual supplemental payments paid by 60 percent, resulting in $12 million, which is the amount described in Step 4 as the total amount that the state would be permitted to require the managed care plans to make in pass-through payments to inpatient hospitals for each rating period during the pass-through payment transition period described in proposed paragraph (d)(6)(iv).

In an effort to provide network providers, states, and managed care plans with adequate time to design and implement payment systems that link provider reimbursement with services, we also propose, in new paragraph (d)(6)(iv), to allow states a transition period for up to 3 years to transition FFS supplemental payments into payments linked to services and utilization under the managed care contract. We are proposing the 3-year pass-through payment transition period to provide states with time to integrate pass-through payment arrangements into allowable payment structures under actuarially sound capitation rates, including value-based purchasing, enhanced fee schedules, Medicaid-specific delivery system reform, or the other approaches consistent with § 438.6(c). A state may elect to use a shorter transition period but would be permitted a maximum of 3 years to phase out the pass-through payments. We believe that the proposed 3-year pass-through payment transition period in paragraph (d)(6)(iv) is appropriate because states have not yet transitioned these services (and corresponding supplemental payments) into managed care contracts; therefore, states should be in a better position to design payment structures that appropriately account for these payments during the transition to managed care (unlike the current pass-through payments rules, which only provide transition periods for pass-through payments that were already incorporated into managed care contracts and rates prior to the adoption of specific limits on the state direction of payments made by managed care plans). We specifically invite comment on whether the 3-year pass-through payment transition period is the appropriate transition time.

Unlike the 2016 final rule, this proposal would not set a specific calendar date by which states must end pass-through payments; rather, our proposal would provide a transition period for up to 3 years from the beginning of the first rating period in which the services were transitioned from payment in a FFS delivery system to a managed care contract, provided that during the 3 years, the services continue to be provided under a managed care contract with an MCO, PIHP, or PAHP. By providing states, network providers, and managed care plans time and flexibility to integrate current pass-through payment arrangements into permissible managed care payment structures, states would be able to avoid disruption to safety-net provider systems that they have developed in their Medicaid programs.

We solicit comments on our proposals.

d. Payments to MCOs and PIHPs for Enrollees That Are a Patient in an Institution for Mental Disease (IMD) (§ 438.6(e))

Under the policies we adopted in the 2016 final rule at § 438.6(e), we permitted FFP for a full monthly capitation payment to an MCO or PIHP for an enrollee aged 21 to 64 who received inpatient treatment in an institution for mental disease (IMD) for part of the month when certain requirements are met, including a requirement that the stay in the IMD be for no more than 15 days in the month for which the capitation payment is made (81 FR 27563). Since publication of the 2016 final rule, we have heard from states and other stakeholders that FFP should be provided for capitation payments made for months that include stays longer than 15 days, especially on behalf of Medicaid enrollees who may require substance use disorder (SUD) treatment as a result of the ongoing opioid crisis.

We considered proposing changes to the regulation at § 438.6(e); however, after careful review, we still believe that the underlying legal analysis regarding the transfer of risk that underpinned the policy in the 2016 final rule is appropriate. We have also conducted a literature and data review since publication of the rule but could not identify any new data sources other than those we relied upon in the 2016 final rule that supported 15 days (81 FR 27560). We request public comment on additional data sources that we should review. We also have concerns about the potential for cost-shifting to the federal government. Therefore, to address concerns expressed by Medicaid directors regarding the 15-day limit in the context of SUD treatment and the ongoing opioid crisis, we encourage states to apply for a section 1115(a) SUD demonstration to enable states to receive FFP for longer lengths of stay in IMDs. In November 2017, we developed the current section 1115(a) SUD demonstration initiative [6] that greatly simplified the application and approval process, offered more streamlined and flexible components, and included enhanced monitoring and evaluation features. We have already approved several states and are actively working with additional states that have indicated an interest in applying.

[6] SMD #17–003: Strategies to Address the Opioid Epidemic: *https://www.medicaid.gov/federal-policy-guidance/downloads/smd17003.pdf.*

5. Rate Certification Submission (§ 438.7)

Section 438.7(c)(3) gives states flexibility to make *de minimis* rate adjustments during the contract year by enabling states to increase or decrease the capitation rate certified per rate cell by 1.5 percent (resulting in an overall 3 percent range) without submitting a revised rate certification. We stated in the 2016 final rule that the fluctuation of plus or minus 1.5 percent does not change the actuarial soundness of a capitation rate as that percentage is generally not more than the risk margin incorporated into most states' rate development process and reasoned that the resulting rate would remain actuarially sound (81 FR 27568). By giving states the flexibility to make small adjustments around the certified rate, we intended to ease the administrative burden of rate review on states while meeting our goals of transparency and integrity in the rate-setting process.

Since the publication of the 2016 final rule, some stakeholders have expressed a desire for CMS to clearly express that once a state has certified the final capitation rate paid per rate cell under each risk contract, the state can adjust the certified rate plus or minus 1.5 percent at any time within the rating period without submitting justification to CMS. We clarify here that when states are adjusting a final certified rate within the contract year within the range of 1.5 percent up or down from the final certified rate, states do not need to submit a revised rate certification or justification to CMS, unless documentation is specifically requested by CMS in accordance with our proposed revisions in paragraph (c)(3). Proposed § 438.7(c)(3) would include the existing text authorizing the state to increase or decrease the capitation rate per rate cell up to 1.5 percent without submitting a revised rate certification. Proposed paragraph (c)(3) would also retain the remaining text in current § 438.7(c)(3) that such adjustments to the final certified rate must be consistent with a modification of the contract as required in § 438.3(c) and adds new proposed text to specify that the adjustments would also be subject to the requirements at § 438.4(b)(1), and that we would be able to require a state to provide documentation for adjustments permitted under § 438.7(c)(3) to ensure that modifications to a final certified capitation rate comply with the requirements in §§ 438.3(c) and (e), and 438.4(b)(1).

In the 2016 final rule, we highlighted our concerns that different capitation rates based on the FFP associated with a particular population could be indicative of cost shifting from the state to the federal government and were not consistent with generally accepted actuarial principles (81 FR 27566). The rate development standards we instituted with the final rule sought to eliminate such practices. The +/− 1.5 percent rate changes permitted in § 438.7(c)(3) are not intended to be used by states to shift costs to the federal government. To ensure against cost shifting, we are explicitly requiring that any changes of the capitation rate within the permissible 1.5 percent are subject to the requirement in § 438.4(b)(1), which prohibits differing capitation rates based on FFP and requires that any proposed differences among capitation rates according to covered populations be based on valid rate development standards and not based on the rate of FFP associated with the covered populations. In addition, § 438.4(b)(1) requires that rates be developed in accordance with § 438.5 and generally accepted actuarial principles and practices; using this cross-reference to regulate mid-year changes of capitation rates within the +/− 1.5 percent range ensures that these changes are not arbitrary or designed to shift costs to the federal government. The proposed regulation permits CMS to require documentation as to how the adjusted rate is consistent with that requirement and other criteria related to the actuarial soundness of rates.

Nationally, states are expanding their managed care programs to include more Medicaid beneficiaries, and both plans and states have requested additional guidance regarding our rate review and approval process. We believe that additional guidance can serve to enhance the efficiency of the review and approval process for states and CMS alike, particularly for states that are new to Medicaid managed care. When states first transition from a FFS delivery system to a managed care delivery system, they often need extra assistance to enable them to be more efficient in developing procurement processes and to increase their likelihood of setting actuarially sound capitation rates. Additionally, competitive procurement processes can be costly and time consuming when considering the scope and number of stakeholders involved in the process. Rate setting can be particularly challenging when it is part of the competitive bidding process. As such, we believe that additional guidance from CMS may benefit those

states and us in the rate review and approval process.

To respond to these needs, we propose to add § 438.7(e) to commit CMS to, at least annually, issuing guidance that describes: (1) The federal standards for capitation rate development; (2) the documentation required to determine that the capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of a contract; (3) the documentation required to determine that the capitation rates have been developed in accordance part 438; (4) any updates or developments in the rate review process to reduce state burden and facilitate prompt actuarial reviews; and (5) the documentation necessary to demonstrate that capitation rates competitively bid through a procurement process have been established consistently with the requirements of § 438.4 through § 438.8. We note here that CMS would not adopt new requirements in this guidance; such guidance would only interpret the regulations and specify procedural rules for complying with the requirements in the rule, such as the information provided in rate certifications. This guidance will be published as part of the annual rate guide for Medicaid managed care under the PRA package, CMS–10398 #37, OMB control number 0938–1148.

Although we have published rate review guidance every year since 2014, particularly for those areas described in proposed § 438.7(e)(1) through (3), we propose to codify this practice in § 438.7(e) to demonstrate our commitment to efficient review and approval processes. Although the current rate review guidance has not previously addressed those areas described in proposed § 438.7(e)(4) and (5), we propose that annual guidance include these because states have specifically requested guidance in these areas. We will continue to work with states to ensure greater transparency regarding the rate review process and ensure that states are optimally informed to prepare and submit rate certifications for our review and approval.

We solicit comments on our proposals and whether additional areas of guidance would be helpful to states.

6. Medical Loss Ratio (MLR) Standards: Technical Correction (§ 438.8)

In the 2015 proposed rule (80 FR 31109), we proposed at § 438.8(e)(4) that expenditures related to fraud prevention activities, as set forth in § 438.608(a)(1) through (5), (7), (8) and (b), may be attributed to the numerator but would be limited to 0.5 percent of MCO's, PIHP's, or PAHP's premium revenues. The MLR numerator is defined in § 438.8(e); the numerator of an MCO's, PIHP's, or PAHP's MLR for a MLR reporting year is the sum of the MCO's, PIHP's, or PAHP's incurred claims; the MCO's, PIHP's, or PAHP's expenditures for activities that improve health care quality; and fraud prevention activities. This proposal was never finalized and does not align with the MLR requirements for Medicare or the private market. We proposed a corresponding requirement, at paragraph (k)(1)(iii), for submission by each managed care plan of data showing the expenditures for activities described in § 438.608(a)(1) through (5), (7), (8) and (b). In the 2016 final rule (81 FR 27530), we did not finalize § 438.8(e)(4) as proposed, and instead finalized § 438.8(e)(4) to provide that MCO, PIHP, or PAHP expenditures on activities related to fraud prevention, as adopted for the private market at 45 CFR part 158, would be incorporated into the Medicaid MLR calculation in the event the private market MLR regulations were amended. However, we erroneously finalized § 438.8(k)(1)(iii) as proposed instead of referencing the updated finalized regulatory language in § 438.8(e)(4). Therefore, we are proposing in this rule to revise § 438.8(k)(1)(iii) to replace ''expenditures related to activities compliant with § 438.608(a)(1) through (5), (7), (8) and (b)'' with ''fraud prevention activities as defined in § 438.8(e)(4)'' to be consistent with our changes to § 438.8(e)(4) in the previous final rule. We are also proposing to correct a technical error in paragraph (e)(4) by removing the phrase ''fraud prevention as adopted'' and adding in its place the phrase ''fraud prevention consistent with regulations adopted'' to clarify the regulatory text.

7. Non-Emergency Medical Transportation PAHPs (§ 438.9)

In the 2016 final rule, at § 438.9(b)(2), we inadvertently failed to exempt NEMT PAHPs from complying with § 438.4(b)(9). Section 438.9(b) generally exempts NEMT PAHPs from complying with regulations in part 438 unless the requirement is listed. Under the regulation, NEMT PAHPs are not required to comply with the MLR standards. Therefore, we believe that the inclusion of all of § 438.4 in § 438.9(b)(2) causes a conflict because § 438.4(b)(9) specifically addresses states' responsibility to develop capitation rates to achieve a medical loss ratio of at least 85 percent. To eliminate that conflict, we propose to revise § 438.9(b)(2) by adding ''except § 438.4(b)(9).''

8. Information Requirements (§ 438.10)

a. Language and Format (§ 438.10(d))

In the 2016 final rule, we finalized provisions at § 438.10(d)(2), (d)(3), and (d)(6)(iv), requiring that states and managed care plans include taglines in prevalent non-English languages and in large print in all written materials for potential enrollees and enrollees. Based on print document guidelines from the American Printing House for the Blind, Inc., we defined large print to mean no smaller than 18-point font (81 FR 27724).[7] Taglines required to be large print are those that explain the availability of written translation or oral interpretation, how to request auxiliary aids and services for individuals who have limited English proficiency or a disability, and the toll-free phone number of the entity providing choice counseling services.

Our goal remains to ensure that materials for enrollees and potential enrollees are accessible for individuals who are vision-impaired. However, since the publication of the final rule, states and plans have found that requiring taglines in 18-point font size sometimes increases overall document length, thereby decreasing the ease of use by enrollees and eliminating the use of certain effective formats such as postcards and trifold brochures.

To address these issues, we propose to replace the requirement to include taglines on ''all written materials'' with a requirement for taglines only on materials for potential enrollees that ''are critical to obtaining services'' in § 438.10(d)(2). This proposed change aligns the documents that require taglines with the documents that must be translated into prevalent non-English languages and facilitates the use of smaller, more user-friendly documents. We note that states have the ability to require taglines on any additional materials that they choose, as including taglines only on documents that are critical to obtaining services is a minimum standard.

Additionally, we propose to revise § 438.10(d)(2) by deleting the definition of large print as ''no smaller than 18-point'' and adopting the ''conspicuously visible'' standard for taglines that is codified at 45 CFR 92.8(f)(1), a regulation implementing section 1557 of the Patient Protection and Affordable Care Act of 2010 (PPACA) (Pub. L. 111–148, enacted March 23, 2010 as

[7] American Printing House for the Blind, Inc. Print Document Guidelines. *http://www.aph.org/research/design-guidelines/.*

amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010)).[8] Section 1557 of the PPACA prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs, including Medicaid. We believe that adopting a more flexible requirement would encourage states to use effective forms of written communication and avoid unnecessarily long documents. For example, taglines in a font size smaller than 18-point would permit states to more easily use postcards and tri-fold brochures, which may be more effective for relaying certain information since they are shorter and offer more design options for visual appeal. We note again that states would retain the ability to create additional requirements for greater specificity of font size for taglines for written materials subject to § 438.10 as long as they meet the standard of conspicuously-visible and comply with all other federal non-discrimination standards, including providing auxiliary aids and services to ensure effective communications for individuals with disabilities.

In § 438.10(d)(3), we propose to make the same substantive changes proposed for § 438.10(d)(2) above, as well as to reorganize the paragraph for clarity. We believe that combining the requirements for the provision of alternative formats, taglines, and inclusion of the managed care plan's member/customer service unit telephone number into one sentence in paragraph (d)(3), would improve readability and clarity.

Section 438.10(d)(6) addresses requirements for all written materials provided by states and MCOs, PIHPs, PAHPs, primary care case management (PCCM) and PCCM entities to enrollees and potential enrollees. As we are proposing to limit the tagline requirement to materials that are critical to obtaining services, we propose to delete § 438.10(d)(6)(iv).

b. Information for All Enrollees of MCOs, PIHPs. PAHPs, and PCCM Entities: General Requirements (§ 438.10(f))

In the comprehensive revision to federal regulations governing Medicaid managed care in 2002, we required notice to enrollees of a provider's termination within 15 days of a covered plan's receipt or issuance of the termination notice (67 FR 41015). For purposes of this provision, an affected enrollee is one who received his or her primary care from, or was seen on a regular basis by, the terminated provider. We established the 15-day time-period following receipt of notice because we wanted to ensure that enrollees received notice of the provider terminations in advance given the reality that providers often give little notice of their plans to terminate participation in a network (67 FR 41015). Section 438.10(f)(1) requires that a managed care plan must make a good-faith effort to provide notice of the termination of a contracted in-network provider to each affected enrollee within 15 days of receipt or issuance of the termination notice. However, there can be circumstances when plans or providers send a termination notice to meet their contractual obligations but continue negotiating in an effort to resolve the issue(s) that triggered the decision to commence termination procedures. If the issue(s) can be amicably resolved, then the termination notice is sometimes rescinded and the provider remains in the network. In these situations, the issuance of notices by a state to enrollees before resolution efforts have been attempted, can cause alarm and confusion for enrollees who believe that they need to locate a new provider.

In an effort to prevent unnecessary notices from being sent to enrollees, proposed § 438.10(f)(1) would change the requirement that managed care plans issue notices within 15 calendar days after receipt or issuance of the termination notice to the later of 30 calendar days prior to the effective date of the termination or 15 calendar days after the receipt or issuance of the notice. For example, if the plan receives a termination notice from a provider on March 1 for a termination that is effective on May 1, the proposed regulation would contemplate written notice to enrollees be provided by April 1 (30 days prior to effective date) or by March 16 (within 15 days of receipt of the termination notice), whichever is later. In this example, the managed care plan would have to issue a notice to the enrollees by April 1, since it is later.

c. Information for All Enrollees of MCOs, PIHPs. PAHPs and PCCM Entities: Enrollee Handbooks (§ 438.10(g))

In the 2016 final rule, an erroneous reference was included in § 438.10(g)(2)(ii)(B) to ''. . . paragraph (g)(2)(i)(A). . . .'' Because there is no such paragraph as § 438.10(g)(2)(i)(A), we propose in this rule to correct the reference to ''. . . paragraph (g)(2)(ii)(A). . . .''

d. Information for All Enrollees of MCOs, PIHPs. PAHPs and PCCM Entities: Provider Directories (§ 438.10(h))

In the 2016 final rule, we added the requirement at § 438.10(h)(1)(vii) that managed care plans include information in their provider directories on whether the provider has completed cultural competence training. We added this requirement to the final rule in recognition of the linguistic and cultural diversity of Medicaid beneficiaries (81 FR 27724). After the final rule was published, the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016) (the Cures Act) amended section 1902 of the Act,[9] to add requirements for publication of a FFS provider directory.[10] Now that the Congress has established new standards for provider directories in FFS Medicaid, we believe that it is beneficial to Medicaid managed care enrollees to align the requirements for Medicaid managed care with the FFS directories, especially since many managed care enrollees also receive some services on a FFS basis. The proposed amendment would require that the information in the directory include the physician's or provider's cultural and linguistic capabilities, including the languages spoken by the physician or provider or by the skilled medical interpreter providing interpretation services at the physician's or provider's office. The statute does not require information on whether the provider has completed cultural competence training. Therefore, we propose to amend § 438.410(h)(1)(vii) to eliminate the phrase ''and whether the provider has completed cultural competence training.''

In the 2016 final rule, we finalized at § 438.10(h)(3) requirements that information in a paper directory must be updated at least monthly and electronic provider directories must be updated no later than 30 calendar days of receiving updated provider information. In paragraph (h)(1), we clarified that paper provider directories need only be provided upon request, and we encouraged plans to find efficient ways to provide accurate directories within the required timeframes (81 FR 27729).

Since the publication of the 2016 final rule, states and managed care plans have raised concerns about the cost of reprinting the entire directory monthly. While the final rule did not require that the directory be reprinted in its entirety monthly, many managed care plans

[8] Nondiscrimination in Health Programs and Activities final rule (81 FR 31375).

[9] Section 1902(a)(83)(A)(ii)(II) of the Act.

[10] Section 5006 of the Cures Act added paragraph (83)(A)(ii)(II) to section 1902(a) of the Act.

were forced to do so to recognize savings from printing in large quantities. To address this inefficiency, as well as to provide managed care plans with another option for reducing the number of paper directories requested by enrollees due to the lack of access to a computer, we propose to modify the requirements for updating the paper provider directory that would permit less than monthly updates to paper directories if the managed care plan offers a mobile-enabled, electronic directory.

Research has shown that 64 percent of U.S. adults living in households with incomes less than $30,000 a year owned smartphones in 2016.[11] Further, lower-income adults are more likely to rely on a smartphone for access to the internet, because they are less likely to have an internet connection at home.[12] Recent studies show that the majority of Americans have used their smartphones to access information about their health,[13] and consider online access to health information important.[14] We believe that providing mobile-enabled access to online provider directories may provide additional value to enrollees by allowing them to access the information anytime, anywhere which is not feasible with a paper directory. Mobile applications for beneficiaries are increasingly available in programs serving older adults and individuals with disabilities and include access to Medicare marketing materials [15] and medical claims on Blue Button [16] to empower enrollees to better manage and coordinate their healthcare. For enrollees that request a paper directory, we believe the quarterly updates will not significantly disadvantage them as other avenues for obtaining provider information are readily available, such as the managed care plan's customer service or the state's beneficiary support system.

To reflect this change and modify the requirements for updating the paper provider directory to permit less than monthly updates if the managed care plan offers a mobile-enabled directory, we propose several revisions to § 438.10(h)(3). First, we propose to add paragraphs (i) and (ii) to § 438.10(h)(3) which would delineate requirements for paper directories from those for electronic directories. Second, we propose to add paragraphs (i)(A) and (B) which would reflect, respectively, that monthly updates are required if a plan does not offer a mobile enabled directory and that only quarterly updates are required for plans that do offer a mobile enabled directory. Lastly, we propose to make ''directories'' singular (''directory'') at § 438.10(h)(3)(ii) which would avoid implying that a managed care plan must have more than one directory of providers.

We remind managed care plans that some individuals with disabilities, who are unable to access web applications or require the use of assistive technology to access the internet, may require auxiliary aids and services to access the provider directory. In keeping with the requirement that managed care plans must provide auxiliary aids and services to ensure effective communication for individuals with disabilities consistent with section 504 of the Rehabilitation Act of 1973 (Pub. L. 93–112, enacted on September 26, 1973) and section 1557 of the PPACA, these individuals should, upon request, be given the most current provider directories in the same accessible format (paper or electronic) that they receive other materials.

We encourage managed care plans to perform direct outreach to providers on a regular basis to improve the accuracy of their provider data and to ensure that all forms of direct enrollee assistance (such as telephone assistance, live web chat, and nurse help lines) are effective, easily accessible, and widely publicized.

9. Disenrollment: Requirements and Limitations (§ 438.56)

We inadvertently included PCCMs and PCCM entities in paragraph § 438.56(d)(5) related to grievance procedures. Because PCCMs and PCCM entities are not required by § 438.228, which does impose such a requirement on MCOs, PIHPs and PAHPs, to have an appeals and grievance process, we propose to revise § 438.56(d)(5) to delete references to PCCMs and PCCM entities. We note that states may impose additional requirements on their managed care plans but believe that our regulations should be internally consistent on this point.

10. Network Adequacy Standards (§ 438.68)

As discussed in the 2015 proposed rule (80 FR 31144 through 31146), we proposed a new § 438.68 to stipulate that a state must establish network adequacy standards for specified provider types. We proposed in § 438.68(b)(1) that states develop and enforce time and distance standards for specified provider types (if covered under the contract). In that proposed rule, we explained that states were encouraged to use other measures in addition to time and distance. In response to comments on the 2015 proposed rule, we declined to set other national requirements or specific benchmarks for time and distance (for example, 30 miles or 30 minutes) in the 2016 final rule (81 FR 27661). Instead, we noted that we believed it best not to be overly prescriptive and give states the flexibility to build upon the required time and distance standards as they deem appropriate and meaningful for their programs and populations. (81 FR 27661).

In the 2015 proposed rule discussion of the requirement now codified at § 438.68(b)(2), we requested comment on network adequacy standards for LTSS. As noted in the final rule, commenters recommended that we adopt some form of network adequacy standards for LTSS, but the comments were few in number and lacked consensus regarding specific standards that have been used or that have proven adequate to assure network adequacy. For these reasons, we stated that the best strategy was for states to develop their own time and distance standards for LTSS provider types to which a beneficiary travels. Similarly, we did not require any specific type of minimum network adequacy standard for LTSS provider types that travel to the beneficiary, and instead deferred such an analysis to the states (81 FR 27665).

As states have worked to comply with the final rule, they have alerted us to increasing concerns about the appropriateness of uniformly applying time and distance standards. In some situations, time and distance may not be the most effective type of standard for determining network adequacy and some states have found that time and distance analysis produces results that do not accurately reflect provider availability. For example, a state that has a heavy reliance on telehealth in certain areas of the state may find that a provider to enrollee ratio is more useful in measuring meaningful access, as the enrollee could be well beyond a normal time and distance standard but can still easily access many different providers on a virtual basis. A 2017 Brookings/Schaefer Center report notes that in some clinical areas, telemedicine

[11] *http://www.pewinternet.org/fact-sheet/mobile/.*

[12] *Id.*

[13] *http://www.pewresearch.org/fact-tank/2015/04/30/racial-and-ethnic-differences-in-how-people-use-mobile-technology/.*

[14] *https://www.ncbi.nlm.nih.gov/pubmed/27413120.*

[15] 2016 Medicare Marketing Guideline 100.6. *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017MedicareMarketingGuidelines2.pdf.*

[16] *http://bluebuttonconnector.healthit.gov/.*

could make proximity measures obsolete, or counterproductive.[17]

To address states' concerns and ensure that states use the most effective and accurate standards for their programs, we propose to revise § 438.68(b)(1) and (b)(2) by deleting the requirements for states to set time and distance standards and adding a more flexible requirement that states set a quantitative minimum access standard for specified health care providers and LTSS providers. We believe that this change would enable states to choose from a variety of quantitative network adequacy standards that meet the needs of their respective Medicaid programs in more meaningful and effective ways. Quantitative standards that states may elect to use include, but are not limited to, minimum provider-to-enrollee ratios; maximum travel time or distance to providers; a minimum percentage of contracted providers that are accepting new patients; maximum wait times for an appointment; hours of operation requirements (for example, extended evening or weekend hours); and combinations of these quantitative measures. We believe it is particularly important that states have flexibility for the standards for LTSS programs given the often very limited supply of providers and the potential functional limitations of the LTSS population. We encourage states to solicit stakeholder input in the development of their network standards. By proposing these changes, the requirements for network adequacy standards would be consistent for all provider types. As such, we propose to remove paragraphs § 438.68(b)(2)(i) and (b)(2)(ii), and reflect all LTSS network adequacy requirements in § 438.68(b)(2).

We propose to use the broader standard of ''a quantitative network adequacy standard'' rather than ''time and distance,'' because each type of standard addresses a different issue. For example, a time and distance standard addresses how long or far an enrollee may have to travel for care, whereas ''wait-times for an appointment'' address the availability or capacity of providers in the network to serve enrollees in a timely manner. We encourage states to use the quantitative standards in combination—not separately—to ensure that there are not gaps in access to and availability of services for enrollees.

[17] Hall, Mark, A. and Ginsburg, Paul, B. A Better Approach to Regulating Provider Network Adequacy (September 2017). Available at *https://www.brookings.edu/wp-content/uploads/2017/09/regulatory-options-for-provider-network-adequacy.pdf.*

Section 438.68(b)(1) specifies the provider types for which states are required to establish network adequacy standards. Section 438.68(b)(1)(iv) requires states to establish time and distance standards for ''specialist, adult and pediatric.'' As noted in the final rule, we believe that states should set network adequacy standards that are appropriate at the state level and are best suited to define the number and types of providers that fall into the ''specialist'' category based on differences under managed care contracts, as well as state Medicaid programs. Therefore, we believe it would be inappropriate for us to define ''specialist'' at the federal level (81 FR 27661). Since the publication of the 2016 final rule, we have received numerous questions from states and other stakeholders about who should define the types of providers to be included as specialists. We are clarifying with this proposal that states have the authority under the final rule to define ''specialist'' in whatever way they deem most appropriate for their programs. To make this authority clear, we propose to revise § 438.68(b)(1)(iv) to add ''(as designated by the state)'' after ''specialist.'' This proposed change would eliminate potential uncertainty regarding who has responsibility to select the provider types included in this category for the purposes of network adequacy. In addition, the proposed modification to § 438.68(b)(1)(iv) would reduce the burden on a state by eliminating the need to set a standard for every possible specialist, as a few states interpreted the text of the final rule.

In § 438.68(b)(1)(viii), we require states to establish time and distance standards for ''additional provider types when it promotes the objectives of the Medicaid program, as determined by CMS, for the provider type to be subject to time and distance access standards.'' In the 2016 final rule, we finalized the language in § 438.68(b)(1)(viii) because it provided the flexibility to address future national provider workforce shortages and future network adequacy standards (81 FR 27660). Additionally, we noted that if we ever elected to utilize this provision to identify additional provider types, we would only do so after soliciting public input (81 FR 27660). Since the 2016 final rule was published, states have expressed concern that if we rely on this authority and its flexibility of identifying ''additional provider types,'' managed care plans may have to assess network adequacy and possibly build network capacity without sufficient time. Based on these comments, we propose to remove § 438.68(b)(1)(viii) to eliminate any uncertainty states may have regarding this requirement.

11. Adoption of Practice Guidelines (§ 438.236)

In the 2016 final rule, we attempted to remove the terminology ''contracting health care professionals'' throughout the rule because it is not defined in any regulation or statute and we believed that use of ''network provider'' as defined in § 438.2 was more accurate. We inadvertently missed removing the term at § 438.236(b)(3). To correct this, we propose to remove the words ''contracting health care professionals'' and insert ''network providers'' in § 438.236(b)(3).

12. Enrollee Encounter Data (§ 438.242(c))

In § 438.242(b)(3) of the final rule, we required that all contracts between a state and an MCO, PIHP, or PAHP provide for the submission of all enrollee encounter data that the state is required to submit to CMS under § 438.818. Since the final rule, some states and managed care plans have expressed concern about, and been hesitant to submit, certain financial data—namely, the allowed amount and the paid amount. Managed care plans consider this information to be proprietary and inappropriate for public disclosure. We understand this concern but emphasize the importance of these data for proper monitoring and administration of the Medicaid program, particularly for capitation rate setting and review, financial management, and encounter data analysis. Additionally, the allowed and paid amounts of claims are routinely included on explanation of benefits provided to enrollees; thus making this information already publicly available. To clarify the existing requirement and reflect the importance of this data, we propose to revise § 438.242(c)(3) to explicitly include ''allowed amount and paid amount.'' We note that the proposed change to § 438.242(c)(3) would in no way change the rights of federal or state entities using encounter data for program integrity purposes to access needed data. Nor would it change the disclosure requirements for explanation of benefits notices or other disclosures to enrollees about their coverage.

The health insurance industry has consistently asserted that the contractual payment terms between managed care plans and providers is confidential and trade secret information and that the disclosure of this information could cause harm to

the competitive position of the managed care plan or provider. We recognize the significance of managed care plans' concerns and commit to treating this data as trade secret when the requirements for such a classification are met. CMS recognizes the significance of the volume of data collected in the Transformed Medicaid Statistical Information System (T–MSIS) and takes its obligations seriously to protect from disclosure information that is protected under federal law. Our goal in proposing to explicitly name allowed and paid amount in § 438.242(b)(3) is to ensure that the scope of the collection of encounter data is clear. We affirm our commitment to safeguarding data protected by federal law from inappropriate use and disclosure.

13. Medicaid Managed Care Quality Rating System (QRS) (§ 438.334)

In the 2016 final rule (81 FR 27686), we established at § 438.334 the authority to require states to operate a Medicaid managed care quality rating system (QRS) and incorporated this provision in its entirety into CHIP at § 457.1240(d). The regulation provides that CMS, in consultation with states and other stakeholders, develop a QRS framework, including the identification of performance measures and methodologies, which states could adopt. States have the option to use the CMS-developed framework or establish a state-specific QRS producing substantially comparable information about plan performance subject to CMS approval of the alternative system.

Several policy objectives are supported by the QRS requirement. First, implementation of a QRS provides a vehicle to hold states and plans accountable for the care provided to Medicaid and CHIP beneficiaries. Second, a QRS empowers beneficiaries by providing them with information about the plans in their state, enabling them to be more informed health care consumers. Third, a QRS provides an important tool for states to drive improvements in plan performance and the quality of care provided by their programs.

Since publication of the 2016 final rule, we have begun the early stages of a stakeholder engagement process needed for the CMS-developed framework. We have conducted interactive listening sessions with various stakeholders, including state and health plan stakeholder groups directors, and interviewed several beneficiaries. We also have convened a diverse technical expert panel (TEP) to meet periodically to advise CMS on the framework, objectives, measures, and methodologies for the CMS-developed QRS. The TEP includes representatives from state Medicaid and CHIP agencies, plans, beneficiary advocates, and quality measurement experts. We expect that this robust engagement of states and other stakeholders would continue through the publication of the notice of a proposed QRS framework called for in the current regulations at § 438.334(b).

The requirement in the current regulations that all Medicaid and CHIP QRS yield substantially comparable information serves to enable comparison of plans performance across states. States and beneficiary advocates have expressed strong support for this goal. In addition, the standardization of measures and methodologies necessary to generate comparable information would reduce burden on plans with products in multiple states. During our early stakeholder engagement sessions, however, the technical and methodological complexities of producing substantially comparable information to enable meaningful comparisons between plans across states, was raised—challenges which are heightened by the heterogeneous nature of states' Medicaid and CHIP programs. Some states expressed concern that the 2016 final rule may not have struck the optimal balance between the interests of standardization and state flexibility. We agree, and therefore, are proposing to make several revisions to the QRS regulations at § 438.334 (note that we propose no changes to § 457.1240(d), therefore all proposed changes would apply equally to both a state's Medicaid and CHIP programs). These revisions are intended to better balance the goal of facilitating inter-state comparisons of plan performance and reducing plan burden with the need for state flexibility and the practical challenges inherent in producing comparable ratings across states.

Specifically, we propose to revise the requirement in § 438.334(c)(1)(i) (redesignated as paragraph (c)(1)(ii) in this proposed rule) that an alternative state QRS produce substantially comparable information to that yielded by the CMS-developed QRS to require that the information yielded be substantially comparable to the extent feasible to enable meaningful comparison across states, taking into account differences in state programs that complicate achieving comparability. We also propose to add a new paragraph (c)(4) to explicitly provide that we would engage with states and other stakeholders in developing subregulatory guidance on what it means for an alternative QRS to yield substantially comparable information, and how a state would demonstrate it meets the standard. We also propose revisions to paragraph (b) to provide that, in developing the CMS-developed QRS framework in consultation with states and other stakeholders and using public notice and an opportunity to comment, we would identify a set of mandatory performance measures. We propose to redesignate § 438.334(c)(1)(i) and (c)(1)(ii) as paragraphs (c)(1)(ii) and (c)(1)(iii), respectively, and add new paragraph (c)(1)(i) which would provide that a state alternative QRS must include the mandatory measures identified in the framework. Recognizing the challenges that exist in achieving comparable ratings across states, we believe that identifying a uniform set of mandatory measures which are key to high-quality Medicaid and CHIP programs in any state would be critical. The QRS is subject to the Paperwork Reduction Act approval process, including notice and comment under the PRA, and is included in CMS–10553, OMB Control Number 0938–1281. States would retain flexibility to include additional measures important to serving their quality goals and meeting the needs of their beneficiaries and stakeholder communities. We note that Medicaid and CHIP QRS and our recently-launched Scorecard Initiative serve related goals, and we expect to coordinate the measures selected for the Scorecard initiative and those selected for the CMS-developed QRS.

The current regulation provides that the CMS-developed QRS would ''align with the summary indicators'' used by the QRS developed for the qualified health plans (QHP) in the Federally-Facilitated Exchange (FFE) (hereinafter referred to as the ''QHP QRS''). In the QRS listening sessions and TEP meetings held to date, states and other stakeholders have raised that, because the populations served by the QHPs, Medicaid and CHIP are different (with both Medicaid and CHIP serving a significantly higher proportion of children and Medicaid serving a significantly greater proportion of older adults and individuals with disabilities), complete alignment with the QHP QRS may not make sense for Medicaid and CHIP. Therefore, we propose to revise § 438.334(b) to provide that the CMS-developed QRS would align with the QHP QRS where appropriate. Some stakeholders also have suggested that the Medicaid and CHIP QRS also should align, where appropriate, with the Medicare Advantage 5-Star Rating System and the

Medicare-Medicaid Plan (MMP) Financial Alignment Initiative integrated Star Rating strategy (currently in development) in order to reduce reporting burden on plans that operate in the other markets, as well as offering Medicaid and CHIP managed care plans. We agree that aligning the Medicaid and CHIP QRS with these other rating systems, to the extent appropriate given the different populations served by each program and benefit variations between programs, would reduce burden and confusion for plan issuers, which may offer products in more than one program. Therefore, we propose revisions at § 438.334(b) that the CMS-developed QRS also align, where appropriate, to other CMS approaches to rating managed care plans. Alignment will be determined as part of the ongoing development of the proposed measures and methodologies and will be addressed in the QRS-specific rulemaking.

Currently, § 438.334 requires states to obtain our approval prior to implementing an alternative QRS. Pre-approval enables us to determine if an alternative QRS complies with the regulation and meets the ''substantially comparable'' standard before a state invests resources into QRS implementation. However, some states have expressed concern about having enough time to implement a QRS if prior approval from CMS is required. To reduce the upfront administrative burden on states and speed time for implementation, we propose to revise the current introductory language in § 438.334(c)(1) and (c)(1)(ii) to eliminate the requirement that states obtain prior approval before implementing an alternative QRS. In addition, the use of mandatory measures in addition to state-selected measures provides some assurance about the comparability of the alternative QRS developed by the state. Instead of prior CMS approval, we propose at § 438.334(c)(3) that states would, upon CMS request, submit their alternative QRS framework, including the performance measures and methodology to be used in generating plan ratings; documentation of the public comment process described in § 438.334(c)(2)(i) and (ii) including issues raised by the Medical Care Advisory Committee and the public, any policy revisions or modifications made in response to the comments, and rationale for comments not accepted; and other information specified by CMS to demonstrate compliance with § 438.334(c). As part of our general oversight responsibilities, we would still review states' alternative QRS and work with states on any identified deficiencies. This approach is similar to the oversight process CMS uses for states' eligibility verification plans (§ 435.945(j), incorporated into the CHIP requirements by reference at § 457.380(i)), which requires states to submit eligibility verification plans to CMS for finalization upon request, in a manner and format prescribed by CMS.

We solicit comments on these proposals.

14. Managed Care State Quality Strategy (§ 438.340)

Current § 438.340 sets forth the minimum elements of a managed care state quality strategy and the requirements for development, evaluation, revision and public display of the quality strategy. Each state contracting with an MCO, PIHP, or PAHP as defined in § 438.2 or with a risk-bearing PCCM entity, as described in § 438.310(c)(2), must draft and implement a written quality strategy for assessing and improving the quality of health care and services furnished by the MCO, PIHP, PAHP, or PCCM entity. Section 438.340(b) sets forth the minimum elements of a managed care state quality strategy.

In the 2016 final rule, we expanded the previous state managed care quality strategy requirements, which applied to states contracting with MCOs and PIHPs, to also apply to states contracting with PAHPs or PCCM entities described in § 438.310(c)(2). As part of that revision, and to conform to other changes in this part, we added paragraph (b)(8), which requires a description of how the state would assess the performance and quality outcomes achieved by each PCCM entity described in § 438.310(c)(2). This paragraph was intended to capture the application of all relevant areas of the state's quality strategy to risk-bearing PCCM entities, in conformance with the inclusion of PCCM entities at § 438.340(a). We intended that states which contract with PCCM entities described in § 438.310(c)(2) would design and describe all of the quality strategy elements to include PCCM entities as appropriate; for example, within the state's goals and objectives for continuous quality improvement in paragraph (b)(2). We similarly intended that other aspects of the managed care quality strategy would apply equally to these PCCM entities, including § 438.340(b)(3)(i) (relating to quality metrics and performance targets); § 438.340(b)(6) (relating to the state's plan to identify, evaluate and reduce health disparities and to provide demographic information to managed care plans); and § 438.340(c)(1)(ii) (regarding Tribal consultation for states who enroll Indians in PCCM entities). However, current § 438.340(b)(2), (b)(3)(i), (b)(6) and (c)(1)(ii) do not explicitly reference PCCM entities, resulting in possible confusion about the application of these quality strategy elements to states which contract with PCCM entities. Our intention in the 2016 final rule was to apply these provisions equally to PCCM entities. Therefore, we propose to add PCCM entities described in § 438.310(c)(2) to the list of managed care plans identified in § 438.340(b)(2), (b)(3)(i), (b)(6) and (c)(1)(ii). We also propose for greater clarity to delete § 438.340(b)(8) and to redesignate paragraphs (b)(9), (b)(10), and (b)(11) as paragraphs (b)(8), (b)(9), and (b)(10), respectively.

We do not propose to add a reference to PCCM entities described in § 438.310(c)(2) to § 438.340(b)(1) because the regulations cross-referenced in paragraph (b)(1)—that is, § 438.68 (relating to state-defined network adequacy), § 438.206 (relating to availability of service standards), and § 438.236 (relating to clinical practice guidelines)—do not apply to PCCM entities. Similarly, we do not propose to add PCCM entities to the list of managed care entities in § 438.340(b)(3)(ii) (related to performance improvement projects (PIPs)) because states are not required under § 438.330(d) to require that PCCM entities conduct PIPs. However, since states have the option to require PIPs for PCCM entities, we encourage states that choose to have their PCCM entities conduct PIPs to describe these PIPs in their managed care quality strategy.

Section 438.340(b)(6) of the current regulations requires that states include, as an element of the managed care quality strategy, their plan to identify, evaluate, and reduce, to the extent practicable, health disparities based on six demographic factors (age, race, ethnicity, sex, primary language, and disability status). It also requires states to transmit this demographic information for each Medicaid enrollee to the enrollee's managed care plan at the time of enrollment into the plan. Section 438.340(b)(6) currently provides that ''disability status,'' for the purposes of this paragraph, means whether the individual qualified for Medicaid on the basis of a disability.

We are concerned that this definition of ''disability status'' may be unintentionally narrow. For example, some individuals with disabilities may not be eligible for Medicaid on the basis of disability, or their disability status may change over time. Others may not

be disabled under the definition used by the Medicaid program, but may be considered disabled under other state or federal laws or regulations (for example, the Americans with Disabilities Act). We believe states should provide a managed care plan with the most accurate, complete, and current demographic information about an enrollee available to the state, regardless of whether this information is from an enrollee's Medicaid eligibility application or from another source. We recognize that the most common source of information about an individual's disability status will be that obtained during the application process, and states are not required to actively seek out sources of information not readily available to the state. However, if states have other or more current sources of information for these six demographic factors, states would be expected to use and transmit that more current information.

Therefore, we propose to remove the sentence defining disability status from § 438.340(b)(6) in addition to adding the reference to PCCM entities described in § 438.310(c)(2). Under the proposed revised regulation, qualifying for Medicaid on the basis of disability would be one source of information to determine a beneficiary's disability status, but not necessarily the only source of this information. We note that this requirement for states to provide demographic information for each Medicaid enrollee to the managed care plan at the time of enrollment is a minimum standard; we encourage states to send updated demographic information to an enrollee's managed care plan whenever updated demographic information is available to the state.

We solicit comments on these proposals.

15. Activities Related to External Quality Review (§ 438.358)

Section 438.358(b)(1) sets forth the mandatory external quality review (EQR)-related activities states must require for their MCOs, PIHPs, and PAHPs. Section 438.358(b)(1)(iii) requires a review, conducted within the previous 3-year period, to determine the MCO's, PIHP's, or PAHP's compliance with certain managed care standards. In the 2016 final rule, the cross-citation in § 438.358(b)(1)(iii) to standards at § 438.204(g) was replaced with a streamlined cross-reference to part 438 subpart D (81 FR 27706). We noted that the streamlining of the cross-reference did not propose a significant change from what comprises the current compliance review activity. Subpart D previously had contained cross-references to all of the applicable standards for access to care and structure and operations that are contained in subparts A, B, C, and F. However, several of those cross-references within subpart D were removed in the 2016 final rule, specifically references to § 438.56 (Disenrollment requirements and limitations), § 438.100 (Enrollee rights), and § 438.114 (Emergency and post-stabilization services). The removal of these cross-references from subpart D inadvertently dropped reference citations for these critical standards from the EQR compliance review. This was not our intention, as these sections have been included in the EQR protocol for the compliance review activity since the initial release of the protocols in 2003 and in all subsequent revisions of the protocols. Therefore, we propose a technical correction to add directly to § 438.358(b)(1)(iii) the three cross-references to §§ 438.56, 438.100 and 438.114.

We solicit comments on these proposals.

16. Exemption From External Quality Review (§ 438.362)

Section 438.362 implements section 1932(c)(2)(C) of the Act, which provides that a state may exempt an MCO from undergoing an EQR when certain conditions are met. First, the MCO must have a current Medicare contract under part C of Title XVIII or under section 1876 of the Act, as well as the current Medicaid contract under section 1903(m) of the Act. Second, the two contracts must cover all or part of the same geographic area within the state. Third, the Medicaid contract must have been in effect for at least 2 consecutive years before the effective date of the exemption and during those 2 years, the MCO has been found to be performing acceptable for the quality, timeliness, and access to health care services it provides to Medicaid beneficiaries. Neither the statute nor § 438.362 requires states to exempt plans from EQR; this is provided only as an option for states. States have discretion to require all their managed care plans to undergo EQR, even those that appear eligible for an exemption under this section.

In the 2016 final rule (81 FR 27713), we received comments regarding limiting the use of exemption which also raised transparency concerns. Since the issues raised in the comments were outside the scope of that rulemaking, we encouraged, but did not require, states to make public which Medicaid health plans have been exempted from EQR under § 438.362 and for how long. We indicated we would consider proposing in future rulemaking, a requirement that states post this information publicly. Therefore, we propose to add § 438.362(c) to require that states annually identify on their website, in the same location where EQR technical reports are posted, the names of the MCOs it has exempted from EQR, and when the current exemption period began. We believe that posting this information on the state's website would not present a burden to states since states already make exemption determinations, inform their EQRO of which plans are exempted from EQR, and maintain EQR information on their website, activities which are already accounted for in the associated information collections.

As an alternative, we are considering revising § 438.364(a) (External Quality Review Results-Information that must be produced) to require that states identify the exempted plans and the beginning date of the current exemption period in the annual EQR technical report. This identification could be in addition to or as an alternative to posting this information directly on the state's website. We could revise paragraph (a)(i) to add a sentence incorporating the same information we propose to add to § 438.362.

We solicit comments on this proposal. We also welcome information about how states are currently using the exemption provision and how states currently make that information publicly available.

17. External Quality Review Results (§ 438.364)

On page 27886 of the Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability final rule (81 FR 27498, May 6, 2018), we made a technical error in the regulation text of § 438.364(d) (Safeguarding patient identity). In this paragraph, we inadvertently referenced paragraph (b) of this section (Revision) instead of referencing paragraph (c) of this section (Availability of Information). Accordingly, we propose to revise § 438.364(d) to reflect the correct reference.

18. Grievance and Appeal System: Statutory Basis and Definitions (§ 438.400)

In the 2016 final rule, we finalized at § 438.400(b)(3) the definition of an ''adverse benefit determination'' including denials in whole or in part of payment for service. The term adverse

benefit determination was proposed and finalized in the 2016 final rule as a replacement for the term ''action,'' which had been defined with the same definition in the 2002 rule. Under § 438.404(a), managed care plans are required to give enrollees timely notice of an adverse benefit determination in writing and consistent with the requirements in § 438.10 generally. Given the broad meaning of the term ''denial of a payment,'' some managed care plans may be generating a notice to each enrollee for every denied claim, even those that are denied for purely administrative reasons (such as missing the National Provider Identifier, missing the enrollee's sex, or because the claim is a duplicate) and which generate no financial liability for the enrollee. Issuing notices of such adverse benefit determinations for which the enrollee has no financial liability nor interest in appealing simply to comply with § 438.404(a) may create administrative and economic burdens for plans, and unnecessary confusion and anxiety for enrollees who frequently misunderstand the notices as statements of financial liability.

To alleviate unnecessary burden on the managed care plans and enrollees, we propose to add language in § 438.400(b)(3), that would indicate that a denial, in whole or in part, of a payment for a service because the claim does not meet the definition of a clean claim at § 447.45(b) [18] is not an adverse benefit determination. As such, the notice requirements in § 438.404 would not be triggered. We believe this proposed modification would eliminate burden on plans to send unnecessary notices and avoid anxiety for enrollees receiving such notices. This proposed change is not expected to expose enrollees to financial liability without notice, or jeopardize their access to care or rights to an appeal.

While notices to enrollees for claims that do not comply with the clean claim definition in § 447.45(b) would not be required under our proposed amendment to § 438.400(b)(3), the notice requirements for all future claims (including resubmission of the same claim) would have to be independently determined. For example, if a provider resubmits a clean claim after the initial one was not processed because it did not comply with the requirements in § 447.45(b), and the managed care plan subsequently issues an adverse benefit determination, the managed care plan would still be required to issue a timely notice under § 438.404(a) for the second claim. Whether an adverse benefit determination notice is required would have to be determined for each claim, regardless of whether notices were required for previously submitted claims.

We solicit comments on our proposal.

19. Grievance and Appeal System: General Requirements (§§ 438.402 and 438.406)

In the 2016 final rule, we adopted the requirement that an oral appeal must be followed by a written, signed appeal at § 438.402(c)(3)(ii).[19] This requirement was also included at § 438.406(b)(3), regarding handling of grievances and appeals, where managed care plans must treat oral inquiries seeking to appeal an adverse benefit determination as appeals and that such oral inquiries must be confirmed in writing. We received comments to the proposed rule that stated that the written, signed requirements added an unnecessary barrier to enrollees filing an appeal with the managed care plan. At that time, we believed that this requirement was necessary to ensure appropriate and accurate documentation of enrollees' appeals. While the resolution timeframe for an oral appeal begins on the date of the oral appeal, managed care plans cannot issue a resolution until the enrollee submits the written, signed appeal (81 FR 27511). Managed care plans have found that some enrollees may take too long to submit the written, signed appeal, while others fail to submit the written appeal at all. This creates problems for managed care plans who must invest resources to encourage enrollees to submit the documentation, as well as uncertainty for managed care plans as to how to comply with § 438.406 (Handling Grievances and Appeals) in cases when the enrollee does not submit the written, signed appeal.

After the opportunity to hear from states regarding their experience with this requirement, we propose to eliminate the requirement for enrollees to submit a written, signed appeal after an oral appeal is submitted. We believe the removal of the requirement would reduce barriers for enrollees who would not have to write, sign, and submit the appeal, decrease the economic and administrative burden on plans, and would expedite the appeals process. This proposed change would also harmonize the managed care appeal process with the state fair hearing process.[20]

We considered retaining the written, signed appeal requirement, but permitting the managed care plan to proceed with the process in the absence of it, if the managed care plan demonstrates that a good faith effort was made to obtain the written, signed appeal. However, we believed that demonstrating a good faith effort increased burden on the states and plans with no additional benefit for the enrollee. Therefore, we are proposing the elimination of the written, signed appeal requirement in §§ 438.402(c)(3)(ii) and 438.406(b)(3), as we believe the elimination of the written requirement benefits all parties involved. Although we are proposing to eliminate the requirement that an oral appeal must be followed by a written, signed appeal, as we noted in the 2016 final rule, we continue to expect managed care plans to treat oral appeals in the same manner as written appeals (81 FR 27511). We are proposing to retain the current regulatory language in § 438.406(b)(3) that specifies that oral inquiries seeking to appeal an adverse benefit determination are treated as appeals.

20. Resolution and Notification: Grievances and Appeals (§ 438.408)

In the 2016 final rule, we revised the timeframe for enrollees to request a state fair hearing to 120 calendar days at § 438.408(f)(2). We adopted this timeframe because we believed it would give enrollees more time to gather the necessary information, seek assistance for the state fair hearing process, and make the request for a state fair hearing (81 FR 27516). However, we have heard from stakeholders that the 120-calendar day requirement has created an inconsistency in filing timeframes between Medicaid FFS and managed care, creating administrative burdens for states and confusion for enrollees. The FFS rule limits the timeframe beneficiaries have to request a hearing to no more than 90 days (§ 431.221(d)).[21] It was not our intent to burden states with additional tracking of the fair hearing process in multiple systems, on multiple timeframes. Nor do

[18] Under § 447.5(b), a clean claim means one that can be processed without obtaining additional information from the provider of the service or from a third party. It includes a claim with errors originating in a States claim system. It does not include a claim from a provider who is under investigation for fraud or abuse, or a claim under review for medical necessity.

[19] Redesignated from § 438.402(b)(3)(ii) in the 2002 final rule (67 FR 41110).

[20] Section 431.221(a)(1)(i) requires state Medicaid agencies to permit an individual or authorized representative of the individual to submit state hearing requests via different modalities—including telephone—without requiring a subsequent written, signed appeal.

[21] 42 CFR 431.221(d) states that the agency must allow the applicant or beneficiary a reasonable time, not to exceed 90 days from the date that notice of action is mailed, to request a hearing.

we want to confuse enrollees in states where some services are provided through FFS and others through managed care.

Therefore, we propose to revise § 438.408(f)(2) to stipulate that the timeframe for enrollees to request a state fair hearing would be no less than 90 calendar days and no greater than 120 calendar days from the date of the MCO's, PIHP's, or PAHP's notice of resolution. We believe the proposed revision would allow states that wish to align managed care with the FFS filing timeframe to do so while not jeopardizing the enrollee's ability to gather information and prepare for a state hearing. This proposal would also allow states that have already implemented the 120-calendar day timeframe to maintain that timeframe without the need for additional changes.

We solicit comments on our proposal.

II. Children's Health Insurance Program (CHIP) Managed Care

A. Background

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5, enacted February 17, 2009), the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3, enacted on February 4, 2009), and the PPACA made applicable to CHIP several Medicaid managed care provisions in section 1932 of the Act, including section 1932(a)(4), Process for Enrollment and Termination and Change of Enrollment; section 1932(a)(5), Provision of Information; section 1932(b), Beneficiary Protections; 1932(c), Quality Assurance Standards; section 1932(d), Protections Against Fraud and Abuse; and section 1932(e), Sanctions for Noncompliance. In addition, the PPACA applied to CHIP sections 1902(a)(77) and 1902(kk) of the Act related to provider and supplier screening, oversight, and reporting. Our 2016 final rule implemented these statutory provisions and built on initial guidance provided in State Health Official (SHO) letters 09–008 and 09–013, issued on August 31, 2009 and October 21, 2009, respectively. The provisions in the 2016 final rule both reflected and superseded this earlier guidance.

Since the publication of the 2016 final rule, and subsequent technical corrections to the rule in a correction notice published on January 3, 2017 (82 FR 37) (the 2017 correction notice), we have observed the need for additional minor technical or clarifying changes to the CHIP managed care provisions, primarily to clarify that certain Medicaid requirements do not apply to CHIP. These changes are described in more detail below.

B. Updates to CHIP Managed Care

1. Compliance Dates for Part 457 Managed Care Provisions

The compliance section of the preamble to the 2016 final rule states that unless otherwise noted, states would not be held out of compliance with new requirements in part 457 of this final rule until CHIP managed care contracts as of the state fiscal year beginning on or after July 1, 2018, so long as they comply with the previously applicable regulations (that is, the regulations in place before the 2016 final rule). (81 FR 27499). Some stakeholders have expressed that the compliance section as drafted is not clear about when states need to comply with the CHIP managed care regulations. We clarify here that, except as otherwise noted, compliance with the revisions to the CHIP managed care regulations in part 457 under the 2016 final rule is required as of the first day of the state fiscal year beginning on or after July 1, 2018, regardless of whether or not the managed care contract in effect is a multi-year contract entered into a previous fiscal year or is a new contract effective for the first state fiscal year beginning on or after that date.

2. Information Requirements (§ 457.1207)

Section 457.1207 sets forth the CHIP requirements for providing enrollment notices, informational materials, and instructional materials for enrollees and potential enrollees of managed care entities by adopting the Medicaid requirements in § 438.10 by cross-reference. We inadvertently failed to exclude three cross references that should not apply to CHIP.

Section 438.10(c)(2) requires states to utilize the state's beneficiary support system as specified in § 438.71. CHIP does not adopt the beneficiary support system requirements; therefore, we did not intend that states would be required to use these systems for CHIP enrollees and we propose to modify the language in § 457.1207 to reflect this technical correction.

Section 438.10(g)(2)(xi)(E) requires that enrollee handbook notify enrollees that, when requested, benefits will continue when the enrollee files an appeal or state fair hearing (also known as ''aid paid pending''). CHIP does not adopt the Medicaid appeals process known as ''aid paid pending'' and we intended to exclude the requirement to notify CHIP enrollees of this requirement from the handbook, as the option does not exist in CHIP (we explicitly exclude this provision in § 457.1260). We propose to modify the language in § 457.1207 to reflect this technical correction.

Additionally, § 438.10(g)(2)(xii) requires that the enrollee handbooks for MCOs, PIHPs, PAHPs, and PCCM entities must provide information on how to exercise an advance directive, as set forth in § 438.3(j). CHIP does not adopt advanced directive requirements, and therefore, we did not intend that plans would be required to notify CHIP enrollees on how to exercise advanced directives and we propose to modify the language in § 457.1207 to reflect this technical correction.

We solicit comments on these proposals.

3. Structure and Operations Standards (§ 457.1233)

In the 2016 final rule, at § 457.1233(b), we adopted the provisions in § 438.230 related to MCO, PIHP, PAHP and PCCM entity requirements for contracting with subcontractors. However, in § 457.1233(b) we inadvertently included PCCMs instead of PCCM entities. We propose to revise § 457.1233 in this rulemaking to conform to the requirement that § 438.230 applies to PCCM entities.

Also, at § 457.1233(d), we adopted the provisions in § 438.242 that require states operating a separate CHIP to collect enrollee encounter data from managed care plans. In finalizing § 438.242, we also intended to apply to CHIP the requirements of § 438.818, which is cross-referenced in § 438.242 and requires the submission of enrollee encounter data to CMS. We propose to revise § 457.1233 in this rulemaking to make explicit our intention to apply the terms of § 438.818 to CHIP.

Finally, in the 2016 final rule at § 457.1233(d) we made a technical error regarding the CHIP applicability date. Our cross-reference to § 438.242 inadvertently applied the Medicaid applicability date of July 1, 2017 for the health information system requirements instead of the later compliance date generally applicable to CHIP (which is as of the first day of the state fiscal year beginning on or after July 1, 2018) that was specified in the 2016 final rule (''Except as otherwise noted, states will not be held out of compliance with new requirements in part 457 of this final rule until CHIP managed care contracts as of the state fiscal year beginning on or after July 1, 2018, so long as they comply with the corresponding standard(s) in *part 457* contained in the parts 430 through 481, edition revised

as of October 1, 2015.'') and discussed in detail in section II.B.1 of this proposed rule. Therefore, we also propose to revise § 457.1233(d) to address this technical correction.

We solicit comments on our proposals.

4. Quality Measurement and Improvement (§ 457.1240)

In the 2016 final rule, we aligned CHIP quality measurement and improvement standards (with minor exceptions) for CHIP MCOs, PIHPs and PAHPs with the Medicaid standards at §§ 438.330, 438.332, 438.334, and 438.340 by adopting references to those sections in § 457.1240(b). Where appropriate, § 457.1240 of the 2016 final rule also applied these Medicaid standards to PCCM entities. However, we inadvertently missed a cross-reference to one of the Medicaid standards—§ 438.330(b)(2), relating to the collection and submission of quality performance measurement data—which we intended to apply to PCCM entities. We propose revisions to § 457.1240(b) to correct this omission and reflect application of § 438.330(b)(2) to PCCM entities in CHIP. The proposed changes in § 438.340, as discussed in the preamble at section I.B.13 of this proposed rule, are addressed with regard to CHIP in section II.B.8. of this proposed rule.

Additionally, we inadvertently failed to exclude references to consultation with the state's Medical Care Advisory Committee when drafting or revising the state's quality strategy in § 438.330(c)(1)(i) and if the state chooses to use an alternative managed care QRS in § 438.334(c)(2)(i) and (c)(3). Consultation with the Medical Care Advisory Committee is required for Medicaid under § 431.12. However, CHIP is not subject to § 431.12, and therefore, the consultation requirements in § 438.330(c)(1)(i) and § 438.334(c)(2)(i) and (c)(3) are not applicable to CHIP. We propose to revise § 457.1240 to correct these errors.

We solicit comments on our proposal.

5. Grievance System (§ 457.1260)

In the 2016 final rule, we aligned CHIP with the Medicaid grievance and appeals provisions in subpart F of part 438, by incorporating those subpart F, part 438 provisions into § 457.1260, with two substantive exceptions. First, § 457.1260 provides that references to ''state fair hearings'' in the part 438 provisions should be read as referring to part 457, subpart K (which imposes certain CHIP applicant and enrollee protections). Second, § 457.1260 excludes the applicability date in § 438.400(c) from applying in the CHIP context. Since that 2016 final rule, we have become aware of a number of issues related to how § 457.1260 currently incorporates the requirements applicable to Medicaid managed care plans and we are proposing here to amend § 457.1260 to address those concerns.

To avoid a lengthy list of excluded provisions from a general incorporation of subpart F of part 438, we are proposing new regulation text that incorporates specific provisions from subpart F of part 438, does not incorporate the specific paragraphs and provisions that have raised the issues detailed below, and fills in the blanks of how MCEs in state CHIPs must establish and operate their grievance and appeals system. No revisions are proposed to CHIP's current incorporation of § 438.406, § 438.410, § 438.412 or § 438.416. CHIP did not adopt § 438.420 in the 2016 final rule. The proposed revisions address the following items in § 438.400, § 438.402, § 438.404, § 438.408, and § 438.424:

- *Definition of adverse benefit determination (§ 438.400):* We inadvertently failed to exclude a reference to paragraph (6) of the definition of adverse benefit determination in § 438.400. This paragraph includes in the definition of adverse benefit determination the denial of enrollee's request to exercise his or her choice to obtain services outside the network under § 438.52. We did not adopt § 438.52 in CHIP, and therefore, this should not have been included in the definition of adverse benefit determination for CHIP. Our proposed regulation text at § 457.1260(a)(2) incorporates the definitions adopted in § 438.400 excluding this one provision in the definition of adverse benefit determination.
- *External medical reviews (§ 438.402):* At § 457.1120(a), CHIP already provides states with two options to conduct an external review of a health services matter and we inadvertently applied to CHIP an additional, optional external medical review in the Medicaid rule at § 438.402(c)(1)(i)(B). We now realize that this additional external medical review has been incorporated under our current regulation text. Therefore, within § 457.1260(b) which corresponds to § 438.402, we do not include the Medicaid external medical review provisions (§ 438.402(c)(1)(B)) from the list of appeal and grievance provisions that we are proposing to incorporate in proposed § 457.1260. In addition, proposed § 457.1260(b)(2) through (4) replace § 438.402(c)(1)(i)(A), (c)(1)(ii), and (c)(2), respectively, by substituting references to ''state fair hearings'' from the Medicaid rules for references to part 457, subpart K (which imposes certain CHIP applicant and enrollee protections, including the external review). This approach is substantively consistent with the current rule. Our proposed regulation text, at § 457.1260(b), continues to incorporate Medicaid grievance and appeals system establishment and operation rules in § 438.402(a), (b), (c)(2) and (3).
- *Timing of notice of adverse benefit determinations (§ 438.404):* We have realized that there may have been some confusion about whether states should follow the timing of notice of adverse benefit determination requirements described in § 438.404(c)(1) or § 457.1180. We propose to clarify that we did not intend to incorporate the requirements of 42 CFR part 431, subpart E into CHIP from § 438.404(c)(1) and that states may continue, under proposed § 457.1260(c)(3), to provide timely written notice for termination, suspension, or reduction of previously authorized CHIP-covered services, which mirrors the timing of notice requirements in § 457.1180. We propose that for denials and limitations of services, the timing of notices would continue to follow § 438.404(c)(3). In addition, proposed § 457.1260(c)(2) replaces § 438.404(b)(3) by substituting the reference to ''state fair hearings'' with the reference to part 457, subpart K. However, our proposed regulation text, at § 457.1260(c), continues to incorporate the notice requirements of Medicaid adverse benefit determination rules in § 438.404(a), (b)(1), (2), and (4) through (6), and (c)(2) through (6).
- *Resolution and notification (§ 438.408):* Proposed § 457.1260(e)(2) mirrors the language of § 438.408(a) but we have proposed a restatement of the text within § 457.1260 so that the use of ''this section'' in the text now refers to the language in § 457.1260 in lieu of § 438.408. In addition, proposed § 457.1260(e)(3) through (7) replace § 438.408(b)(3), (e)(2), (f)(1), (f)(1)(i), and (f)(2), respectively, by substituting references to ''state fair hearings'' for references to part 457, subpart K. For the reasons discussed above, we do not include the Medicaid external medical review provisions (§ 438.408(f)(1)(ii)) from the list of appeal and grievance provisions that we are proposing to incorporate in proposed § 457.1260. However, our proposed regulation text, at § 457.1260(e), continues to incorporate the resolution and notification requirements of Medicaid grievance and appeals rules in

§ 438.408(b), (c)(1) and (2), (d), (e)(1), and (f)(3).

• *Services not furnished (§ 438.424):* The current regulation inadvertently incorporates and applies the Medicaid standard at § 438.424(b), which requires a state to pay for disputed services furnished while an appeal is pending—which we did not intend to apply to CHIP. The Medicaid rule at § 438.420, regarding the continuation of benefits while an appeal is pending is not a policy that we wish to incorporate into CHIP. Therefore, the CHIP regulation at § 457.1260 should not include either § 438.420 or § 438.424(b), which provides that a state must pay for those disputed services furnished while the appeal is pending if the decision to deny authorization of the services is reversed. Therefore, in proposed § 457.1260, we do not incorporate § 438.420 or § 438.424(b). However, proposed § 457.1260(h) mirrors § 438.424(a) except for substituting the reference to ''state fair hearings'' with the reference to part 457, subpart K.

Accordingly, we propose to revise § 457.1260 to better reflect CMS policy for CHIP. We solicit comment on whether our more detailed regulation text, which incorporates specific provisions of subpart F of part 438, is sufficiently clear and detailed for the appropriate administration of grievances and appeals in the CHIP context.

We solicit comments on our proposal.

6. Sanctions (§ 457.1270)

In the 2016 final rule, CHIP adopted the Medicaid requirements related to sanctions in part 438 subpart I at § 457.1270. We inadvertently did not include a provision in § 457.1270 that states may choose to establish sanctions for PCCMs and PCCM entities as specified in § 438.700(a). In addition, we did not indicate that references in § 438.706(a)(1) and (b) should be read to refer to the requirements of subpart L of part 457, rather than references to sections 1903(m) and 1932 of the Act. We are revising the language of § 457.1270 to reflect these technical changes.

We solicit comments on our proposal.

7. Program Integrity Safeguards (§ 457.1285)

Section 457.1285 sets forth the CHIP requirements for providing enrollment notices, informational materials, and instructional materials for enrollees and potential enrollees of managed care entities by adopting the Medicaid requirements in subpart H of part 438, except for the terms of § 438.604(a)(2), by cross-reference. We inadvertently failed to exclude one cross reference that should not apply to CHIP. CHIP does not adopt the Medicaid actuarial soundness requirements, therefore, states do not need to use the specified plan information collected in § 438.608(d)(1) and (3) for setting actuarially sound capitation rates as required by Medicaid in § 438.608(d)(4) and we are seeking to modify the language of § 457.1285 to reflect this technical correction.

We solicit comments on our proposal.

8. CHIP Conforming Changes To Reflect Medicaid Managed Care Proposals

In the 2016 final rule, CHIP adopted many of the Medicaid regulations via cross-reference. We are proposing in this rulemaking to revise some of these Medicaid regulations. While we are not revising the cross-references to these regulations, we wanted to highlight that the changes proposed to the following Medicaid regulations in this rulemaking also would apply, by existing cross-reference, to CHIP. We welcome comments on the proposed changes as they apply to CHIP:

• *MLR standards (§ 438.8(k)):* As discussed in section I.B.6. of this proposed rule, we proposed revisions to § 438.8(k)(1)(iii) and (e)(4). Section 438.8(k) is incorporated into the CHIP regulations in § 457.1203(e) and (f).

• *Information requirements (§ 438.10):* As discussed in section I.B.8 of this proposed rule, we proposed several revisions to § 438.10. Section 438.10 is incorporated into the CHIP regulations at §§ 457.1206(b)(2) (via cross-reference to § 457.1207), 457.1207, and 457.1210(c)(5) (via cross-reference to § 457.1207).

• *Disenrollment: Requirements and limitations (§ 438.56):* As discussed in section I.B.9. of this proposed rule, we proposed revisions to § 438.56(d)(5) by deleting ''PCCMs or PCCM entities.'' Section 438.56 is adopted in CHIP at § 457.1212.

• *Network adequacy standards (§ 438.68):* As discussed in section I.B.10. of this proposed rule, we are proposing revisions to the provider-specific network adequacy standards in § 438.68(b). The Medicaid network adequacy standards are applied to CHIP per § 457.1218.

• *Practice guideline (§ 438.236):* As discussed in the preamble at section I.B.11. of this proposed rule, we proposed revisions to § 438.236(b)(3) by deleting contracting health care professionals and replacing it with network providers. Section 438.236 is incorporated into the CHIP regulations at § 457.1233(c).

• *Health information systems (§ 438.242):* As discussed in section I. B.12. of this proposed rule, we are proposing revisions to the health information systems requirements in § 438.242. Section 438.242 is adopted in CHIP at § 457.1233(d).

• *Medicaid managed care QRS (§ 438.334):* As discussed in the section I.B.13. of this proposed rule, we proposed revisions to § 438.334(b), (c)(1), and (c)(1)(ii), redesignating current paragraphs (c)(1)(i) and (c)(1)(ii) as (c)(1)(ii) and (c)(1)(iii), respectively, and adding new paragraph (c)(1)(i). We also proposed revisions to redesignated paragraph (c)(1)(ii) and adding new paragraph (c)(4). Section 438.334 is adopted in CHIP at § 457.1240(d).

• *Managed care State quality strategy (§ 438.340):* As discussed in the preamble at section I.B.14. of this proposed rule, we proposed revisions to § 438.340(b)(2), (b)(3)(i), (b)(6), and (c)(1)(ii).We also proposed removing § 438.340(b)(8), and redesignating paragraphs (b)(9), (b)(10), and (b)(11) as paragraphs (b)(8), (b)(9) and (b)(10), respectively. Section 438.340 is incorporated into the CHIP regulations at § 457.1240(e).

• *Activities related to EQR (§ 438.358):* As discussed in section I.B.15. of this proposed rule, we proposed revisions to § 438.358(b)(1)(iii). Section 438.358 is incorporated into the CHIP regulations at § 457.1250(a).

• *EQR Results (§ 438.364(d)):* As discussed in section I.B.17 of this proposed rule, we proposed revisions to § 438.364(d). Section 438.364 is incorporated into CHIP regulations at § 457.1250(a).

• *Statutory basis, definitions, and applicability (§ 438.400):* As discussed in section I.B.18. of this proposed rule, we proposed revisions to § 438.400(b)(3). Section 438.400 is incorporated into the CHIP regulations at § 457.1260.

• *General requirements (§§ 438.402 and 438.406):* As discussed in section I.B.19. of this proposed rule, we proposed revisions to §§ 438.402(c)(3)(ii) and 438.406(b)(3). Sections 438.402 and 438.406 are incorporated in CHIP in § 457.1260.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section

3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

A. Background

The burden associated with the requirements under part 438 is the time and effort it would take each of the state Medicaid programs to comply with this proposed rule. This proposed rule would revise certain Medicaid managed care regulations based on state and consumer experience with the requirements adopted in the 2016 final rule (81 FR 27497) in order to reflect a broader strategy to relieve regulatory burdens; support state flexibility and local leadership; and promote transparency, flexibility, and innovation in the delivery of care.

To estimate the burden for these proposals in part 438, we utilized state submitted data for enrollment in managed care plans for CY 2016. The enrollment data reflected 54,588,095 enrollees in MCOs, 17,941,681 enrollees in PIHPs or PAHPs, and 5,399,640 enrollees in PCCMs, for a total of 80,184,501 managed care enrollees. This includes duplicative counts when enrollees are enrolled in multiple managed care plans concurrently. This data also showed 42 states that contract with 519 MCOs, 14 states that contract with 134 PIHPs or PAHPs, 19 states that contract with 21 non-emergency transportation PAHPs, 18 states with 26 PCCM or PCCM entities, and 20 states that contract with one or more managed care plans for managed LTSS) Many states contract with more than one entity; however, we de-duplicated the counts to determine that 40 states contract with MCOs, PIHPs, or PAHPs; and 47 states contract with MCOs, PIHPs, PAHPs, or PCCMs. To estimate the burden for these proposals in part 457, we utilized state submitted data for enrollment in managed care plans for CY 2016. The enrollment data reflected 9,013,687 managed care enrollees. This data also showed that 32 states use managed care entities for CHIP enrollment.

B. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for Direct Health and Medical Insurance Carriers (NAICS 524114) (*https://www.bls.gov/oes/current/naics5_524114.htm*). Table 1 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1—OCCUPATION TITLES AND WAGE RATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Actuary	15–2011	$49.81	$49.81	$99.62
Business Operations Specialist	13–1000	34.11	34.11	68.22
Computer Programmer	15–1131	43.42	43.42	86.84
General Operations Mgr	11–1021	72.51	72.51	145.02
Office and Administrative Support Worker	43–9000	19.02	19.04	38.08

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. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

C. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding Standard Contract Requirements (§ 438.3)

Proposed amendments to § 438.3(t) would permit states to choose between requiring their MCOs, PIHPs, and PAHPs to sign a COBA with Medicare, or requiring an alternative method for ensuring that each MCO, PIHP, or PAHP receives all appropriate crossover claims. If the state elects to use a methodology other than requiring the MCO, PIHP, or PAHP to enter into a COBA with Medicare, that methodology must ensure that the submitting provider is promptly informed on the state's remittance advice that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration. We estimate it would take 1 hour for a programmer to implement the message on the remittance advice. If 10 states elect to pursue an alternative method, we estimate an aggregate one-time state burden of 10 hrs (10 states × 1 hour) and $860.84 (10 hrs × $86.84 for a computer programmer). As this would be a one-time expense, we annualize this amount to 3.33 hrs and $286.95.

Additionally, for states that elect to require an alternative method, the proposed amendments to § 438.3(t) would also alleviate managed care plans in those states of the burden of obtaining a COBA. We estimate 6 states with 25 plans may elect this option and save 4 hours per plan by a Business Operations Specialist −100 hrs (25 plans × 4 hrs) and −$6,822 (100 hrs × $68.22/hr). As this would be a one-time savings, we annualize this amount to −1.33 hrs and −$2,274.

2. ICRs Regarding Special Contract Provisions Related to Payment (§ 438.6)

Proposed amendments to § 438.6(c) would remove the requirement for states to obtain prior approval for directed payment arrangements that utilize a state approved FFS fee schedule. To obtain prior approval, states submit a preprint (OMB control #0938–1148 (CMS–10398 #52)) to CMS. We estimate that 20 states may elect annually to request approval for 40 directed payments that utilize a state approved FFS fee schedule. By eliminating the requirement that states submit a preprint for each arrangement, we estimate that a state could save 1 hour per directed payment arrangement for a Business Operations Specialist at $68.22/hr. We estimate an annual savings of −40 hours (20 states × 2 preprints each × 1 hour per preprint) and −$2,728.80 (40 hours × $68.22/hr).

3. ICRs Regarding Information Requirements (§ 438.10)

Proposed amendments to § 438.10(d)(2) and (d)(3) would no longer require states or plans to add taglines in prevalent languages to all written materials, nor to use 18-point font size. Instead, states and plans would have the ability to include taglines only on materials critical to obtaining services and could select any font size they deem to be conspicuously visible. While we have no data indicating how many states experienced increased document length or an increase in postage costs as a result of these requirements, we believe that this proposed revision will likely reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of −$12,009,380.89 ((−$272,940.47 = $.005 × 54,588,095) + (−$272,940.47 = 0.005 × 54,588,095) + (−$11,463,499.95 = $.21 × 54,588,095)). These estimates are based on commonly available prices for bulk paper and toner purchases.

4. ICRs Regarding Network Adequacy Standards (§ 438.68)

Proposed amendments to § 438.68(a) would eliminate a requirement that states develop time and distance standards for provider types set forth in § 438.68(b)(1) and for LTSS providers if covered in the MCO, PIHP, or PAHP contract; the proposal would replace the requirement to adopt time and distance standards with a requirement to adopt a quantitative standard to evaluate network adequacy. We previously estimated in the 2016 final rule that states would spend 10 hr in the first year developing the network adequacy standards for the provider types specified in § 438.68(b)(1) and did not estimate additional burden for states after the first year (81 FR 27777). We further estimated a one-time state burden of 10 additional hrs at $64.46/hr for a business operations specialist to develop LTSS standards. We propose to eliminate the time and distance requirement and replace it with a more flexible requirement that states develop any quantitative network adequacy standard for the same provider types. Since time and distance is a quantitative network adequacy standard, for states that used time and distance prior to the 2016 final rule or for those that have adopted time and distance in order to comply with the 2016 final rule, discontinuing the use of time and distance is merely an option that they may elect. Additionally, as clarified in the 2016 final rule (81 FR 27661), states have always had the ability to have network adequacy standards in addition to time and distance if they choose. We believe the proposed change increases flexibility for states without affecting burden on states.

5. ICRs for Grievance and Appeal System: Statutory Basis, Definitions, and Applicability

Proposed amendments to § 438.400(b) would revise the definition of an ''adverse benefit determination'' to exclude claims that do not meet the definition of ''clean claim'' at § 447.45(b), thus eliminating the requirement for the plan to send an adverse benefit notice. While we have no data on the number of adverse benefit notices are sent due to denials of unclean claims, we believe that at least one unclean claim may be generated for half of all enrollees; thus, this proposal could reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of −$10,644,678.32 ((−$136,470.23 = $.005 × 27,294,047) + (−$136,470.23 = 0.005 × 27,294,047) + (−$10,371,737.86 = $.38 × 27,294,047)). These estimates are based on commonly available prices for bulk paper and toner purchases and bulk postage rates.

6. ICRs Regarding Grievance and Appeal System: General Requirements (§ 438.402)

Proposed amendments to §§ 438.402(c)(3)(ii) and 438.406(b)(3) would no longer require enrollees to follow up an oral appeal with a written appeal. This change would alleviate the burden on plans to follow up with enrollees that do not submit the written appeal. We estimate that plans may have an Office and Administrative Support Worker spend up to 2 hours per appeal calling or sending letters to enrollees in an effort to receive the written appeal. We estimate that 300 plans in 20 states have an average of 200 oral appeals that are not followed up with a written appeal. We estimate an aggregate annual private sector burden reduction of −120,000 hours (300 plans × 200 appeals × 2 hrs) and −$4,569,600 (− 120,000 hrs × $38.08/hour).

7. ICRs Regarding Information Requirements (§ 457.1207)

Section 438.10(d)(2) and (d)(3) are adopted by cross-;reference in the CHIP regulations at § 457.1207. As discussed above, proposed amendments to § 438.10(d)(2) and (d)(3) would remove requirements for states or plans to add taglines in prevalent languages to all written materials, nor to use 18-point font size. Instead, states and plans would have the ability to include taglines only on materials critical to obtaining services and could select any font size they deem to be conspicuously visible. As discussed above, while we have no data indicating how many states experienced increased document length and/or an increase in postage costs as a result of these requirements, we believe that this proposed revision will likely reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of −$1,983,013.15 ((−$45,068.44 = $.005 × 9,013,687) + (−$45,068.44 = $.005 × 9,013,687) + (−$1,892,876.27 = $.21 × 9,013,687)). These estimates are based on commonly available prices for bulk paper and toner purchases.

8. ICRs for Grievance and Appeal System: Definitions (§ 457.1260)

Section 438.400(b) is adopted by cross-reference in the CHIP regulations at § 457.1260. As discussed above, proposed amendments to § 438.400(b) would revise the definition of an ''adverse benefit determination'' to exclude claims that do not meet the definition of ''clean claim'' at § 447.45(b), thus eliminating the requirement for the plan to send an adverse benefit notice. As also discussed above, while we have no data on the number of adverse benefit notices are sent due to denials of unclean claims, we believe that at least one unclean claim may be generated for half of all enrollees; thus, this proposal could reduce paper, toner, and postage costs for some states. If we assume that in the aggregate, this change may save one sheet of paper, printer toner, and increased postage (per ounce) per enrollee, we estimate a savings of −$1,757,669.16 ((−$22,534.22 = $.005 × 4,506,844) + (−$22,534.22 = $.005 × 4,506,844) + (−$1,712,600.72 = $.38 × 4,506,844)). These estimates are based on commonly available prices for bulk paper and toner purchases and bulk postage rates.

D. Summary of Proposed Burden and Burden Reduction Estimates

Tables 2 and 3 set out our proposed annual burden and burden reduction estimates. While the annual burden estimates are unchanged over the 3-year approval period, the one-time estimates have been annualized by 3 to account

for OMB's 3-year approval period. The burden and burden reduction associated with this proposed rule would be included in revised PRA packages. PRA package CMS–10108 would continue to contain all of part 438 except for those related to subpart E. Provisions related to quality measurement and improvement (§§ 438.310, 438.320, 438.330, 438.332, 438.334, and 438.340) would remain in the separate CMS–10553. Provisions related to EQR (§§ 438.350, 438.352, 438.354, 438.356, 438.358, 438.360, 438.362, 438.364, and 438.370) would remain in the separate CMS–R–305 and are unchanged by this proposed rule. The proposed CHIP managed care regulation burden would remain in PRA package CMS–10554.

TABLE 2—SUMMARY OF ANNUAL PROPOSED PRA-RELATED REQUIREMENT AND BURDEN UNDER 42 CFR PART 438

CFR section	Number of respondents	Number of responses	Burden per response (hours)	Total annual hours	Labor rate $/hr	Cost ($) per response	Total cost ($)	Frequency	Annualized hours	Annualized costs ($)
§ 438.3(t)	10	10	1	10	$86.84	$86.84	$860.84	Once	0.333	$286.95
§ 438.3(t)	6	25	−4	−100	68.22	−272.88	−6,822	Once	−1.333	−2,274
§ 438.6(c)	20	2	−1	−40	68.22	−68.22	−2,728.80	Annual	−40	−2,728.80
§ 438.10(d)(2–3)	42	54,588,095	n/a	n/a	n/a	0.005	−272,940.47	Annual	n/a	−272,940.47
§ 438.10(d)(2–3)	42	54,588,095	n/a	n/a	n/a	0.005	−272,940.47	Annual	n/a	−272,940.47
§ 438.10(d)(2–3)	42	54,588,095	n/a	n/a	n/a	0.21	−11,463,499.95	Annual	n/a	−11,463,499.95
§ 438.400(b)	42	27,294,047	n/a	n/a	n/a	0.005	−136,470.23	Annual	n/a	−136,470.23
§ 438.400(b)	42	27,294,047	n/a	n/a	n/a	0.005	−136,470.23	Annual	n/a	−136,470.23
§ 438.400(b)	42	27,294,047	n/a	n/a	n/a	0.38	−10,371,738	Annual	n/a	−10,371,738
§ 438.402(c)(3)(i)	300	60,000	−2	−120,000	38.08	−76.16	−4,569,600	Annual	−120,000	−4,569,600
Total				−120,130		−329.81	−27,232,349.31			−27,228,375.20

TABLE 3—SUMMARY OF ANNUAL PROPOSED PRA-RELATED REQUIREMENT AND BURDEN UNDER 42 CFR PART 457

CFR section	Number of respondents	Number of responses	Burden per response (hours)	Total annual hours	Labor rate $/hr	Cost ($) per response	Total cost ($)	Frequency	Annualized hours	Annualized costs ($)
§ 457.1207	32	9,013,687	n/a	n/a	n/a	$0.005	−$45,068.44	Annual	n/a	−$45,068.44
§ 457.1207	32	9,013,687	n/a	n/a	n/a	0.005	−45,068.44	Annual	n/a	−45,068.44
§ 457.1207	32	9,013,687	n/a	n/a	n/a	0.21	−1,892,876.27	Annual	n/a	−1,892,876.27
§ 457.1260	32	4,506,844	n/a	n/a	n/a	0.005	−22,534.22	Annual	n/a	−22,534.22
§ 457.1260	32	4,506,844	n/a	n/a	n/a	0.005	−22,534.22	Annual	n/a	−22,534.22
§ 457.1260	32	4,506,844	n/a	n/a	n/a	0.38	−1,712,600.72	Annual	n/a	−1,712,600.72
Total										−3,740,682.31

E. Exempt ICRs

1. Fewer Than 10 Respondents

While the requirements under §§ 438.7, 438.10(h)(3), and 438.408(f)(2) are subject to the PRA, in each instance we estimate fewer than 10 respondents would engage in the optional activities to take advantage of the flexibility proposed in this proposed rule in connection with the proposed amendments to these regulation sections. Consequently, the information collection requirements are exempt (5 CFR 1320.3(c)) from the PRA requirements (44 U.S.C. 3501 *et seq.*).

Proposed amendments to § 438.7 would require states that make modifications to the capitation rate within the permissible 1.5 percent range to submit documentation if requested by CMS. We do not expect to have reason to request documentation for more than 5 certifications from 1–5 states per year.

Proposed amendments to § 438.10(h)(3) would allow states to only update paper directories quarterly if they have a mobile-enable provider directory. Given the costs of developing a mobile-enabled provider directory, and the modest cost reduction associated with updating monthly versus quarterly, as well as the cost savings associated with printing on demand, we estimate that fewer than 10 states would opt to require their plans to utilize this provision.

Proposed amendments to § 438.408(f)(2) would change the timeframe in which an enrollee must request a state fair hearing from 120 calendar days to no fewer than 90 calendar days and no greater than 120 calendar days. As most states have already implemented the 120-calendar day timeframe for managed care, and the proposed change imposes no requirement for states to change their filing timeframe, we believe that fewer than 10 respondents would elect to change the timeframe for enrollees to request a state fair hearing.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, we request that you please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule. However, all comments received within the 60-day comment period provided for by the PRA will be reviewed and considered.

Comments must be received on/by January 14, 2019.

IV. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We would consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we would respond to the comments in the preamble to that document.

V. Regulatory Impact Analysis

A. Statement of Need

As described in detail in section I.B. of this proposed rule, many of the revisions to part 438 outlined in this proposed rule are part of the agency's broader efforts to reduce administrative burden and to achieve a better balance between appropriate federal oversight and state flexibility, while also maintaining critical beneficiary protections, ensuring fiscal integrity, and improving the quality of care for Medicaid beneficiaries. This proposed rule seeks to streamline the managed care regulations by reducing unnecessary and duplicative administrative burden and further reducing federal regulatory barriers to

help ensure that state Medicaid agencies are able to work efficiently and effectively to design, develop, and implement Medicaid managed care programs that best meet each state's local needs and populations.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year). Based on our analysis, this rule does not reach the economic threshold, and thus, is not considered a major rule.

We have examined the proposed provisions in this rule and determined that most of the proposed revisions to part 438 outlined in this proposed rule are expected to reduce administrative burden as we noted in the COI (see section IV. of this proposed rule). Aside from our analysis on burden reduction in the COI, we believe that the only provision in this proposed rule that we should specifically analyze in this regulatory impact analysis is the proposed revision to managed care pass-through payments because of the general magnitude associated with managed care payments and our previous efforts to analyze financial impacts associated with managed care pass-through payments.

The May 6, 2016 final rule (81 FR 27830) and the January 18, 2017 pass-through payment final rule (82 FR 5425) both contained regulatory impact analyses that discussed the financial and economic effects of pass-through payments. In the May 6, 2016 final rule, we did not project a significant fiscal impact for § 438.6(d). When we reviewed and analyzed the May 6, 2016 final rule, we concluded that states would have other mechanisms to build in the amounts currently provided through pass-through payments in approvable ways, such as approaches consistent with § 438.6(c). If a state was currently building in $10 million in pass-through payments to hospitals under their current managed care contracts, we assumed that the state would incorporate the $10 million into their managed care rates in permissible ways rather than spending less in Medicaid managed care. We expected that the long pass-through payment transition periods provided under the May 6, 2016 final rule would help states to integrate existing pass-through payments into actuarially sound capitation rates or permissible Medicaid financing structures, including enhanced fee schedules or the other approaches consistent with § 438.6(c) that tie managed care payments to services and utilization covered under the contract.

In the January 18, 2017 pass-through payment final rule, we noted that a number of states had integrated some form of pass-through payments into their managed care contracts for hospitals, nursing facilities, and physicians. We also noted that as of the effective date of the May 6, 2016 final rule, we estimated that at least eight states had implemented approximately $105 million in pass-through payments for physicians annually; we estimated that at least three states had implemented approximately $50 million in pass-through payments for nursing facilities annually; and we estimated that at least 16 states had implemented approximately $3.3 billion in pass-through payments for hospitals annually. We noted that the amount of pass-through payments often represented a significant portion of the overall capitation rate under a managed care contract, and that we had seen pass-through payments that had represented 25 percent, or more, of the overall managed care contract and 50 percent of individual rate cells. In our analysis of that final rule, we concluded that while it was difficult for CMS to conduct a detailed quantitative analysis given considerable uncertainty and lack of data, we believed that without the pass-through payment final rule, which prohibited new and increased pass-through payments that were not in place as of the effective date of the May 6, 2016 final rule, states would continue to increase pass-through payments in ways that were not consistent with the pass-through payment transition periods established in the May 6, 2016 final rule.

Since there is still considerable uncertainty regarding accurate and reliable pass-through payment data, we are only including a qualitative discussion for the proposed revisions in this RIA. Under proposed § 438.6(d)(6), we are proposing to assist states with transitioning some or all services or eligible populations from a Medicaid FFS delivery system into a Medicaid managed care delivery system by allowing states to make pass-through payments under new managed care contracts during a specified transition period if certain criteria in the proposed rule are met. One of the proposed requirements in the rule is that the aggregate amount of the pass-through payments for each rating period of the transition period that the state requires the managed care plan to make must be less than or equal to the payment amounts attributed to and actually paid as Medicaid FFS supplemental payments to hospitals, nursing facilities, or physicians in Medicaid FFS. This means that under this new pass-through payment transition period, the aggregate payments added to Medicaid managed care contracts as pass-through payments must be budget neutral to the aggregate payments transitioned from Medicaid FFS. We also note that under the new pass-through payment transition period, states would only have 3 years to include these payments as pass-through payments before needing to transition the payments into allowable payment structures under actuarially sound capitation rates.

We acknowledge that relative to the current pass-through payment baseline, this proposed rule permits states to incorporate new pass-through payments under a new transition period when states are transitioning some or all services or eligible populations from a Medicaid FFS delivery system into a Medicaid managed care delivery system; however, the net financial impact to state and federal governments, and the Medicaid program, must be zero given the proposed requirements in this rule that aggregate pass-through payments under the new transition period must be less than or equal to the payment amounts attributed to and actually paid as Medicaid FFS supplemental payments in Medicaid FFS. Since this proposal only permits payment amounts attributed to Medicaid FFS to be made under Medicaid managed care contracts, this is not an increase in Medicaid payments; rather, these payments only represent a movement of funding across Medicaid delivery systems for a limited and targeted amount of time when

Medicaid populations or services are initially transitioning from a Medicaid FFS delivery system to a Medicaid managed care delivery system. Without this proposed transition period, we believe that existing federal pass-through payment requirements could incentivize states to retain some Medicaid populations and/or Medicaid services in their Medicaid FFS programs. We also believe that some states may choose to delay implementation of Medicaid managed care programs, especially if states have not already been working with stakeholders regarding existing Medicaid FFS supplemental payments. As we noted in our proposal, we want to ensure that federal pass-through payment rules do not unintentionally incent states to keep populations or services in Medicaid FFS, and we do not want federal rules to unintentionally create barriers that prevent states from moving populations or services into Medicaid managed care. As noted in the 2016 final rule (81 FR 27852), potential benefits to the changes in the Medicaid managed care rule include improved health outcomes for Medicaid enrollees through improved care coordination and case management, as well as improved access to care. We believe that this limited and targeted transition period will help states further these goals.

Finally, as noted throughout this rule, this limited and targeted transition period is only available if the state actually made Medicaid FFS supplemental payments to hospitals, nursing facilities, or physicians during the 12-month period immediately 2 years prior to the first rating period of the transition period, and the aggregate amount of the pass-through payments that the state requires the managed care plan to make must be less than or equal to the amounts paid under Medicaid FFS. As noted in our proposal, states would be required to calculate and demonstrate that the aggregate amount of the pass-through payments for each rating period of the transition period is less than or equal to the amounts attributed to and actually paid as Medicaid FFS supplemental payments to hospitals, nursing facilities, or physicians. As a practical matter, states would be required to use MMIS-adjudicated claims data from the 12-month period immediately 2 years prior to the first rating period of the transition period for the purposes of these calculations, and we would verify that the pass-through payment amounts are permissible under these proposed rules, including that the aggregate payments added to Medicaid managed care contracts as pass-through payments must be budget neutral to the aggregate payments transitioned from Medicaid FFS. Therefore, we are not projecting a specific fiscal impact to state or federal governments, or the Medicaid program, as we expect the net financial impact of the proposed provision to be budget neutral. We request public comments on our assumptions and analysis here.

C. Anticipated Effects

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We believe that all Medicaid managed care plans have annual revenues in excess of $38.5 million; therefore, we do not believe that this proposed rule will have a significant economic impact on a substantial number of small businesses. We seek comment on this belief.

In addition, section 1102(b) of the Act requires CMS to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. We do not anticipate that the provisions in this proposed rule will have a substantial economic impact on most hospitals, including small rural hospitals. The proposed provisions in this rule place no direct requirements on individual hospitals, and we note that any impact on individual hospitals will vary according to each hospital's current and future contractual relationships with MCOs, PIHPs, and PAHPs. We expect that any additional burden (or burden reduction) on small rural hospitals should be negligible. We seek comment on this analysis and our assumptions. Therefore, we are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that is approximately $150 million. We believe that this proposed rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirements costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this proposed rule does not impose any substantial costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise issues, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. Many of the revisions to part 438 outlined in this proposed rule are expected to reduce administrative burden; therefore, if the rule is finalized as proposed, we expect that this rule would, on net, be an E.O. 13771 deregulatory action.

D. Alternatives Considered

One alternative we considered was leaving the 2016 final rule as it is today; however, since the rule was finalized in 2016, we continued to hear from stakeholders that the 2016 final rule was overly prescriptive and included provisions that were not cost-effective for states to implement. As a result, we undertook a review of the current regulations to ascertain if there were ways to achieve a better balance between appropriate federal oversight and state flexibility, while also maintaining critical beneficiary protections, ensuring fiscal integrity, and improving the quality of care for Medicaid beneficiaries. This proposed rule is the result of that review and seeks to streamline the managed care regulations by reducing unnecessary

and duplicative administrative burden and further reducing federal regulatory barriers to help ensure that state Medicaid agencies are able to work efficiently and effectively to design, develop, and implement Medicaid managed care programs that best meet each state's local needs and populations.

We are seeking comment on a number of requirements included in this proposed rule to identify potential alternatives to proposed provisions.

E. Uncertainties

We have attempted to provide a framework for common definitions and processes associated with the statutory provisions being implemented by this rule. It is possible that some states may need to use alternative definitions to be consistent with state law, and we are seeking comment on these kinds of issues with the intent to modify and add to the common terminology proposed in this rule as appropriate based on the comments received.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

F. Accounting Statement

As discussed in this RIA, the benefits, costs, and transfers of this proposed rule are identified in Table 4.

TABLE 4—ACCOUNTING STATEMENT

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate	Period covered	
Benefits							
Non-Quantified	Benefits include: Consistency with the statutory requirements in section 1903(m) of the Act and regulations for actuarially sound capitation rates; improved transparency in rate development processes; greater incentives for payment approaches that are based on the utilization and delivery of services to enrollees covered under the contract, or the quality and outcomes of such services; improved support for delivery system reform that is focused on improved care and quality for Medicaid beneficiaries; and improved health outcomes for Medicaid enrollees through improved care coordination and case management, as well as improved access to care.						
Costs							
Annualized Monetized $ millions/year	−30.97			2017		Annual	
Non-Quantified	Costs to state or federal governments should be negligible. Burden and/or burden reduction estimates associated with the activities (other than information collection as defined in the Paperwork Reduction Act) that would be necessary for generating the benefits listed above.						
Transfers							
Non-Quantified	Relative to the current pass-through payment baseline, this proposed rule permits states to incorporate new pass-through payments under a new transition period when states are transitioning some or all services or eligible populations from a FFS delivery system into a managed care delivery system; however, the net financial impact to state and federal governments, and the Medicaid program, must be zero given the proposed requirements in this rule that aggregate pass-through payments under the new transition period must be less than or equal to the payment amounts attributed to and actually paid as FFS supplemental payments in Medicaid FFS. Therefore, we are not projecting a specific fiscal impact to state or federal governments, as we expect the net financial impact of the proposed provision to be budget neutral.						

List of Subjects

42 CFR Part 438

Grant programs—health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

Administrative practice and procedure, Grant programs—health, Health insurance, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 438—MANAGED CARE

■ 1. The authority citation for part 438 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Section 438.3 is amended by revising paragraph (t) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(t) *Requirements for MCOs, PIHPs, or PAHPs responsible for coordinating benefits for dually eligible individuals.* In a State that enters into a Coordination of Benefits Agreement (COBA) with Medicare for Medicaid, an MCO, PIHP, or PAHP contract that includes responsibility for coordination of benefits for individuals dually eligible for Medicaid and Medicare must specify the methodology by which the State would ensure that the appropriate MCO, PIHP, or PAHP would receive all applicable crossover claims for which the MCO, PIHP, or PAHP is responsible. If the State elects to use a methodology other than requiring the MCO, PIHP, or PAHP to enter into a COBA with Medicare, that methodology must ensure that the submitting provider is promptly informed on the State's remittance advice that the claim has been sent to the MCO, PIHP, or PAHP for payment consideration.

* * * * *

■ 3. Section 438.4 is amended by—

■ a. Revising paragraph (b)(1); and

■ b. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 438.4 Actuarial soundness.

* * * * *

(b) * * *

(1) Have been developed in accordance with the standards specified

in § 438.5 of this chapter and generally accepted actuarial principles and practices. Any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations must be based on valid rate development standards that represent actual cost differences in providing covered services to the covered populations. Any differences in the assumptions, methodologies, or factors used to develop capitation rates must not vary with the rate of Federal financial participation (FFP) associated with the covered populations in a manner that increases Federal costs consistent with paragraph (d) of this section.

* * * * *

(c) *Option to develop and certify a rate range.* (1) Notwithstanding the provision at paragraph (b)(4) of this section, the State may develop and certify a range of capitation rates per rate cell as actuarially sound, when all of the following conditions are met:

(i) The rate certification identifies and justifies the assumptions, data, and methodologies specific to both the upper and lower bounds of the rate range.

(ii) Both the upper and lower bounds of the rate range must be certified as actuarially sound consistent with the requirements of this part.

(iii) The upper bound of the rate range does not exceed the lower bound of the rate range multiplied by 1.05.

(iv) The rate certification documents the State's criteria for paying MCOs, PIHPs, and PAHPs at different points within the rate range.

(v) The State does not use as a criterion for paying MCOs, PIHPs, and PAHPs at different points within the rate range any of the following:

(A) The willingness or agreement of the MCOs, PIHPs, or PAHPs or their network providers to enter into, or adhere to, intergovernmental transfer (IGT) agreements; or

(B) The amount of funding the MCOs, PIHPs, or PAHPs or their network providers provide through IGT agreements.

(2) When a State develops and certifies a range of capitation rates per rate cell as actuarially sound consistent with the requirements of this paragraph (c), the State must:

(i) Document the capitation rates, prior to the start of the rating period, for the MCOs, PIHPs, and PAHPs at points within the rate range, consistent with the criteria in paragraph (c)(1)(iv) of this section.

(ii) Not modify the capitation rates under § 438.7(c)(3).

(iii) Not modify the capitation rates within the rate range, unless the State provides a revised rate certification, which demonstrates that—

(A) The criteria in paragraph (c)(1)(iv) of this section, as described in the initial rate certification, were not applied accurately;

(B) There was a material error in the data, assumptions, or methodologies used to develop the initial rate certification and that the modifications are necessary to correct the error; or

(C) Other adjustments are appropriate and reasonable to account for programmatic changes.

(d) *Capitation rate development practices that increase Federal costs and vary with the rate of Federal financial participation (FFP).* The determination that differences in the assumptions, methodologies, or factors used to develop capitation rates for MCOs, PIHPs, and PAHPs increase Federal costs and vary with the rate of FFP associated with the covered populations must be evaluated for the entire managed care program and include all managed care contracts for all covered populations.

(1) Capitation rate development practices that increase Federal costs and vary with the rate of FFP are prohibited, including but not limited to, the following:

(i) A State may not use higher profit margin, operating margin, or risk margin when developing capitation rates for any covered population, or contract, than the profit margin, operating margin, or risk margin used to develop capitation rates for the covered population, or contract, with the lowest average rate of FFP;

(ii) A State may not factor into the development of capitation rates the additional cost of contractually required provider fee schedules, or minimum levels of provider reimbursement, above the cost of similar provider fee schedules, or minimum levels of provider reimbursement, used to develop capitation rates for the covered population, or contract, with the lowest average rate of FFP; and

(iii) A State may not use a lower remittance threshold for a medical loss ratio for any covered population, or contract, than the remittance threshold used for the covered population, or contract, with the lowest average rate of FFP.

(2) CMS may require a State to provide written documentation and justification that any differences in the assumptions, methodologies, or factors used to develop capitation rates for covered populations or contracts, not otherwise referenced in paragraphs (d)(1)(i) through (iii) of this section, represent actual cost differences based on the characteristics and mix of the covered services or the covered populations.

■ 4. Section 438.5 is amended by revising paragraph (c)(3)(ii) to read as follows:

§ 438.5 Rate development standards.

* * * * *

(c) * * *

(3) * * *

(ii) States that request an exception from the base data standards established in this section must set forth a corrective action plan to come into compliance with the base data standards no later than 2 years after the last day of the rating period for which the deficiency was identified.

* * * * *

■ 5. Section 438.6 is amended—

■ a. In paragraph (a) by adding the definitions of ''State plan approved rates'' and ''Supplemental payments'' in alphabetical order;

■ b. By revising paragraphs (b)(1), (c)(1)(iii), and (c)(2); and

■ c. By adding paragraphs (c)(3) and (d)(6).

The revisions and additions read as follows:

§ 438.6 Special contract provisions related to payment.

(a) * * *

* * * * *

State plan approved rates means amounts calculated as a per unit price of services described under CMS approved rate methodologies in the Medicaid State plan.

Supplemental payments means amounts paid by the State in its FFS Medicaid delivery system to providers that are described and approved in the State plan or under a waiver thereof and are in addition to the amounts calculated through an approved State plan rate methodology.

* * * * *

(b) * * *

(1) If used in the payment arrangement between the State and the MCO, PIHP, or PAHP, all applicable risk-sharing mechanisms, such as reinsurance, risk corridors, or stop-loss limits, must be documented in the contract and rate certification documents for the rating period prior to the start of the rating period, and must be developed in accordance with § 438.4, the rate development standards in § 438.5, and generally accepted actuarial principles and practices. Risk-sharing mechanisms may not be added

or modified after the start of the rating period.

* * * * *

(c) * * *

(1) * * *

(iii) The State may require the MCO, PIHP, or PAHP to:

(A) Adopt a minimum fee schedule for network providers that provide a particular service under the contract using State plan approved rates as defined in paragraph (a) of this section. Supplemental payments contained in a State plan are not, and do not constitute, State plan approved rates.

(B) Adopt a minimum fee schedule for network providers that provide a particular service under the contract using rates other than the State plan approved rates defined in paragraph (a) of this section.

(C) Provide a uniform dollar or percentage increase for network providers that provide a particular service under the contract.

(D) Adopt a maximum fee schedule for network providers that provide a particular service under the contract, so long as the MCO, PIHP, or PAHP retains the ability to reasonably manage risk and has discretion in accomplishing the goals of the contract.

(E) Adopt a cost-based rate, a Medicare equivalent rate, a commercial rate, or other market-based rate for network providers that provide a particular service under the contract.

(2) *Process for approval.* (i) All contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i) through (iii) of this section must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices.

(ii) Contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraphs (c)(1)(i), (ii), and (c)(1)(iii)(B) through (E) of this section must have written approval prior to implementation. Contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraph (c)(1)(iii)(A) of this section do not require written approval prior to implementation but are required to meet the criteria in paragraphs (c)(2)(ii)(A) through (F) of this section. To obtain written approval, a State must demonstrate, in writing, that the arrangement—

(A) Is based on the utilization and delivery of services;

(B) Directs expenditures equally, and using the same terms of performance, for a class of providers providing the service under the contract;

(C) Expects to advance at least one of the goals and objectives in the quality strategy in § 438.340;

(D) Has an evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the quality strategy in § 438.340;

(E) Does not condition network provider participation in contract arrangements under paragraphs (c)(1)(i) through (iii) of this section on the network provider entering into or adhering to intergovernmental transfer agreements; and

(F) May not be renewed automatically.

(iii) Any contract arrangements that direct the MCO's, PIHP's, or PAHP's expenditures under paragraph (c)(1)(i) or (ii) of this section must also demonstrate, in writing, that the arrangement—

(A) Must make participation in the value-based purchasing initiative, delivery system reform or performance improvement initiative available, using the same terms of performance, to a class of providers providing services under the contract related to the reform or improvement initiative;

(B) Must use a common set of performance measures across all of the payers and providers; and

(C) Does not allow the State to recoup any unspent funds allocated for these arrangements from the MCO, PIHP, or PAHP.

(3) *Approval timeframes.* (i) Approval of a payment arrangement under paragraph (c)(1)(i) and (ii) of this section is for one rating period unless a multi-year approval is requested and meets all of the following criteria:

(A) The State has explicitly identified and described the payment arrangement in the contract as a multi-year payment arrangement, including a description of the payment arrangement by year, if the payment arrangement varies by year.

(B) The State has developed and described its plan for implementing a multi-year payment arrangement, including the State's plan for multi-year evaluation, and the impact of a multi-year payment arrangement on the State's goals and objectives in the State's quality strategy in § 438.340.

(C) The State has affirmed that it will not make any changes to the payment methodology, or magnitude of the payment, described in the contract for all years of the multi-year payment arrangement without CMS prior approval. If the State determines that changes to the payment methodology, or magnitude of the payment, are necessary, the State must obtain prior approval of such changes under paragraph (c)(2) of this section.

(ii) Approval of a payment arrangement under paragraph (c)(1)(iii) of this section is for one rating period.

(d) * * *

(6) *Pass-through payments for States transitioning services and populations from a fee-for-service delivery system to a managed care delivery system.* Notwithstanding the restrictions on pass-through payments in paragraphs (d)(1), (3), and (5) of this section, a State may require the MCO, PIHP, or PAHP to make pass-through payments to network providers that are hospitals, nursing facilities, or physicians under the contract, for each rating period of the transition period for up to 3 years, when Medicaid populations or services are initially transitioning from a fee-for-service (FFS) delivery system to a managed care delivery system, provided the following requirements are met:

(i) The services will be covered for the first time under a managed care contract and were previously provided in a FFS delivery system prior to the first rating period of the transition period.

(ii) The State made supplemental payments, as defined in paragraph (a) of this section, to hospitals, nursing facilities, or physicians during the 12-month period immediately 2 years prior to the first year of the transition period.

(iii) The aggregate amount of the pass-through payments that the State requires the MCO, PIHP, or PAHP to make is less than or equal to the amounts calculated in paragraphs (d)(6)(iii)(A), (B), or (C) of this section for the relevant provider type for each rating period of the transition period. In determining the amount of each component for the calculations contained in paragraphs (d)(6)(iii)(A) through (C), the State must use the amounts paid for services during the 12-month period immediately 2 years prior to the first rating period of the transition period.

(A) *Hospitals.* For inpatient and outpatient hospital services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through payment rates for hospital services that are being transitioned from payment in a FFS delivery system to the managed care contract by the total amount paid through payment rates for hospital services made in the State's FFS delivery system.

(B) *Nursing facilities.* For nursing facility services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through payment rates for nursing facility services that are being transitioned from payment in a FFS

delivery system to the managed care contract by the total amount paid through payment rates for nursing facility services made in the State's FFS delivery system.

(C) *Physicians.* For physician services, calculate the product of the actual supplemental payments paid and the ratio achieved by dividing the amount paid through payment rates for physician services that are being transitioned from payment in a FFS delivery system to the managed care contract by the total amount paid through payment rates for physician services made in the State's FFS delivery system.

(iv) The State may require the MCO, PIHP, or PAHP to make pass-through payments for Medicaid populations or services that are initially transitioning from a FFS delivery system to a managed care delivery system for up to 3 years from the beginning of the first rating period in which the services were transitioned from payment in a FFS delivery system to a managed care contract, provided that during the 3 years, the services continue to be provided under a managed care contract with an MCO, PIHP, or PAHP.

* * * * *

■ 6. Section 438.7 is amended by revising paragraph (c)(3) and adding paragraph (e) to read as follows:

§ 438.7 Rate certification submission.

* * * * *

(c) * * *

(3) The State may increase or decrease the capitation rate per rate cell, as required in paragraph (c) of this section and § 438.4(b)(4), up to 1.5 percent without submitting a revised rate certification, as required under paragraph (a) of this section. However, any changes of the capitation rate within the permissible range must be consistent with a modification of the contract as required in § 438.3(c) and are subject to the requirements at § 438.4(b)(1). Notwithstanding the provisions in paragraph (c) of this section, CMS may require a State to provide documentation that modifications to the capitation rate comply with the requirements in §§ 438.3(c) and (e), and 438.4(b)(1).

* * * * *

(e) *Provision of additional guidance.* CMS will issue guidance, at least annually, which includes all of the following:

(1) The Federal standards for capitation rate development.

(2) The documentation required to determine that the capitation rates are projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms.

(3) The documentation required to determine that the capitation rates have been developed in accordance with the requirements of this part.

(4) Any updates or developments in the rate review process to reduce State burden and facilitate prompt actuarial reviews.

(5) The documentation necessary to demonstrate that capitation rates competitively bid through a procurement process have been established consistent with the requirements of §§ 438.4 through 438.8.

■ 7. Section 438.8 is amended—

■ a. In paragraph (e)(4) by removing the phrase ''fraud prevention as adopted'' and adding in its place the phrase ''fraud prevention consistent with regulations adopted''; and

■ b. Revising paragraph (k)(1)(iii).

The revision reads as follows:

§ 438.8 Medical loss ratio (MLR) standards

* * * * *

(k) * * *

(1) * * *

(iii) Fraud prevention activities as defined in paragraph (e)(4) of this section.

* * * * *

■ 8. Section 438.9 is amended by revising paragraph (b)(2) to read as follows:

§ 438.9 Provisions that apply to non-emergency medical transportation PAHPS.

* * * * *

(b) * * *

(2) The actuarial soundness requirements in § 438.4, except § 438.4(b)(9).

* * * * *

■ 9. Section 438.10 is amended by—

■ a. Revising paragraphs (d)(2) and (3);

■ b. Removing paragraph (d)(6)(iv);

■ c. Revising paragraph (f)(1);

■ d. In paragraph (g)(2)(ii)(B) by removing the reference ''paragraph (g)(2)(i)(A) of this section'' and adding in its place the reference ''paragraph (g)(2)(ii)(A) of this section'' and

■ e. Revising paragraphs (h)(1)(vii) and (h)(3).

The revisions read as follows:

§ 438.10 Information requirements.

* * * * *

(d) * * *

(2) Make oral interpretation available in all languages and written translation available in each prevalent non-English language. Written materials that are critical to obtaining services for potential enrollees must include taglines in the prevalent non-English language in the State, explaining the availability of written translations or oral interpretation to understand the information provided and the toll-free telephone number of the entity providing choice counseling services as required by § 438.71(a). Taglines for written materials critical to obtaining services must be printed in a conspicuously-visible font size.

(3) Require each MCO, PIHP, PAHP, and PCCM entity to make its written materials that are critical to obtaining services, including, at a minimum, provider directories, enrollee handbooks, appeal and grievance notices, and denial and termination notices, available in the prevalent non-English languages in its particular service area. Written materials that are critical to obtaining services must also be made available in alternative formats upon request of the potential enrollee or enrollee at no cost, include taglines in the prevalent non-English languages in the State and in a conspicuously visible font size explaining the availability of written translation or oral interpretation to understand the information provided, and include the toll-free and TTY/TDY telephone number of the MCO's, PIHP's, PAHP's or PCCM entity's member/customer service unit. Auxiliary aids and services must also be made available upon request of the potential enrollee or enrollee at no cost.

* * * * *

(f) * * *

(1) The MCO, PIHP, PAHP and, when appropriate, the PCCM entity, must make a good faith effort to give written notice of termination of a contracted provider to each enrollee who received his or her primary care from, or was seen on a regular basis by, the terminated provider. Notice to the enrollee must be provided by the later of 30 calendar days prior to the effective date of the termination, or 15 calendar days after receipt or issuance of the termination notice.

* * * * *

(h) * * *

(1) * * *

(vii) The provider's cultural and linguistic capabilities, including languages (including American Sign Language) offered by the provider or a skilled medical interpreter at the provider's office.

* * * * *

(3) Information included in—

(i) A paper provider directory must be updated at least—

(A) Monthly, if the MCO, PIHP, PAHP, or PCCM entity does not have a mobile-enabled, electronic directory; or

(B) Quarterly, if the MCO, PIHP, PAHP, or PCCM entity has a mobile-enabled, electronic provider directory.

(ii) An electronic provider directory must be updated no later than 30 calendar days after the MCO, PIHP, PAHP, or PCCM entity receives updated provider information.

* * * * *

■ 10. Section 438.56 is amended by revising the heading of paragraph (d)(5), and paragraphs (d)(5)(i) and (iii), to read as follows:

§ 438.56 Disenrollment: Requirements and limitations.

* * * * *

(d) * * *

(5) *Use of the MCO's, PIHP's, PAHP's grievance procedures.* (i) The State agency may require that the enrollee seek redress through the MCO's, PHIP's, or PAHP's grievance system before making a determination on the enrollee's request.

* * * * *

(iii) If, as a result of the grievance process, the MCO, PIHP, or PAHP approves the disenrollment, the State agency is not required to make a determination in accordance with paragraph (d)(4) of this section.

* * * * *

■ 11. Section 438.68 is amended by—

■ a. Revising paragraph (b)(1) introductory text, and paragraph (b)(1)(iv);

■ b. Removing paragraph (b)(1)(viii); and

■ c. Revising paragraph (b)(2).

The revisions read as follows:

§ 438.68 Network adequacy standards.

* * * * *

(b) * * *

(1) At a minimum, a State must develop a quantitative network adequacy standard for the following provider types, if covered under the contract:

* * * * *

(iv) Specialist (as designated by the State), adult and pediatric.

* * * * *

(2) *LTSS.* States with MCO, PIHP, or PAHP contracts which cover LTSS must develop a quantitative network adequacy standard for LTSS provider types.

* * * * *

§ 438.236 [Amended]

■ 12. Section 438.236 is amended in paragraph (b)(3) by removing the term ''contracting health care professionals'' and adding in its place the term ''network providers.''

■ 13. Section 438.242 is amended by revising paragraph (c)(3) to read as follows:

§ 438.242 Health information systems.

* * * * *

(c) * * *

(3) Submission of all enrollee encounter data, including allowed amount and paid amount, that the State is required to report to CMS under § 438.818.

* * * * *

■ 14. Section 438.334 is amended by –

■ a. Revising paragraphs (b) and (c)(1) introductory text;

■ b. Redesignating paragraphs (c)(1)(i) and (ii), as paragraphs (c)(1)(ii) and (iii), respectively;

■ c. Adding a new paragraph (c)(1)(i);

■ d. Revising newly redesignated paragraph (c)(1)(ii), and paragraphs (c)(2) and (3); and

■ e. Adding new paragraph (c)(4).

The revisions and additions read as follows:

§ 438.334 Medicaid managed care quality rating system.

* * * * *

(b) *Quality rating system.* CMS, in consultation with States and other stakeholders and after providing public notice and opportunity to comment, will develop a framework for a Medicaid managed care quality rating system (QRS), including the identification of a set of mandatory performance measures and a methodology, that aligns where appropriate with the qualified health plan quality rating system developed in accordance with 45 CFR 156.1120, the Medicare Advantage 5-Star Rating System, and other related CMS quality rating approaches.

(c) * * *

(1) A State may implement an alternative Medicaid managed care quality rating system that utilizes different performance measures or applies a different methodology from that described in paragraph (b) of this section provided that—

(i) The alternative quality rating system includes the mandatory measures identified in the framework developed under paragraph (b) of this section; and,

(ii) The ratings generated by the alternative quality rating system yield information regarding MCO, PIHP, and PAHP performance which is substantially comparable to that yielded by the framework developed under paragraph (b) of this section to the extent feasible, taking into account such factors as differences in covered populations, benefits, and stage of delivery system transformation, to enable meaningful comparison of performance across States.

* * * * *

(2) Prior to implementing an alternative quality rating system, or modification of an alternative quality rating system, the State must—

(i) Obtain input from the State's Medical Care Advisory Committee established under § 431.12 of this chapter; and,

(ii) Provide an opportunity for public comment of at least 30 days on the proposed alternative Medicaid managed care quality rating system or modification.

(3) Upon request, a State must submit to CMS a copy of the alternative quality rating system framework, including the performance measures and methodology to be used in generating plan ratings; documentation of the public comment process specified in paragraphs (c)(2)(i) and (ii) of this section, including issues raised by the Medical Care Advisory Committee and the public, any policy revisions or modifications made in response to the comments, and the rationale for comments not accepted; and other information specified by CMS to demonstrate compliance with this paragraph (c).

(4) The Secretary, in consultation with States and other stakeholders, shall issue guidance which describes the criteria and process for determining if an alternative QRS system is substantially comparable to the Medicaid managed care quality rating system in paragraph (b) of this section.

* * * * *

■ 15. Section 438.340 is amended—

■ a. By revising paragraphs (b)(2), (b)(3)(i), and (b)(6);

■ b. By removing paragraph (b)(8);

■ c. By redesignating paragraphs (b)(9), (10), and (11), as paragraphs (b)(8), (9) and (10), respectively;

■ d. By revising paragraph (c)(1)(ii); and

■ e. In paragraph (c)(3)(ii) by removing the reference ''paragraph (b)(11)'' and adding in its place the reference ''paragraph (b)(10)''.

The revisions read as follows:

§ 438.34 Managed care State quality strategy.

* * * * *

(b) * * *

(2) The State's goals and objectives for continuous quality improvement which must be measurable and take into consideration the health status of all populations in the State served by the MCO, PIHP, PAHP, and PCCM entity described in § 438.310(c)(2).

(3) * * *

(i) The quality metrics and performance targets to be used in measuring the performance and improvement of each MCO, PIHP, PAHP, and PCCM entity described in

§ 438.310(c)(2) with which the State contracts, including but not limited to, the performance measures reported in accordance with § 438.330(c). The State must identify which quality measures and performance outcomes the State would publish at least annually on the website required under § 438.10(c)(3); and,

* * * * *

(6) The State's plan to identify, evaluate, and reduce, to the extent practicable, health disparities based on age, race, ethnicity, sex, primary language, and disability status. States must identify this demographic information for each Medicaid enrollee and provide it to the MCO, PIHP, PAHP, or PCCM entity described in § 438.310(c)(2) at the time of enrollment.

* * * * *

(c) * * *

(1) * * *

(ii) If the State enrolls Indians in the MCO, PIHP, PAHP, or PCCM entity described in § 438.310(c)(2), consulting with Tribes in accordance with the State's Tribal consultation policy.

* * * * *

■ 16. Section 438.358 is amended by revising paragraph (b)(1)(iii) to read as follows:

§ 438.358 Activities related to external quality review.

* * * * *

(b) * * *

(1) * * *

(iii) A review, conducted within the previous 3-year period, to determine the MCO's, PIHP's, or PAHP's compliance with the standards set forth in subpart D of this part, the disenrollment requirements and limitations described in § 438.56, the enrollee rights requirements described in § 438.100, the emergency and post-stabilization services requirements described in § 438.114, and the quality assessment and performance improvement requirements described in § 438.330.

* * * * *

■ 17. Section 438.362 is amended by adding paragraph (c) to read as follows:

§ 438.362 Exemption from external quality review.

* * * * *

(c) *Identification of exempted MCOs.* The State must annually identify, on the website required under § 438.10(c)(3) and in the same location as the EQR technical reports per § 438.364(c)(2)(i), the names of the MCOs exempt from external quality review by the State, including the beginning date of the current exemption period.

■ 18. Section 438.364 is amended by revising paragraph (d) to read as follows:

§ 438.364 External quality review results.

* * * * *

(d) *Safeguarding patient identity.* The information released under paragraph (c) of this section may not disclose the identity or other protected health information of any patient.

■ 19. Section 438.400 is amended in paragraph (b) by revising paragraph (3) of the definition of ''Adverse benefit determination'' to read as follows:

§ 438.400 Statutory basis, definitions, and applicability.

* * * * *

(b) * * *

Adverse benefit determination * * *

(3) The denial, in whole or in part, of payment for a service. A denial, in whole or in part, of a payment for a service because the claim does not meet the definition of a ''clean claim'' at § 447.45(b) of this chapter is not an adverse benefit determination.

* * * * *

■ 20. Section 438.402 is amended by revising paragraph (c)(3)(ii) to read as follows:

§ 438.402 General requirements.

* * * * *

(c) * * *

(3) * * *

(ii) *Appeal.* The enrollee may request an appeal either orally or in writing.

■ 21. Section 438.406 is amended by revising paragraph (b)(3) to read as follows:

§ 438.406 Handling of grievances and appeals.

* * * * *

(b) * * *

(3) Provide that oral inquiries seeking to appeal an adverse benefit determination are treated as appeals.

* * * * *

■ 22. Section 438.408 is amended by revising paragraph (f)(2) to read as follows:

§ 438.408 Resolution and notification: Grievances and appeals.

* * * * *

(f) * * *

(2) *State fair hearing.* The enrollee must have no less than 90 calendar days and no more than 120 calendar days from the date of the MCO's, PIHP's, or PAHP's notice of resolution to request a State fair hearing.

* * * * *

PART 457—ALLOTMENTS AND GRANTS TO STATES

■ 23. The authority citation for part 457 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 24. Section 457.1207 is revised to read as follows:

§ 457.1207 Information requirements.

The State must provide, or ensure its contracted MCO, PAHP, PIHP, PCCM and PCCM entities provide, all enrollment notices, informational materials, and instructional materials related to enrollees and potential enrollees in accordance with the terms of § 438.10 of this chapter, except that the terms of § 438.10(c)(2), (g)(2)(xi)(E) and (g)(2)(xii) of this chapter do not apply.

■ 25. Section 457.1233 is amended by revising paragraphs (b) and (d) to read as follows:

§ 457.1233 Structure and operation standards.

* * * * *

(b) *Subcontractual relationships and delegation.* The State must ensure, through its contracts, that each MCO, PIHP, PAHP, and PCCM entity complies with the subcontractual relationships and delegation requirements as provided in § 438.230 of this chapter.

* * * * *

(d) *Health information systems.* The State must ensure, through its contracts, that each MCO, PIHP, and PAHP complies with the health information systems requirements as provided in § 438.242 of this chapter, except that the applicability date of § 438.242(e) of this chapter does not apply. The State is required to submit enrollee encounter data to CMS in accordance with § 438.818 of this chapter.

* * * * *

■ 26. Section 457.1240 is amended by revising paragraph (b) to read as follows:

§ 457.1240 Quality measurement and improvement.

* * * * *

(b) *Quality assessment and performance improvement program.* The State must require, through its contracts, that each MCO, PIHP, and PAHP must establish and implement an ongoing comprehensive quality assessment and performance improvement program for the services it furnishes to its enrollees as provided in § 438.330 of this chapter, except that:

(1) The terms of § 438.330(d)(4) of this chapter (related to dually eligible beneficiaries) do not apply.

(2) The reference to consultation with the Medical Care Advisory Committee

described in § 438.330(c)(1)(i) of this chapter does not apply.

(3) The terms of § 438.334(c)(2)(i) of this chapter (related to consultation with the Medical Care Advisory Committee) do not apply.

(4) The reference to consultation with the Medical Care Advisory Committee described in § 438.334(c)(3) of this chapter does not apply.

(5) In the case of a contract with a PCCM entity described in paragraph (f) of this section, § 438.330(b)(2) and(3), (c), and (e) of this chapter apply.

* * * * *

■ 27. Section 457.1260 is revised to read as follows:

§ 457.1260 Grievance system.

(a) *Statutory basis and definitions*—(1) *Statutory basis.* This section implements section 2103(f)(3) of the Act, which provides that the State CHIP must provide for the application of subsections section 1932(a)(4), (a)(5), (b), (c), (d), and (e) of the Act (relating to requirements for managed care) to coverage, State agencies, enrollment brokers, managed care entities, and managed care organizations. Section 1932(b)(4) of the Act requires managed care plans to establish an internal grievance procedure under which an enrollee, or a provider on behalf of such an enrollee, may challenge the denial of coverage of or payment for covered benefits.

(2) *Definitions.* The following definitions from § 438.400(b) of this chapter apply to this section—

(i) Paragraphs (1) through (5) and (7) of the definition of Adverse benefit determination; and

(ii) The definitions of appeal, grievance, and grievance and appeal system.

(b) *General requirements.* (1) The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions of § 438.402(a), (b), (c)(2) and (3) of this chapter with regard to the establishment and operation of a grievances and appeals system.

(2) An enrollee may file a grievance and request an appeal with the MCO, PIHP, or PAHP. An enrollee may request a State external review in accordance with the terms of subpart K of part 457 of this chapter after receiving notice under § 438.408 of this chapter that the adverse benefit is upheld.

(3) In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements specified in § 438.408 of this chapter, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State external review in accordance with the terms of subpart K of this part.

(4) If State law permits and with the written consent of the enrollee, a provider or an authorized representative may request an appeal or file a grievance, or request a State external review in accordance with the terms of subpart K of this part, on behalf of an enrollee. When the term ''enrollee'' is used throughout this rule, it includes providers and authorized representatives consistent with this paragraph.

(c) *Timely and adequate notice of adverse benefit determination.* (1) The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.404(a), (b)(1), (2), and (4) through (6), and (c)(2) through (6) of this chapter.

(2) The notice must explain the enrollee's right to request an appeal of the MCO's, PIHP's, or PAHP's adverse benefit determination, including information on exhausting the MCO's, PIHP's, or PAHP's one level of appeal described at § 438.402(b) of this chapter and the right to request a State external review in accordance with the terms of subpart K of this part.

(3) For termination, suspension, or reduction of previously authorized CHIP-covered services, the MCO, PIHP, or PAHP must provide timely written notice.

(d) *Handling of grievances and appeals.* The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.406 of this chapter.

(e) *Resolution and notification: Grievances and appeals.* (1) The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.408(b), (c)(1) and (2), (d), (e)(1), and (f)(3) of this chapter.

(2) Each MCO, PIHP, or PAHP must resolve each grievance and appeal, and provide notice, as expeditiously as the enrollee's health condition requires, within State-established timeframes that may not exceed the timeframes specified in this section.

(3) In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements of this section, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State external review in accordance with the terms of subpart K of this part.

(4) For appeals not resolved wholly in favor of the enrollees, the content of the notice of appeal resolution required in § 438.408(e) of this chapter must include the following:

(i) The right to request a State external review in accordance with the terms of subpart K of this part, and how to do so.

(ii) The right to request and receive benefits while the review is pending, and how to make the request.

(iii) That the enrollee may, consistent with State policy, be held liable for the cost of those benefits if the hearing decision upholds the MCO's, PIHP's, or PAHP's adverse benefit determination.

(5) An enrollee may request a State external review only after receiving notice that the MCO, PIHP, or PAHP is upholding the adverse benefit determination.

(6) In the case of an MCO, PIHP, or PAHP that fails to adhere to the notice and timing requirements in § 438.408 of this chapter and this section, the enrollee is deemed to have exhausted the MCO's, PIHP's, or PAHP's appeals process. The enrollee may initiate a State external review.

(7) The enrollee must request a State external review no later than 120 calendar days from the date of the MCO's, PIHP's, or PAHP's notice of resolution.

(f) *Expedited resolution of appeals.* The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.410 of this chapter.

(g) *Information about the grievance and appeal system to providers and subcontractors.* The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.414 of this chapter.

(h) *Recordkeeping requirements.* The State must ensure that its contracted MCOs, PIHPs, and PAHPs comply with the provisions at § 438.416 of this chapter.

(i) *Services not furnished while the appeal is pending.* If the MCO, PIHP, or PAHP, or the result of a State external review in accordance with the terms of subpart K of this part reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the MCO, PIHP, or PAHP must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

■ 28. Section 457.1270 is revised to read as follows:

§ 457.1270 Sanctions.

(a) The State must comply with §§ 438.700 through 438.704, § 438.706(c) and (d), and §§ 438.708 through 438.730 of this chapter.

(b) *Optional imposition of sanction.* If the State imposes temporary

management under § 438.702(a)(2) of this chapter, the State may do so only if it finds (through onsite surveys, enrollee or other complaints, financial status, or any other source) any of the following:

(1) There is continued egregious behavior by the MCO, including but not limited to behavior that is described in § 438.700 of this chapter, or that is contrary to any of the requirements of this subpart.

(2) There is substantial risk to enrollees' health.

(3) The sanction is necessary to ensure the health of the MCO's enrollees—

(i) While improvements are made to remedy violations under § 438.700 of this chapter.

(ii) Until there is an orderly termination or reorganization of the MCO.

(c) *Required imposition of sanction.* The State must impose temporary management (regardless of any other sanction that may be imposed) if it finds that an MCO has repeatedly failed to meet substantive requirements in this subpart. The State must also grant enrollees the right to terminate enrollment without cause, as described in § 438.702(a)(3) of this chapter, and must notify the affected enrollees of their right to terminate enrollment.

■ 29. Section 457.1285 is revised to read as follows:

§ 457.1285 Program integrity safeguards.

The State must comply with the program integrity safeguards in accordance with the terms of subpart H of part 438 of this chapter, except that the terms of § 438.604(a)(2) and (d)(4) of this chapter do not apply.

Dated: October 31, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 2, 2018.

Alex M. Azar II.,

Secretary, Department of Health and Human Services.

[FR Doc. 2018–24626 Filed 11–8–18; 11:15 am]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 83 Wednesday,
No. 220 November 14, 2018

Part V

The President

Federal Register
Vol. 83, No. 220
Wednesday, November 14, 2018

Presidential Documents

Title 3—

The President

Proclamation 9820 of November 8, 2018

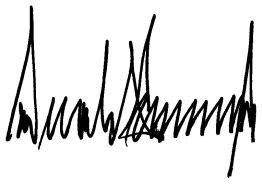
Honoring the Victims of the Tragedy in Thousand Oaks, California

By the President of the United States of America

A Proclamation

As a mark of solemn respect for the victims of the terrible act of violence perpetrated in Thousand Oaks, California, on November 7, 2018, by the authority vested in me as President of the United States by the Constitution and the laws of the United States of America, I hereby order that the flag of the United States shall be flown at half-staff at the White House and upon all public buildings and grounds, at all military posts and naval stations, and on all naval vessels of the Federal Government in the District of Columbia and throughout the United States and its Territories and possessions until sunset, November 10, 2018. I also direct that the flag shall be flown at half-staff for the same length of time at all United States embassies, legations, consular offices, and other facilities abroad, including all military facilities and naval vessels and stations.

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



[FR Doc. 2018–25042
Filed 11–13–18; 11:15 am]
Billing code 3295–F9–P

Presidential Documents

Proclamation 9821 of November 8, 2018

World Freedom Day, 2018

By the President of the United States of America

A Proclamation

The Berlin Wall stood as a harrowing barrier for nearly three decades, dividing East and West Germans from their families and friends, and symbolizing the suffocating oppression of Soviet-backed totalitarian regimes. On World Freedom Day, we remember the struggle and sacrifice of those who braved severe hardships under communism's brutal reign, and we celebrate November 9, 1989, as the day when freedom-loving people on both sides of the wall came together to begin tearing down this hated obstruction to liberty. We also honor the unwavering resolve of those who confronted the evils of corrupt despots and reaffirm our support for people around the world seeking to live in freedom and to enjoy the blessings of liberty.

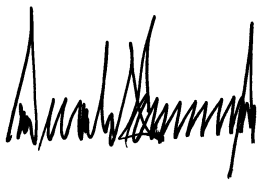
As of this year, Germany has been reunified for longer than it was divided by the Berlin Wall, which imprisoned the people of East Germany for more than 28 years. While it stood, the Berlin Wall was both a physical barrier and a symbol of oppression. Few dared to dream of reunification. The courageous and unwavering determination of those who dared to confront it and those who guarded it day and night, however, inspired millions to prove that freedom prevails over tyranny. The fall of the Berlin Wall marked a major step in the disintegration of the Iron Curtain, paving the way to the liberation of Eastern and Central Europe from the grip of communism and marking a decisive victory for freedom-loving people across Europe. Many countries that lived under the shadow of communism emerged as new democracies and reclaimed their right to determine their own futures. Today, they continue to defend their cherished independence.

Unfortunately, we know freedom is repressed in too many places around the world, particularly where terrorism and extremism continue to pose grave threats. Americans have always held boldly and unapologetically to the truth that liberty is an inherent human right, and we reaffirm our commitment to keeping the light of freedom burning bright and shining out to the entire world.

Today, we pay tribute to the brave individuals who, despite all risks, have challenged injustice and fought for freedom, especially those who have made the ultimate sacrifice. We stand in solidarity with those who still live under tyrannical governments and emphasize that the world will be better off when all governments respect the right of all people to live in freedom.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 9, 2018, as World Freedom Day. I call upon the people of the United States to observe this day with appropriate ceremonies and activities, reaffirming our dedication to freedom and democracy.

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



[FR Doc. 2018–25046
Filed 11–13–18; 11:15 am]
Billing code 3295–F9–P

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Federal Register

Vol. 83, No. 220

Wednesday, November 14, 2018

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FEDERAL REGISTER PAGES AND DATE, NOVEMBER

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List November 7, 2018

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